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Diabetes Self-Management and Leptin in Mexican Americans with Type 2 Diabetes: The Starr County Border Health Initiative

Sharon A. Brown, School of Nursing, The University of Texas at Austin

Kamiar Kouzekanani, College of Education, Texas A&M University - Corpus Christi

Alexandra A. García, School of Nursing, The University of Texas at Austin

Philip R. Orlander, The University of Texas Medical School at Houston

Craig L. Hanis School of Public Health, The University of Texas Health Science Center at Houston

Abstract

Purpose—The purpose of the study was to: (1) characterize leptin in Mexican Americans with poorly-controlled T2DM; (2) examine relationships among leptin and indicators of diabetes status (BMI and A1C); and (3) explore the effects of a culturally-tailored DSME intervention on leptin.

Methods—In Starr County, an impoverished Texas-Mexico border community, 252 Mexican Americans with T2DM were recruited to test a DSME intervention culturally tailored in terms of language, dietary recommendations, social emphasis, family participation, and incorporation of cultural health beliefs. Groups of eight participants were randomized to experimental or wait-listed control conditions. Outcomes were measured at 3, 6, and 12 months; by 12 months, 109 had complete leptin data.

Results—Subjects were predominantly female and on average, 55 years of age, diagnosed with diabetes for 8 years, obese, and in poor glycemic control. Three variables — BMI, gender, A1C — explained 36% of the variance in baseline leptin; there were no intervention effects on leptin. Gender, time, and gender-by-time interaction effects on leptin were statistically significant; greater increases in leptin over time occurred in females compared to males. In females, baseline-to-12 month FBG changes significantly predicted baseline-to-12 month leptin changes; in males BMI changes predicted leptin change.

Conclusions—With increasing obesity rates, further research is warranted to determine if leptin is a useful intervention target in T2DM.

Corresponding author: Sharon A. Brown, The University of Texas at Austin, School of Nursing, 1710 Red River Street, Austin, Texas 78701, Phone: (512) 232-4704, Fax: (512) 232-6239, sabrown@mail.utexas.edu.

For more than four decades, Starr County, Texas, has had a history of having one of the highest diabetes prevalence rates and diabetes-related death rates in Texas; more than half of Hispanic adults are affected by diabetes.^{1,2} The authors developed and tested diabetes self-management education (DSME) interventions culturally tailored for Spanish-speaking Mexican Americans in Starr County, a Texas-Mexico border county that is the poorest county in Texas and one of the poorest in the U.S.³ The rationale for designing a lifestyle intervention, rather than one focused on pharmacological treatments, was based on the cultural context of Starr County and many other similar underserved, impoverished communities. Individuals living in poverty do not have the personal resources to pay for medications and the medical care required to monitor treatment success and potential side effects. So, many individuals rely on health advice of friends and relatives.⁴

Across all of the studies conducted in Starr County over the past 20 years, mean baseline glycosylated hemoglobin (A1C) levels were consistently measured at ~12%^{5–7}; A1C levels >10% are associated with 3-year health care costs that are 11% higher than A1C levels 6%.⁸ The authors have previously reported statistically and clinically significant improvements in, as well as intervention dosage effects on, A1C (average reductions of 1.4 to 1.7%-age points), fasting blood glucose (FBG, average reductions of ~28 mg per ml), and diabetes-related knowledge.^{5–7}

Here, the results of a secondary analysis of Starr County data are reported, focusing on leptin, a hormone produced by adipose tissue and a key factor that links obesity, insulin resistance, impaired glucose tolerance, and T2DM.^{9–12} Studies have "reported [an] association between low adiponectin, high leptin, obesity-related metabolic disturbances and incident CAD [coronary artery disease]...¹³ Early evidence in the mid-1990s that exogenous leptin reduced obesity and improved glycemia in experimental rat models created optimism for leptin as a potential treatment for diabetes. Unfortunately, subsequent human studies found that persons with T2DM who were obese (80% to 85% of persons with T2DM are obese) were leptin resistant, exhibited hyperleptinemia (fasting serum leptin levels >15 ng per ml), and were "refractory to [leptin] therapy."¹² Further studies were recommended to understand, and perhaps reduce, the leptin resistance seen in T2DM.

The Study on Lifestyle intervention and Impaired glucose tolerance Maastricht (SLIM), conducted in the Netherlands, found that a lifestyle intervention involving dietary alterations and increased physical activity reduced leptin in persons with impaired glucose tolerance by improving insulin sensitivity.¹⁴ The aim was to determine if leptin patterns reported in the SLIM study were similar in Mexican Americans already diagnosed with T2DM, a generally understudied population. A secondary goal was to determine whether measuring leptin adds value as an outcome of lifestyle interventions involving dietary alterations and increased physical activity in Hispanics.^{14,15} Thus, the specific purposes of the secondary analyses of Starr County data reported here were to: (1) characterize leptin in Mexican Americans with poorly-controlled T2DM; (2) examine the relationships among leptin and indicators of diabetes status, such as BMI and A1C; and (3) explore the effects of a community-based, culturally-tailored lifestyle intervention on leptin.

METHODS

Study Design

Descriptions of study design, setting, intervention, and participants of the previous Starr County studies have been reported elsewhere.^{5–7} Effectiveness of the intervention was examined with a randomized, repeated measures, pretest/posttest control group design. Groups of 8 study participants were randomly assigned to a(n): (1) experimental condition that received a yearlong intensive lifestyle intervention involving 26 educational and group support sessions that focused on preparing and eating healthy Mexican-American foods and increasing physical activity; or (2) wait-listed control condition, individuals who received the full program once the intervention was completed by experimental participants. The following primary outcome variables measured at baseline and 3-, 6-, and 12-months were: A1C, FBG, lipids, blood pressure, health behaviors (physical activity, dietary intake), BMI, health beliefs, and diabetes-related knowledge; and the findings related to these measures have been reported previously.^{5–7} In addition, leptin levels were obtained on a subsample of study participants; by 12 months post entry into the study, the study had complete data on 109 individuals. Here, analyses are reported primarily of the leptin data as they relate to other variables measured on this subsample, such as A1C and BMI.

Community Setting

Starr County, Texas, one of 14 Texas counties bordering Northern Mexico, is located halfway between Brownsville and Laredo. In 2012, the U.S. Census Bureau reported that Starr County had a population of 61,715; 96% was Mexican American; 30% was foreign born; and 96% spoke Spanish.¹⁶ Residents had the lowest personal income in the State; 38% live below the poverty level, compared to 16.8% for the State.¹⁶ The County is populated by many *colonias*, unincorporated settlements along the border that are characterized by poverty, pollution, and deprivation. The County is designated by the State of Texas as a Health Professional Shortage and Medically Underserved Area, with the lowest ratio in the State of primary care physicians to the population; 4,735:1 versus 1,378:1 for the State.³ Thirty-five percent of the residents do not have health insurance.³

Participants

Adults with T2DM were recruited from lists of ongoing epidemiological and genetic studies conducted in Starr County by Hanis et al. Waiting lists served as an additional source of individuals who had been referred by local physicians or who had heard of the program by word-of-mouth. Study participants were required to meet the following inclusion criteria: between 35 and 70 years of age and diagnosed with type 2 diabetes verified by [1] 2 FBG test results of 140 mg/dl. or [2] taking *or* have taken insulin *or* hypoglycemic agents one year. Female study participants were excluded if they were pregnant and any participant was excluded if s/he had medical conditions for which changes in diet and physical activity would be contraindicated (e.g., kidney failure requiring dialysis and special dietary requirements or peripheral vascular disease severe enough to preclude walking three times per week).

Potential participants were contacted by telephone by experienced bilingual staff; approximately 95% of the individuals who were invited to participate agreed to do so. Each subject in the experimental group was assigned to an intervention group held at a site in close proximity to his/her home, thereby fostering neighborhood support within groups between group meetings and also reducing the likelihood of contamination. Individuals were required to partner with a relative, preferably the spouse, or a friend who would attend group sessions and provide support. A mutually convenient time for intervention sessions was negotiated with each experimental group at completion of baseline data collection. For all sessions, transportation and childcare were provided by Research Field Office staff, if required.

Procedures

Baseline and outcome data were collected at the Research Field Office in Rio Grande City, the county seat of Starr County. Experienced Research Field Office staff, some employed for more than 20 years, managed patient flow through the office; conducted basic investigational measurements, such as weights and blood pressures; and handled other organizational activities. Physicians were notified by letter that their patients were participating in the study and follow-up letters were sent to: (1) obtain approval for the diet and physical activity recommendations; (2) notify them of test results; and (3) refer any health problems needing follow up. Project staff established thresholds for referring subjects to their physicians, such as for A1C levels. Institutional review boards of the two collaborating universities approved study procedures.

Primary Measures: Leptin, A1C, and BMI

Blood samples were collected following 10 hours of fasting. Leptin was measured in duplicate from EDTA plasma stored at -80° by radioimmunoassay according to the manufacturer's recommendations (Human Leptin RIA Kit, Linco Research, Inc., St. Charles, MO). Coefficient of variation among assays was 7.7%. A1C was measured by the Glyc-Affin Ghb method (Isolab Inc., Akron, Ohio). Body weights were measured with a balance beam scale with individuals in street clothing and without shoes. Heights were obtained using a secured stadiometer. Body mass index (BMI) was calculated (weight[kg]/ height[meters]²). Project staff enrolled 252 participants in the original study; at 12 months, project staff had collected complete leptin data on 109 cases. There were no significant differences on key variables between individuals who had complete data and those who did not.

Intervention

Characteristics of the intervention have been described previously.⁵ Briefly, the yearlong intervention, 52 contact hours over 26 sessions, was provided in Spanish and was culturally competent in terms of language, dietary recommendations, social emphasis, family participation, and incorporation of cultural health beliefs of Mexican Americans. The intervention was designed to address typical diabetes-self management topics, such as glucose self-monitoring; but the primary focus was on lifestyle, that is, preparing and eating healthier Mexican-American foods and incorporating moderate levels of physical activity. (See Table 1.) Intervention sites included schools, churches, county agricultural extension

offices, adult day care centers, and local health clinics. The program involved 12 consecutive weeks of education followed by 14 biweekly support group sessions; each session, education and support, lasted 2 hours. Each intervention team involved a bilingual Mexican-American nurse, dietitian, and *promotora*, all residents of the Texas-Mexico border area.

Intervention materials were provided in Spanish. Emphasis was on practical aspects of nutrition and increasing physical activity; food preparation demonstrations and return demonstrations; field trips to local grocery stores; and 30 minutes of group stretching, walking, and other activities to enhance physical activity. At each session, healthy, culturally preferred snacks were provided; and at one session, the group, under the supervision of the dietitian, prepared a full meal. A series of seven Spanish-language educational videotapes designed for Mexican Americans and filmed in Starr County provided a discussion focus for group sessions.¹⁷ Support groups were used for longitudinal follow up, problem solving related to dietary and physical activity recommendations, and "coaching" on motivational strategies.

Intervention goals, established with input from focus groups held in the community, were simple and practical:

- reduce dietary intake by 500 to 1,000 kcal per day
- reduce saturated fat (e.g., lard) and sodium in dietary intake and food preparation
- lose a minimum of 7% of body weight in individuals with a BMI >24 kg/m²
- increase physical activity by walking 150 minutes per week

The primary emphasis was on dietary goals, since some Starr County residents lived in *colonias*, areas that did not have paved roads or areas conducive to exercise. The goal of reducing saturated fat was based on focus groups held with local physicians who identified a high intake of saturated fat as a major negative health factor in this community. Typical dietary practices involved the use of large amounts of lard in the preparation of cultural foods. At the local grocery store, women were seen filling their shopping carts with 20-gallon cans of lard. Individualized dietary and exercise prescriptions were recommended and approved by local physicians.

Statistics

Data were analyzed using IBM SPSS statistical software, Version 19.0. The data had been screened for accuracy by checking original data against a computerized listing. Descriptive statistics are presented as means \pm standard deviations. Correlation and stepwise regression analyses were used to identify predictors of baseline leptin and repeated measures ANOVA to examine intervention effects over time. All analyses were conducted at a two-tailed *p* .05 level of significance.

Results

Table 2 shows the characteristics of the subsample (n=109) that provided leptin data for these secondary analyses, based on gender since significant leptin differences were found between male and female participants. Subjects were Mexican American and overall,

predominantly female (64%), 55 years of age (SD=8.0), diagnosed with diabetes for 8 years (SD=6.2), low in acculturation (based on preferred language), obese (mean BMI=32.1±6.5, range 22.5–49.9), and in poor glycemic control (mean A1C= $11.2\% \pm 2.8$, range 5.3%-17.4%; FBG=211.3 mg/dL±70.0). The means and standard deviations for outcome measures are summarized in Table 3. Mean baseline leptin (14.5 ng/dL±14.2 ng/dL) was significantly correlated with: BMI (Pearson r=.52, p<.001, n=109), female gender (r=.38, p<.001, n=109), A1C (*r*=-.23, *p*=.02, *n*=108), and FBG (*r*=-.23, *p*=.02, *n*=109). (See Table 4.) The gender differences in BMI and leptin are clearly demonstrated in Table 5, with females having higher obesity and leptin levels, compared to males. Females had higher baseline leptin levels (18.5 ng/dL±15.2, *n*=69) than males (7.3 ng/dL±8.5, *n*=39), *t*(107)=4.3, p<.001. Stepwise linear regression analysis indicated that three variables — BMI, gender, and A1C — explained 36% of the variance in baseline leptin, F(3,107)=19.7, p<.001. The unique contribution of BMI was 26.6%, p<.001. Gender and A1C accounted for 4.9% and 4.8% of the variation in leptin, respectively (gender p=.007, A1C p=.006). FBG did not enter the model. Consistent with previous research (12), higher levels were seen in individuals treated with insulin, either alone (16.5 ng/dL \pm 13.5, n=24) or in addition to an oral hypoglycemic agent (17.4 ng/dL \pm 17.0, n=11), compared to those treated with diet only (14.7 ng/dL \pm 10.1, n=7) or diet plus an oral hypoglycemic agent (13.3 ng/dL±14.4, n=67). Mean differences were not statistically significant (p=0.70).

To test intervention effects on leptin, univariate repeated measures ANOVA (Table 5) were conducted, which showed a significant time effect; a statistically significant increase in leptin from baseline to 3 months followed by smaller decreases that were not statistically significant from 3 months to 6 months and from 6 months to 12 months. A 2 (intervention versus control) by 4 (measurement periods) repeated measures ANOVA showed neither statistically significant intervention nor intervention-by-time interaction effects on leptin. A 2 (intervention versus control) by 2 (female versus male) by 4 repeated measures ANOVA showed that intervention, intervention-by-gender, intervention-by-time, and intervention-by-gender-by-time had no statistically significant effects on leptin levels. The time-by-gender interaction effect was statistically significant. Analysis of simple effects showed time changes among males were not statistically significant; however, among females, the increase in leptin from baseline to 3 months and a decrease from 3 months to 6 months were statistically significant.

Separate regression analyses based on gender found that, in females, baseline BMI and A1C together explained 30% of the variance in baseline leptin. Baseline-to-12 month FBG change significantly predicted baseline-to-12 month change in leptin (p<.05), explaining 6% of the variance. In males, baseline BMI explained 34% of the variance in baseline leptin. Baseline-to-12 month BMI change predicted the baseline-to-12 month change in leptin, explaining 37% of the variance (p<.001).

Discussion

The increasing obesity rate among Hispanics, including Mexican Americans, the largest Hispanic subgroup, is a foremost contributing factor to the high prevalence rate of type 2 diabetes (T2DM), now a major racial/ethnic health disparity.^{18,19} By the age of 60, 50%

of Mexican Americans have diagnosed diabetes, undiagnosed diabetes, or impaired fasting glucose, conditions that shorten lifespans by at least 10 years.^{20–24} Diabetes and related mortality rates are highest among low-income Mexican Americans, the majority of whom lives in rural, impoverished U.S.-Mexico border communities.²⁵ Almost 50% of border counties are designated as medically underserved, with poor health and quality of life.

Leptin plays a complex role in glucose metabolism, suppressing secretion of insulin while decreasing insulin sensitivity.^{9,11,26} Corpeleijn et al. demonstrated in a Dutch population that a lifestyle intervention in individuals with impaired glucose tolerance (IGT) resulted in a significant decrease in leptin that correlated with improved insulin sensitivity.¹⁴ Mexican Americans have a higher prevalence of insulin resistance and T2DM, compared to non-Hispanic Whites. The Starr County intervention was relatively intensive (52 contact hours) and culturally tailored for Mexican Americans with uncontrolled T2DM (mean baseline A1C~11%). The authors have reported in the past that this intervention resulted in significant improvements in glycemia by 6 months (p<.001, n=225) and 12 months (p<.05, n=223) in the overall sample (6). In this subsample of study participants in which leptin was measured, the intervention also resulted in significant improvements in glycemia by 6 months (p=0.46, n=106) but not at 12 months (p=.45, n=106).

Leptin levels are known to be higher in women than men, increase in response to weight gain and insulin or sulfonylurea therapy, and decrease with physical activity and weight loss.^{27–29} Other studies of Mexican Americans found that leptin did not differ significantly by diabetes status but was significantly correlated with BMI and was higher in women than in men²⁸; similar to what was found in the results reported here. Average baseline BMI for women was 33.7 (SD=6.5, *n*=70); for men, 29.2 (SD=5.5, *n*=39), a statistically significant difference [*t*(107)=3.7, *p*<01]. This likely contributed to the gender differences in leptin.

Despite improvement in glycemia, the intervention had no significant overall effect on leptin. A plausible explanation is the nature of the population, with high baseline A1C and obesity. This glycemic factor, coupled with the lack of reduction in BMI that occurred during the study, was compounded by environmental limitations and personal health issues that posed obstacles to physical activity (e.g., oppressively hot climate, lack of paved roads or hiking trails that could be used for walking, and no available exercise facilities). Irregular access to health care and diabetes medications may have confounded detection of changes in leptin. Due to numerous personal barriers, including severe financial constraints, few (26%) study participants received insulin or engaged in physical activity.

To explore further the potential intervention effects on leptin levels, and based on the fact that the leptin levels were correlated with gender and BMI, data patterns were examined in the 10 individuals who lost the most amount of weight at 6 months compared to those who lost the least amount of weight or who gained weight. Again, there were strong associations between leptin and weight; individuals who lost the most weight by 6 months post-intervention had a mean leptin level of 16.9 ng/dL, while those who lost the least amount of weight or who gained weight had a mean leptin level of 23.2 ng/dL. While the gender breakdown in those who lost weight was relatively even (4 males, 6 females), women

were more represented in the group that lost the least amount of weight or who gained weight (1 male, 9 females).

The Starr County intervention did not result in sufficient changes in insulin use or health behaviors to achieve overall significant weight reduction, improve insulin sensitivity, and subsequently change leptin levels among study participants. With growing obesity rates, particularly among minority women,²⁸ further research is warranted to determine if leptin is an important intervention target in persons with type 2 diabetes as well as in high-risk individuals.^{29,30} Subsequent research in Starr County has attempted to address the remaining barriers to achieving weight loss and increasing physical activity. Improving insulin sensitivity is imperative in such populations who have so few personal resources and who lack regular healthcare access necessary to adequately diagnose and treat diabetes and monitor health outcomes. Further intervention research with these populations is urgently needed or these groups will continue to experience an excessive and growing diabetes burden.

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Table 1.

Intervention Outline*

Session	Content		
1	Introduction to project activities and expected outcomes		
2	General facts about diabetes Need for family support Community resources		
3	Blood glucose self-monitoring **		
4	Nutrition principles		
5	Exercise; relationships among exercise, diet, & medications		
6	Nutrition principles (continued)		
7	Nutrition principles (continued)		
8	Acute complications (hyper- & hypoglycemia)		
9	Medications		
10	General hygiene; illness management		
11	Long-term complications		
12	Summary & introduction to support group sessions		
13–26	Bi-weekly support group sessions		

* Snacks based on culturally preferred foods provided in each session.

** Glucometers distributed.

Table 2.

Characteristics of the Subsample at Baseline (mean±SD)

Characteristic	Males $n = 39$	Females $n = 70$	Total Sample <i>n</i> = 109
Age in years	56.1 ± 7.4	54.3 ± 8.3	54.9 ± 8.0
Time since diagnosis (in years)	9.0 ± 6.3	7.73 ± 6.2	8.2 ± 6.2
Acculturation*	1.0 ± 1.1	1.1 ± 1.0	1.1 ± 1.0
BMI	29.2 ± 5.5	33.7 ± 6.5	32.1 ± 6.5
Fasting blood glucose (mg/dL)	212.4 ± 72.3	210.6 ± 69.1	211.3 ± 70.0
Glycosylated hemoglobin (%)	10.9 ± 2.9	11.3 ± 2.8	11.2 ± 2.8
Leptin (ng/dL)	7.3 ± 8.5	18.5 ± 15.1	14.5 ± 14.2

*Acculturation Scale: range 0-4, with 4 being most acculturated; measured by Hazuda et al.

Table 3.

Leptin (ng/dL), BMI, and A1C by gender and intervention group

Measure	Group	Gender	Time 1 Baseline	Time 2 3 months	Time 3 6 months	Time 4 12 months
Leptin (<i>n</i> =109)	Experimental	Female	18.5 ± 15.0	28.0 ± 18.8	24.3 ± 17.3	24.5 ± 17.5
		Male	6.8 ± 8.7	8.6 ± 8.7	11.0 ± 10.2	8.2 ± 8.8
	Control	Female	18.5 ± 15.4	28.7 ± 16.6	25.0 ± 12.8	21.8 ± 10.1
		Male	8.1 ± 8.3	8.8 ± 7.7	8.0 ± 6.3	6.9 ± 5.1
BMI (<i>n</i> =109)	Experimental	Female	33.3 ± 6.5	33.4 ± 6.6	33.4 ± 6.6	33.6 ± 6.6
		Male	29.4 ± 4.7	29.0 ± 4.5	28.8 ± 4.4	29.0 ± 4.7
	Control	Female	34.2 ± 6.6	33.8 ± 6.2	34.0 ± 6.0	33.7 ± 5.8
		Male	28.7 ± 6.8	28.1 ± 6.4	29.0 ± 6.0	28.1 ± 4.4
A1C (<i>n</i> =108)	Experimental	Female	11.5 ± 2.8	11.0 ± 3.0	11.1 ± 3.4	10.8 ± 2.5
		Male	11.5 ± 2.6	10.7 ± 2.6	10.4 ± 2.3	11.2 ± 2.7
	Control	Female	11.1 ± 2.8	11.1 ± 3.1	12.2 ± 3.4	11.5 ± 3.0
		Male	9.9 ± 3.1	10.5 ± 3.1	11.9 ± 4.2	11.0 ± 2.9

 $\text{mean} \pm \text{SD}$

Table 4.

Correlations Between Measures

MEASURE	Gender B	Time since diagnosis	Diabetes Treatment	BMI	FBG	A1C	Leptin
Age	105	.296***	.147	131	053	.103	117
Gender $^{\beta}$		100	.024	.337**	012	.067	.383 **
Time since diagnosis			.289 **	.014	.377*	.186	086
Diabetes Treatment				.090	.151	.137	.095
BMI					034	066	.519**
FBG						.536 **	229*
A1C							231*

Note:

* p <0.05,

** p <0.01

 $\beta_{\text{Gender coded }0=\text{male, }1=\text{female}}$

Table 5.

Baseline leptin by gender and BMI*

Gender	BMI categories at baseline**	Leptin Mean ± SD
Male	Normal weight (n=10)	3.2 ± 2.3
	Overweight (n=16)	4.5 ± 2.2
	Obese (n=13)	13.8 ± 12.1
	Total (<i>n</i> =39)	7.3 ± 8.5
Female	Normal weight (n=4)	5.6 ± 2.5
	Overweight (n=18)	14.4 ± 9.7
	Obese (<i>n</i> =47)	21.1 ± 16.7
	Total (<i>n</i> =69)	18.5 ± 15.2
Total	Normal weight (n=14)	3.9 ± 2.5
	Overweight (n=34)	9.7 ± 8.7
	Obese (<i>n</i> =60)	19.5 ± 16.0
	Total (<i>n</i> =108)	14.4 ± 14.2

* BMI Categories:

Underweight = <18.5

Normal weight = 18.5-24.9

Overweight = 25–29.9

Obesity = 30

** Note: p<.01