

# Characteristics of Latinas in Puerto Rico and the US Mainland Receiving Teriparatide in the DANCE Observational Study

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**Objective:** The Direct Assessment of Nonvertebral Fractures in Community Experience (DANCE) study investigated the use of teriparatide in men and women with osteoporosis in the United States (US) and Puerto Rico (PR). In a sub-analysis, we evaluated whether the baseline characteristics of Latinas differed from those of white women in the study population and whether any patient attributes affected physicians' decisions to prescribe teriparatide.

**Methods:** We assessed 3 patient cohorts treated with teriparatide 20 µg once daily for up to 24 months: 1) PR Latinas, 2) US Latinas, and 3) white women on the US mainland (white women). We analyzed differences related to ethnicity (Latina vs. white) and geography (PR vs. US mainland).

**Results:** Overall, 302 of the 3243 women (9%) enrolled in DANCE were Latina (205 of these 302 Latinas resided in PR). Significant differences were observed in 7 of 11 baseline characteristics. White women had more prior fragility fractures and family history of hip fracture than Latinas, while PR Latinas were generally older than US Latinas and had more comorbid conditions. A similar proportion of subjects in each cohort had received prior osteoporosis therapy. Physicians prescribed teriparatide more often for Latinas based on multiple risk factors for fracture and intolerance to previous osteoporosis therapy and to white women based on inadequate response to previous therapy or new (incident) fractures. Overall, Latinas were less persistent with teriparatide therapy than white women.

**Conclusion:** We observed significant differences related to ethnicity and geography in the baseline demographics of Latinas enrolled in the DANCE study, criteria cited by physicians for initiating teriparatide therapy, and treatment persistence. [*P R Health Sci J* 2014;33:105-111]

*Key words:* Osteoporosis, Teriparatide, DANCE, Puerto Rico, Latinas

Most data about osteoporosis are from studies of postmenopausal white women. However, people of all ethnic backgrounds are at risk of developing osteoporosis, and risk levels for fractures vary across ethnic groups (1-4). These differences may be attributed to many health determinants, including individual characteristics (genetics) and behavior (lifestyle choices), the social and economic environment, and geographic region (5).

The US Census Bureau (6) projects that the elderly Latino population will increase 202% between 2010 and 2030 (vs. a 59% increase in the elderly white population). Further, the number of hip fractures for Latinos aged 50 to 64 years is expected to increase 400% between 1990 and 2050 (7). Latinas have shown the most rapid increase in osteoporosis risk in recent years (8); however, few studies have examined the diagnosis and treatment of osteoporosis in women of Latino origin.

The Latin American Vertebral Osteoporosis Study (LAVOS) was the first population-based study of vertebral fractures in

women in 5 countries in Latin America, including Puerto Rico (PR) (9). The incidence of radiographic vertebral fractures ranged from 6.9% in women aged 50 to 59 years to 27.8% in women over 80. The authors concluded that the prevalence of vertebral fractures in Latin America was only slightly lower than for white women in the US. Based on data from LAVOS, Haddock et al. reported that the overall weighted prevalence of vertebral fractures in PR was 11.2% (10).

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The primary objective of the Direct Assessment of Nonvertebral Fracture in the Community Experience (DANCE) study was to evaluate the occurrence of nonvertebral fragility fractures in a heterogeneous sample of 4085 subjects with osteoporosis in the US mainland and PR, who had been treated with teriparatide for  $\leq 24$  months. The occurrence of nonvertebral fragility fractures from DANCE is reported separately (11). The goal of the current analysis was to determine whether there were differences in the baseline characteristics of Latinas and to determine whether any patient attributes contributed to differences in physicians' prescribing decisions.

## Material and Methods

### Design

DANCE was a Phase 4, prospective, non-interventional, observational, outpatient study to evaluate, in a community setting, the long-term effectiveness, safety, and tolerability of treatment (up to 24 months) with teriparatide (ClinicalTrials.gov Identifier: NCT01078805). The study protocol was approved by the study centers' ethical review boards, and all subjects provided written consent to release information before enrollment. Subjects were observed for  $\leq 24$  months post therapy, for a total study duration of 48 months. The rationale, objectives, and design of DANCE have been described (12). In brief, physicians specializing in endocrinology, rheumatology, or internal medicine, and those demonstrating an interest in osteoporosis were invited to participate. Subjects were enrolled in DANCE if they met criteria for teriparatide therapy in the opinion of the study physician. Those receiving teriparatide for  $> 2$  weeks directly before study entry were not eligible to enroll.

Study investigators prescribed teriparatide 20  $\mu\text{g}$  once daily for  $\leq 24$  months. Subjects self-administered medication via subcutaneous injection. The timing and frequency of visits were not specified or mandated; it was anticipated that medical evaluations would occur at approximately 6-month intervals. All patient-care decisions, including diagnostic and therapeutic interventions, were made by study physicians according to their clinical judgment. Product labeling was provided to all investigators as a guide. Teriparatide is approved to treat populations with osteoporosis at high risk for fracture, including postmenopausal women and men, and men and women with glucocorticoid-induced osteoporosis. High-risk patients include those with osteoporosis and a history of fracture, those with multiple risk factors for fracture, and those who have failed or are intolerant to other available osteoporosis therapy.

### Assessments

We examined data from 3 cohorts that participated in the 24-month treatment phase of the DANCE study: 1) PR Latinas,

2) US Latinas, and 3) white women in the US mainland (white women). On the case report form used to document ethnicity of patients participating in the DANCE study, *Latina* was defined as being Mexican-American, Mexican, or from Central or South America. No subcategories, such as Puerto Rican, were included in this listing. For this analysis, PR Latinas were defined as women who identified themselves as being of Latino origin and who were residing in PR while participating in the DANCE study. We compared baseline characteristics, prior osteoporosis therapy, comorbid conditions, reasons investigators cited for initiating teriparatide, treatment persistence, and reasons for treatment discontinuation. We analyzed differences based on ethnicity (total Latinas, those residing in PR and the US mainland vs. white women) and geography (PR Latinas vs. US Latinas). Finally, we examined the number and types (incidence) of fractures that occurred during treatment, including vertebral, nonvertebral, and nonvertebral fragility fractures. A fragility fracture was defined as a fracture associated with low trauma, such as a fall from standing height. Nonvertebral fracture sites in this analysis included the ankle, clavicle, distal forearm, hip, humerus, knee, leg, pelvis, rib, shoulder, and sternum.

### Statistical analyses

Statistical analyses were prespecified before the implementation of the current analyses. The statistical analyses population included any women who enrolled in the study and took  $\geq 1$  dose of teriparatide. Summary statistics, including group size, mean and standard deviation (SD), or proportion (%) were provided where appropriate. The chi-square test was used for comparisons of categorical data between groups (e.g., Latinas vs. white women) at a significance level of 0.05. The Wilcoxon rank sum test was applied for comparing continuous variables between groups at the 0.05 significance level. As the main objective was to compare the baseline characteristics between groups, a covariate adjustment was not made in the statistical comparisons. All statistical evaluations were based on 2-sided tests, and no multiplicity adjustments were made in the analysis.

Some subjects may have discontinued and restarted therapy at various times during treatment. To facilitate statistical analyses related to the duration of therapy, we calculated duration as follows: if a subject discontinued treatment for  $> 3$  months, she was considered to be discontinued because of noncompliance, even if she resumed therapy later; if a subject resumed treatment after stopping for  $\leq 3$  months, she was considered to have received continuous treatment, regardless of any intermittent gap(s). Missing therapy start and stop dates were not imputed; for subjects with records of incomplete therapy, start and stop dates were not included in the analysis.

All analyses were conducted using SAS Drug Development software (SAS Institute, Cary, NC, USA).

## Results

A total of 3243 subjects were included in this analysis: 302 Latinas (205 from PR and 97 from the US) and 2941 white women from the US mainland. Baseline demographics and characteristics are shown in Table 1. The mean age (SD) ranged from 65.90 (SD = 11.66) to 68.57 (SD = 11.03) years, well past the average age for menopause. Most women had comorbid conditions (range: 87.6% – 92.7%) and had been treated with prior osteoporosis therapy (range: 84.5% – 89.0%). However, there were significant differences between Latinas compared with white women for 7 of 11 baseline characteristics assessed. In subjects for whom bone mineral density (BMD) data were available, Latinas had significantly lower lumbar spine BMD T-scores and higher femoral neck and total hip BMD T-scores. Latinas were less likely than white women to have a prior fragility fracture or a family history of hip fracture and were less likely to engage in lifestyle behaviors (smoking, using alcohol) that have been identified as risk factors for osteoporosis. The only significant differences in baseline demographics between PR and US Latinas were that PR Latinas were significantly older and had a greater number of comorbid conditions that contributed to increased fracture risk.

Assessment of vitamin D was not mandatory at baseline. Investigators reported that they assessed vitamin D in a lower proportion of Latinas overall than in US white women (41.8% vs. 59.6%;  $P < 0.0001$ ); the reason for this disparity is unknown. Of those women who were tested, more Latinas than white women had vitamin D levels that were less than 30 ng/mL (51.3% and 41.9%, respectively;  $P < 0.05$ ). Investigators reported that they assessed vitamin D levels in a similar proportion of PR Latinas and US Latinas (40.0% vs. 45.3%); in these 2 groups, there was no significant difference in those who had vitamin D levels of less than 30 ng/mL (58.1% and 39.5%, respectively;  $P = 0.0526$ ).

Table 2 presents information about comorbid conditions that may contribute to increased fracture risk. Significantly more Latinas than white women were reported to have asthma, type 2 diabetes, hypertension, and secondary amenorrhea, while significantly more white women were reported to have chronic obstructive pulmonary disease, inflammatory bowel disease, hip replacement, kyphoplasty/vertebroplasty (to address spinal fractures), and corrective lenses. There were fewer significant differences between PR and US Latinas. Of note, 54.6% of PR Latinas had a history of hypertension versus 28.9% of US Latinas ( $P < 0.0001$ ), indicating that the significant

**Table 1.** Baseline demographics

Characteristic <sup>a</sup>	Total Latinas (N = 302)	US Mainland White Women (N = 2941)	Puerto Rican Latinas (n = 205)	US Mainland Latinas (n = 97)
Age (years)	67.71 (11.28)	68.46 (11.47)	68.57* (11.03)	65.90 (11.66)
BMD T-Score <sup>b</sup>				
Lumbar spine	-2.82*** (0.99)	-2.44 (1.39)	-2.79 (0.92)	-2.88 (1.12)
Femoral neck	-2.30 (1.04)	-2.47** (0.89)	-2.37 (0.94)	-2.15 (1.23)
Total hip	-1.86 (0.99)	-2.24*** (0.99)	-1.87 (0.96)	-1.85 (1.07)
Prior fragility fracture <sup>c</sup> (% yes)	41.1	58.7***	38.5	46.4
Prior osteoporosis <sup>d</sup> therapy (% yes)	87.4	89.0	88.8	84.5
Comorbid conditions <sup>e</sup> (% yes)	91.1	89.9	92.7	87.6
Number of comorbid conditions	2.50 (1.69)	2.51 (1.89)	2.70* (1.79)	2.09 (1.37)
Family history of hip fracture (% yes)	10.3	20.5***	8.8	13.4
Smoking (% yes)	7.3	13.4**	5.4	11.3
Alcohol use (% yes)	13.6	26.5***	11.2	18.6

<sup>a</sup>Values are mean (standard deviation); <sup>b</sup>Puerto Rican vs. US mainland Latinas with bone mineral density (BMD) measurements at lumbar spine (PR = 188; US = 83), femoral neck (PR = 176; US = 75), and total hip (PR = 139, US = 53); total Latinas vs. US mainland white women with BMD measurements at lumbar spine (Latinas = 271; white women = 2174), femoral neck (Latina = 251; white women = 2128), and total hip (Latinas = 192; white women = 1801); <sup>c</sup>Fracture data on case report form obtained by patient self-report or confirmed by x-ray or physician report; <sup>d</sup>Osteoporosis medications prescribed prior to enrollment; <sup>e</sup>Comorbid conditions that contribute to increased fracture risk. \* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.0001$  for comparison between either 1) total Latinas vs. US mainland white women or 2) PR Latinas vs. US mainland Latinas. Comparisons of age, T-scores, and number of comorbid conditions between the cohorts were performed using the Wilcoxon rank sum test. Comparisons of other variables were performed using the chi-square test.

difference in hypertension seen between Latinas (46.4%) and white women (36.8%) may be attributed to the PR cohort. Secondary amenorrhea was more prevalent among PR Latinas, while glucocorticoid-induced osteoporosis and kyphoplasty/vertebroplasty were more prevalent in US Latinas.

Table 3 describes previous osteoporosis therapies prescribed for subjects prior to enrollment in DANCE. Alendronate was the prior osteoporosis therapy most often prescribed across all subgroups (range: 55.7% – 66.3%). Raloxifene was prescribed significantly more often for Latinas than for white women and for PR than US Latinas. Risedronate and calcitonin were prescribed significantly more often for white women than for Latinas.

For each subject enrolled, investigators completed an initiation questionnaire to capture the attributes they considered when prescribing therapy with teriparatide. Results are shown in Table 4. For all cohorts, the reason cited most often for initiating therapy was the presence of multiple risk factors for fracture (range: 82.0% – 91.2%). Physicians initiated therapy significantly more often for Latinas than for white women because of multiple risk factors for fracture (including very low BMD, poor visual acuity, and propensity to fall) and for intolerance to previous osteoporosis therapy. Physicians also initiated therapy significantly more often in Latinas than white women in the US if they had adequate insurance coverage (27.8% vs. 22.6%, respectively,  $P < 0.05$ ).

**Table 2.** Comorbid conditions that contribute to increased fracture risk

Condition (% yes)	Total Latinas (N = 302)	US Mainland White Women (N = 2941)	Puerto Rican Latinas (n = 205)	US Mainland Latinas (n = 97)
Asthma	22.2***	13.9	25.4	15.5
Chronic liver disease	1.0	1.7	0.5	2.1
Chronic obstructive pulmonary disease	3.3	9.4**	3.9	2.1
Coronary heart failure	2.0	4.1	2.0	2.1
Coronary artery disease	7.9	9.4	9.3	5.2
Corrective lenses	48.0	62.6***	51.2	41.2
Diabetes type 1	1.0	1.5	1.5	0.0
Diabetes type 2	16.6***	6.4	17.1	15.5
Emphysema	3.6	5.1	4.9	1.0
Glucocorticoid-induced osteoporosis	11.9	9.4	8.3	19.6**
Hip replacement	2.6	7.1**	2.4	3.1
Hypercortisolism	0.3	0.9	0.5	0.0
Hyperparathyroidism	1.3	2.4	1.0	2.1
Hypertension	46.4**	36.8	54.6***	28.9
Hyperthyroidism	5.0	5.4	3.4	8.2
Inflammatory bowel disease	2.6	7.1**	2.9	2.1
Intestinal malabsorption	2.0	2.8	2.4	1.0
Kyphoplasty/vertebroplasty	1.0	5.1**	0.0	3.1*
Rheumatoid arthritis	15.9	13.5	14.1	19.6
Secondary amenorrhea	17.5***	6.5	22.4**	7.2
Hysterectomy/bilateral salpingo-oophorectomy	34.1	31.6	38.5*	24.7

\**P*<0.05; \*\**P*<0.01; \*\*\**P*≤0.0001 for comparison between either 1) total Latinas vs. US mainland white women or 2) PR Latinas vs. US mainland Latinas. A comparison of all variables between groups was performed using the chi-square test.

**Table 3.** Prior osteoporosis therapy

Type of therapy (% yes)	Total Latinas (N = 302)	US Mainland White Women (N = 2941)	Puerto Rican Latinas (n = 205)	US Mainland Latinas (n = 97)
Alendronate	62.9	64.7	66.3	55.7
Ibandronate	2.6	3.2	2.4	3.1
Risedronate	19.5	32.1***	18.5	21.6
Calcitonin	11.9	18.0**	9.8	16.5
Estrogens	21.5	26.4	23.4	17.5
Raloxifene	21.2**	15.3	25.9**	11.3

\**P*<0.05; \*\**P*<0.01; \*\*\**P*<0.0001 for comparison between either 1) total Latinas vs. US mainland white women or 2) PR Latinas vs. US mainland Latinas. A comparison of all variables between groups was performed using the chi-square test.

Physicians initiated therapy more often in white women than Latinas because of new (incident) osteoporotic fractures, a family history of osteoporotic fracture or a previous osteoporotic fracture, if they smoked, and had an inadequate response to previous therapy, including a decline in BMD or a fracture while on other osteoporosis therapy. Physicians cited the absence of extensive prior authorization criteria significantly more often for initiating therapy in white women versus Latinas, although the percentage of women in each group was low (5.1% vs. 1.7%, respectively, *P*<0.01).

There were fewer significant differences between PR versus US Latinas; however, some of the significant differences seen between these cohorts were also reasons physicians cited for

initiating therapy more often in the overall Latina population compared with white women, including very low BMD, poor visual acuity, a propensity to fall, and intolerance to previous therapy. The only significant differences between PR and US Latinas that were not also significantly different between the overall Latina population compared with white women were advanced age and height loss. The absence of extensive prior authorization criteria was the only reason cited for initiating therapy more often in US than PR Latinas (4.1% vs. 0.5%, respectively, *P*<0.05).

We anticipated that subjects would undergo medical evaluations at approximately 6-month intervals. The mean number of days between visits was examined and determined by calculating the mean number of days between visits for each subject and then determining the mean number of days for all the subjects in the cohort. The mean number of days between visits, shown as mean (SD), was greater in white women than in Latinas, 151.80 (75.69) days versus 126.28 (69.51) days, *P*<0.0001. The mean number of days to the first follow-up visit was longer for white women than for Latinas, 110.83 (96.00) versus 89.01 (79.00), *P*=0.0005, and the average number of visits per year was different between white women and Latinas, 2.33 (0.80) versus 2.44 (0.82), *P*<0.05. The only significant difference between PR and US Latinas was that PR Latinas had their first follow-up visit at 78.18 (59.18) days versus 112.05 (106.70) days for US Latinas (*P*<0.05). Subjects in all cohorts had roughly 2+ visits per year during the study.

Persistence to therapy is shown in Figure 1. Latinas had significantly lower persistence rates than white women at each time point measured (month 6: 75.2% vs. 81.5%, *P*<0.01; month 12: 63.6% vs. 71.3%, *P*<0.01; month 18: 51.7% vs. 62.9%, *P*=0.0001; and month 24: 26.5% vs. 35.5%, *P*<0.01). Persistence was also lower in PR than US Latinas at all time points, however, differences were only significant at months 18 and 24.

Reasons for discontinuing therapy are summarized in Table 5. Fewer Latinas completed therapy (18-24 months) than white women (48.7% vs. 58.9%; *P*<0.01) and fewer PR Latinas completed therapy than US Latinas (44.4% vs. 57.7%; *P*<0.05). There were no significant differences in the percentage of subjects discontinuing therapy due to serious adverse events in either of the comparisons (Table 5).

There were no clinically meaningful differences in the proportion of subjects in each cohort who experienced a fracture

**Table 4.** Reasons Cited by Study Physicians for Initiating TPTD Therapy

Reason (% yes)	Total Latinas (N = 302)	US Mainland White Women (N = 2941)	Puerto Rico Latinas (n = 205)	US Mainland Latinas (n = 97)
New (incident) osteoporotic fracture	13.6	21.5**	15.1	10.3
Multiple risk factors for fracture <sup>a</sup>	89.7**	82.0	91.2	86.6
Family history of osteoporotic fracture	11.3	17.9**	10.2	13.4
Very low bone mineral density (BMD)	76.5***	59.7	80.5*	68.0
Previous osteoporotic fracture	21.5	35.2***	21.0	22.7
General frailty	24.2	20.8	25.9	20.6
Poor visual acuity	12.6***	4.4	18.0***	1.0
Propensity to fall	33.1***	16.4	39.0**	20.6
Low body mass index	17.5	17.0	17.1	18.6
Tobacco use	2.0	7.5**	2.0	2.1
Advanced age	20.2	18.8	24.4**	11.3
Chronic glucocorticoid therapy	9.6	9.7	7.8	13.4
Other	2.6	4.2	2.0	4.1
Inadequate response to previous therapy <sup>a</sup>	48.7	59.8**	46.8	52.6
No change in BMD	12.9*	8.9	14.1	10.3
Decline in BMD	29.5	39.1**	27.3	34.0
Fracture while on other osteoporosis therapy	8.6	18.1***	7.3	11.3
Subject meets physician-defined threshold for therapy	57.9	54.2	60.5	52.6
Intolerance to previous osteoporosis therapy	29.8**	22.5	36.1**	16.5
Adequate insurance coverage	27.8*	22.6	30.7	21.6
Absence of extensive prior authorization criteria <sup>b</sup>	1.7	5.1**	0.5	4.1*
Subject request	6.0	5.5	4.4	9.3
Height loss	18.2	17.1	22.0*	10.3

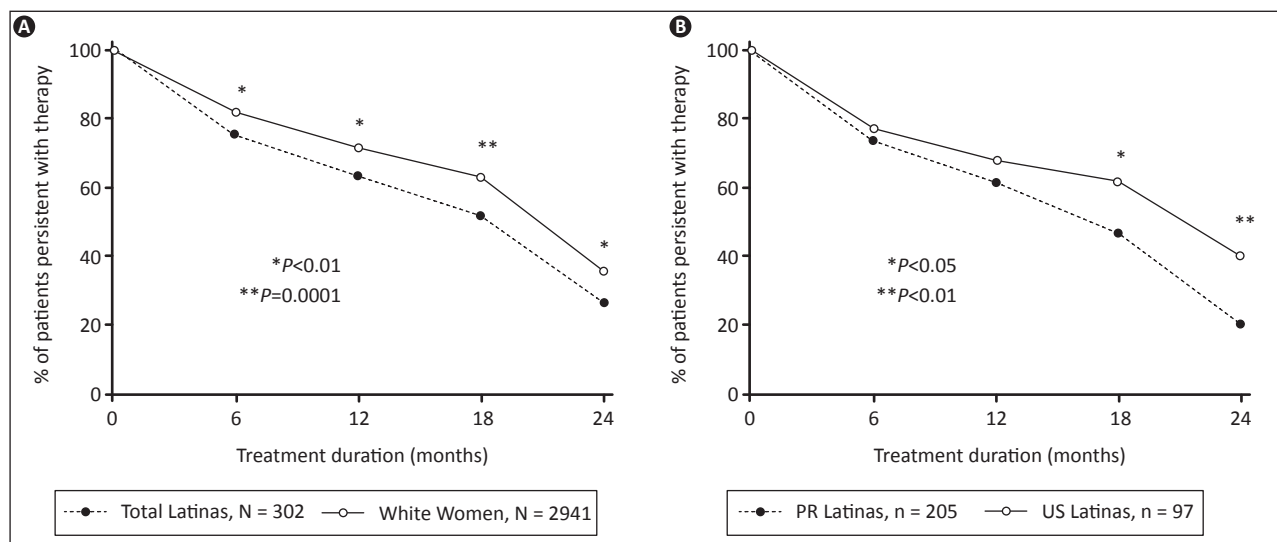
<sup>a</sup>Responses were captured via a teriparatide questionnaire completed by study physicians. More than 1 reason could be selected; <sup>b</sup>In the US, a defined set of criteria that must be met in order for the drug to be covered under a pharmacy benefits plan. \*P<0.05; \*\*P<0.01; \*\*\*P<0.0001 for comparison between either 1) total Latinas vs. US mainland white women or 2) PR Latinas vs. US mainland Latinas

during teriparatide treatment: 234 (7.2%) of 3243 subjects sustained a total of 301 incident fractures, resulting in a fracture incidence rate of 53.13 fractures/1,000 patient-years. Of 234 subjects with fractures, 189 (5.8%) sustained a single fracture, whereas 45 (1.4%) sustained ≥2 fractures. Seventy-four (24.6%) of 301 fractures were clinical vertebral fractures, while 227 (75.4%) were nonvertebral. Of nonvertebral fractures, 95 (41.9%) were reported as fragility fractures. Nonvertebral fragility fractures occurred at the following sites (listed in descending order): wrist (n = 21), hip (n = 15), ribs (n = 13), leg (n = 8), pelvis (n = 7), knee (n = 6), ankle (n = 5), humerus (n = 3), shoulders (n = 1), and clavicle and sternum (n = 0 each), plus n = 16 at other sites not specified.

### Discussion

This large study afforded an opportunity to examine data from Latinas with osteoporosis living in the US mainland and PR. Latinas comprise about 16.7% of the US population (13), making them the nation's largest ethnic or racial minority. However, 302 (9%) of 3243 subjects enrolled in DANCE were Latina, with 97 (about 3%) living in the US mainland. Minorities are generally underrepresented in clinical trials (14); data from observational studies are considered to be more representative of trends seen in clinical practice.

There were many significant differences in baseline characteristics between Latinas and white women enrolled in DANCE. White women



**Figure 1.** Persistence to therapy in A) total Latinas vs. US mainland white women or B) PR Latinas vs. US mainland Latinas

**Table 5.** Reasons to Discontinue Therapy

Reason (% yes)	Total Latinas (N = 302)	US Mainland White Women (N = 2941)	Puerto Rican Latinas (n = 205)	US Mainland Latinas (n = 97)
Patient Decision	31.5**	23.2	32.2	29.9
Physician Decision	5.0	7.8	5.4	4.1
Serious Adverse Event	1.0	2.4	0.5	2.1
Sponsor Decision	0.7*	0.1	1.0	0.0
Other Reason(s)	12.9**	7.2	16.1*	6.2
Conclusion of Therapy <sup>a</sup>	48.7	58.9**	44.4	57.7*

<sup>a</sup>18-24 months. \* $P < 0.05$ ; \*\* $P < 0.01$  for comparison between either 1) total Latinas vs. US mainland white women or 2) PR Latinas vs. US mainland Latinas

seemed to exhibit poorer skeletal health (more prior fragility fractures and family history of hip fracture) and were more likely to engage in lifestyle behaviors (smoking, using alcohol) placing them at risk for osteoporosis. Overall, Latinas had higher hip BMD T-scores and lower lumbar spine BMD T-scores than white women, potentially placing Latinas at higher risk for vertebral fracture. This may be problematic for Latinas because it has been estimated that only about one third of all osteoporotic vertebral fractures come to medical attention (15).

Many factors influence treatment decisions, including comorbidities. White women were more likely than Latinas to have chronic obstructive pulmonary disease or inflammatory bowel disease; however, the percentages for each group were  $< 10\%$ . Conversely, 46.4% of total Latinas vs. 36.8% of white women had hypertension ( $P < 0.01$ ), while 22.2% of Latinas and 13.9% of white women had asthma, and 16.6% of Latinas vs. 6.4% of white women had type 2 diabetes ( $P \leq 0.0001$ ). The higher incidence of hypertension and diabetes in Latinas is consistent with findings of the PR sub-group analysis from the LAVOS study. Hypertension (defined as having a history of taking an antihypertensive agent) was reported by 45% of subjects, while type 2 diabetes was reported by 23% of subjects (10).

While enrollment of Latinas in DANCE was low, a similar proportion of women in each cohort had received prior osteoporosis therapy (range: 84.5% – 89.0%), suggesting that Latinas who were enrolled were not undertreated prior to enrollment. After study entry, Latinas had significantly lower persistence rates than white women at all time points measured. Persistence rates were similar in PR and US Latinas until months 18 and 24, when the difference became statistically significant with PR Latinas being less persistent. The increased age of this cohort, coupled with an increased number of comorbid conditions, may have contributed to lower persistence at later time points.

We did not evaluate adverse events by cohort. However, serious adverse events were evaluated in all subjects who received  $\geq 1$  dose of teriparatide during the treatment phase and are presented elsewhere (11). In the overall study population, the adverse events reported were consistent with current prescribing information.

We also did not identify any differences in fracture incidence that could be attributed to ethnicity or geography. Because of the low incidence of fractures in each of the cohorts, we did not perform extensive analyses of fracture data in this report, which is a study limitation. However, it is reassuring to note that the occurrence of new nonvertebral fractures in the primary analysis of the overall DANCE population was low during the 4 treatment periods assessed: 1.42% at  $> 0$  to  $\leq 6$  months (reference period); 0.91% at  $> 6$  months to  $\leq 12$  months; 0.70% at  $> 12$  months to  $\leq 18$  months; and 0.81% at  $> 18$  months to  $\leq 24$  months. The difference for

each of the 3 treatment periods  $> 6$  months was statistically significantly lower versus the reference period ( $P < 0.05$  for each comparison). The incidence rate of new nonvertebral fractures decreased with duration of teriparatide treatment beyond 6 months compared with the first 6 months. This trend toward lower fracture rates persisted during the 24-month cessation period (11).

The major strength of DANCE is that it allowed investigators to enroll a large, diverse group of patients that facilitated use of a population-based dataset to prospectively evaluate differences between women based on ethnicity (Latina vs. White) and geography (US vs. PR). DANCE also has limitations common to observational studies: the lack of a control group, no mandates on specific intervals for study visits, and that data were collected at the discretion of individual investigators. These limitations are not likely to influence the findings of this analysis. Another potential limitation is that the term *Latina* is not consistently defined in the literature. Women of Latino origin may descend from various genetic groups (i.e., black, Spanish, and Amerindian) and different nationalities (i.e., Mexican, Cuban, and Puerto Rican) and are often referred to as Hispanics. Finally, Latinas comprised only about 10% of the population in this analysis; the unbalanced sample sizes in the various cohorts may limit the generalizability of the findings. However, these exploratory findings provide important insights for hypothesis generation and further research.

## Conclusions

This analysis identified many statistically significant differences between study participants related to ethnicity and geography. These findings are important because the Latino population is expanding and the need for research in this subgroup is growing. Doctors and health care providers (in the US and PR) should recognize the need to improve the screening of osteoporosis in individuals of Latino origin, and researchers need to continue to identify markers that may improve the diagnosis and treatment of osteoporosis in Latinos. Osteoporosis afflicts people of all ethnic groups and is an important public

health concern worldwide because of the significant morbidity and mortality associated with osteoporotic fractures.

## Resumen

**Objetivo:** El estudio de evaluación directa de fracturas no vertebrales en la experiencia comunitaria (Direct Assessment of Nonvertebral Fractures in Community Experience, DANCE) investigó el uso de la teriparatida en mujeres con osteoporosis en los Estados Unidos (EE. UU.) y Puerto Rico (PR). En un subanálisis, evaluamos si las características basales de las mujeres latinas eran diferentes de las mujeres blancas de la población del estudio y si alguno de los atributos de las pacientes afectaban a las decisiones de los médicos de recetar teriparatida. **Métodos:** Evaluamos 3 cohortes de pacientes tratadas con teriparatida 20 µg una vez al día durante un máximo de 24 meses: 1) mujeres latinas de PR; 2) mujeres latinas de EE. UU.; y 3) mujeres blancas del territorio continental de EE. UU. (mujeres blancas). Analizamos las diferencias relacionadas con la etnia (latina frente a blanca) y la geografía (PR frente a territorio continental de EE. UU.). **Resultados:** En conjunto, 302 de las 3243 mujeres (9%) inscritas en DANCE eran latinas (205 de estas 302 mujeres latinas residían en PR). Se observaron diferencias significativas en 7 de 11 características basales. Las mujeres blancas presentaban más fracturas previas por fragilidad y antecedentes familiares de fractura de cadera que las mujeres latinas, mientras que las mujeres latinas de PR eran en general de mayor edad que las mujeres latinas de los EE. UU. y presentaban más afecciones comórbidas. Proporciones similares de sujetos de cada cohorte habían recibido tratamiento para la osteoporosis. Los médicos recetaban teriparatida con mayor frecuencia a las mujeres latinas en función de múltiples factores de riesgo de fractura e intolerancia a tratamientos previos para la osteoporosis, y a las mujeres blancas en función de la respuesta inadecuada a tratamientos previos o fractura nueva (incidental). En conjunto, las mujeres latinas fueron menos persistentes que las mujeres blancas con el tratamiento con teriparatida. **Conclusión:** Observamos diferencias significativas relacionadas con la etnia y la geografía en las características demográficas basales de las mujeres latinas inscritas en el estudio DANCE, los criterios que indicaron los médicos para iniciar el tratamiento con teriparatida y la persistencia con el tratamiento.

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