

Underrepresentation of Racial and Ethnic Diversity in Research Informing the American Urological Association/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction Stress Urinary Incontinence Guideline



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OBJECTIVE	To characterize the racial/ethnic representation in the studies used in the American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction stress urinary incontinence guideline.
METHODS	Cited studies were reviewed using inclusion and exclusion criteria. The inclusion criteria focused on United States literature to allow for demographic comparison with census data. To compare the racial representation in a study to the diversity in the surrounding city, we calculated the differences between county census data and the study race reported data and performed regression analyses.
RESULTS	Eighty-seven cited studies were reviewed, of which 33 were excluded and 52 studies were further evaluated. Seventeen studies were US studies, nine of which reported race. Eighty percent of the women included in the 9 studies were non-Hispanic white women. A diverse geographic region did not correlate with increased study enrollment of non-White patients.
CONCLUSION	The majority of cited studies used to develop the stress urinary incontinence management guidelines did not report the race/ethnicity of participants. Among those studies that did, Asian, Black, and Hispanic women were included at lower rates than non-Hispanic white women, identifying an area of opportunity to improve research recruitment and promote health equity. Non-Hispanic women were consistently overrepresented while other women were either under-represented or completely excluded. UROLOGY 163: 16–21, 2022. © 2021 Elsevier Inc.

Stress urinary incontinence (SUI) is defined by the International Continence Society as leakage of urine with physical exertion, cough, laugh or sneeze.¹ An estimated 200,000 anti-incontinence procedures for SUI are performed annually in the United States, many of which are mid-urethral slings.^{2,3} Chughtai et al

analyzed the case logs of American urologists applying for certification between 2003 and 2012 and found that 93% of all urologists treating female incontinence reported any use of slings and 53% reported exclusive use of slings. While 37% reported any use of endoscopic injections and 10% reported any use of traditional repairs such as the Burch colposuspension.³ Although SUI is not life threatening, it affects up to 56% of women, and the management strategies continue to evolve.⁴ Prior social media analysis of SUI posts identified the negative effect of incontinence on intimate relationships and self-esteem.⁵ Online discussions focused on negative emotions and surgical decision-making for treatment of SUI in the context of mesh use and concomitant prolapse repair.⁵ There has been mounting scrutiny of the use of mesh for pelvic floor disorders over the past fifteen year and most recently

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with the Food and Drug Administration warning.⁵ The American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) created a guideline statement in 2017 delineating available treatment techniques for the management of SUI.⁶

One of the few studies that included a diverse patient population by Thom et al demonstrated that Black women have higher urgency incontinence rates and Hispanic women were twice as likely to experience daily incontinence.⁷ Studies focusing on minority women are limited, and the data available suggests that urinary incontinence disproportionately affects women of color. Considering the higher prevalence of female SUI and high rates of surgical sling procedures among Hispanic women, identifying racial representation, which is currently unspecified in the research studies upon which society-endorsed guidelines are created is paramount.⁸ Yet, the majority of SUI prevalence studies include homogenous convenience sample populations.^{9,10} Research studies should be congruent with the patients we treat. Brown et al examined the studies used to develop the 2019 AUA/SUFU overactive bladder (OAB) guidelines and concluded that most OAB research used to construct that guideline lacked specification of race/ethnicity and was consequently not reflective of United States (US) demographics.¹¹ Similarly, to elucidate the racial and ethnic representation of patients in SUI studies, our objective was to characterize racial demographics in the cited studies used to develop the 2017 AUA/SUFU SUI guideline statement and determine if racial/ethnic distributions were congruent with study geography.

METHODS

The 2017 AUA/SUFU SUI management guideline citations were reviewed to identify publications that reported the race/ethnicity of study participants (Supplementary Fig. 1). The full-text article was obtained for each cited study. We excluded literature classified as systematic reviews, literature reviews, meta-analyses, secondary analyses, analytic, and research modeling techniques. We reviewed the main study objectives, geographic location where the study was conducted, year of publication, funding source, reporting of race/ethnicity demographics, total number and age of participants, and the questionnaires used. Race categories were defined using the National Institutes of Health Office of Management and Budget standards, which include Black, White, Asian, and American Indian/Alaska Native (AIAN). Office of Management and Budget classifies Hispanics or Latinos as an ethnic category.¹² According to the Pew Research Center, despite federal policy defining Hispanic as an ethnicity, the majority of Latinos believe their Hispanic background represents both their ethnic and racial background.¹³ However, the studies that included Hispanics reported this population as a race, so for consistency we included it as a racial demographic. We use the terms Hispanic and Latina women interchangeably, as both are pan-ethnic terms that describe the people living in

the US of that background. However, there is significant variation in how individuals chose to identify.¹⁴ We focused on American studies reporting race in order to compare racial representation of patients in studies to their respective representation in US census data.

We compared the average study race reported data to the average census data in studies to investigate the relative recruitment of participants based on geographic location. The average census data was calculated using the 2019 county specific race data (www.census.gov) for each respective location. Of note, we calculated the average census data for the years 2010, 2011, 2015, and 2019 which were available online. The census race distribution data was consistent throughout the years and did not change significantly over the 10-year period. For consistency, in multicenter studies, we combined race specific percentages and divided the total percentage by the total number of research locations as institution specific recruitment data was not available. To investigate whether a region's census racial demographics influenced the demographics of a study from that location, we created two sets of simple linear regression models. Our first model aimed to measure the correlation between the study demographics and the census demographics where the respective study was conducted. We investigated whether or not a diverse geographic region leads to increased study enrollment of non-White patients. The independent variable was the proportion of people of a specific race in a given region, and the dependent variable was designated as the predicted proportion of that race in a given study.

We hypothesized that those studies with recruitment from more diverse areas would have study enrollment congruent with the racial census representation for a specific region. For consistency, we omitted the "other" demographic. Since most publications we reviewed had low proportions of minority women, our methods would result in studies having smaller differences between the average census data and the reported demographics. In other words, anytime a population is larger, the absolute difference between reported and census data will appear magnified. Therefore, we attempted to control for census proportion and created a second set of simple linear regression models. In this set, the independent variable was the race-specific proportion using census information, and the dependent variable was the difference between the study's reported racial breakdown and regional census-based data.

RESULTS

We reviewed all 87 studies, 35 studies of which were excluded based on our pre-established criteria. Fifty-two studies were further analyzed. Thirty-five (67%) of the included studies published between 1987 and 2016 were not based in the US. Seventeen (33%) of the included studies published between 1998 and 2015 were conducted in major US metropolitan locations with minimal geographic variation (Supplementary Fig. 2). Thirty US institutions, of which 56% were public, were involved in the 52 publications that were utilized.

Table 1 demonstrates the study characteristics for the 52 studies meeting our inclusion criteria. Prospective enrollment of patients occurred in 34 (65%) of the total studies and 59% of the US specific studies. Additionally, no US studies mentioned the use of bilingual recruitment materials or questionnaires. Forty-seven percent of the US research sites received government funding (National Institute of Health, National Institute

Table 1. Characteristics of the studies referenced in the 2017 AUA/SUFU surgical treatment of female stress urinary incontinence guideline

Study Characteristics	N = 52 Studies
Study type, n (%)	
Randomized Trial	26 (50%)
Retrospective cohort	9 (17%)
Prospective cohort	8 (15%)
Cross-sectional	3 (6%)
Other	6 (12%)
Study focus, n (%)	
Midurethral Sling outcomes (TVT, TOT, Biologic, AFS)	22 (42%)
Post-operative outcomes	9 (17%)
Diagnostics	6 (11%)
Perioperative risk factors	5 (10%)
Quality of life	4 (8%)
Prophylactic Midurethral Slings	3 (6%)
Other	3 (6%)
Study size, n (%)	
<99	13 (25%)
100-499	31 (60%)
500-1000	6 (12%)
>700	2 (4%)
Geographic location and Race reported, n (%)	
US based	17 (37%)
Race reported	9/17
Non-US based	35 (67%)
Race reported	0/35
Race/Ethnicity, n (%)	N = 3536 Participants
Non-Hispanic white	2846 (80%)
Hispanic	256 (7%)
Black	138 (4%)
Asian	7 (1%)
Other	289 (8%)

AUA, American Urological Association; SUFU, Society of Uroynamics, Female Pelvic Medicine & Urogenital Reconstruction.

of Diabetes and Digestive and Kidney Diseases, National Institute of Child Health and Human Development, and Office of Research in Women's Health), and 12% were funded by academic sponsorship. Sixty-seven percent of US studies reporting race were conducted with government funds.

Only 9 (53%) US studies reported racial parameters (Table 1). Out of the nine studies reporting race, all studies included non-Hispanic white women, 7 included Black women, 5 included Hispanic women, and 2 included Asian women. Out of the total 3,536 women included in the nine studies, the majority (80%) were non-Hispanic white women, 7% were Hispanic, 4% were Black, 1% were Asian, and the remaining 8% were classified as "other." Of note, studies did not specify which demographics were included in the "other" category and AIAN were not represented.

Table 2 demonstrates the comparison of the study reported racial demographics and the average racial census representation for multicenter and single-center studies. There was significant representation discrepancy between those two respective values. The first linear model (Table 3) revealed that, as might be expected, a census with a higher proportion of Black individuals was significantly associated with an increased trial proportion of Black women (0.46, 95% CI: 0.10; 0.81, $P = .041$). However,

the census breakdown for all the other groups were not significantly associated with that region's demographics. In the second linear model, an increase in a region's census proportion of a particular race/ethnicity was significantly negatively associated with the absolute difference between the study reported and census demographic data for Blacks, Hispanics, and Asians, meaning the more of one race/ethnicity, the less likely they were to participate in a study (Table 4).

DISCUSSION

Overall, we found that very few cited studies supporting the 2017 AUA/SUFU SUI management guideline statement reported racial demographics. Indeed, the guidelines, do not specifically acknowledge the lack of attention to race and ethnicity. Studies did not include equal representation of women from different racial backgrounds, and researchers did not identify which patients were classified as "other." The underrepresentation of historically marginalized communities in clinical research studies has been well documented.^{15,16} Yet, studies do not acknowledge the homogeneity of their study populations. Society-supported management guidelines should highlight the external validity challenges created by the inclusion of homogenous research participants. The majority of included US based studies prospectively enrolled participants. Unlike retrospective cohorts, prospective studies provide more opportunity to specifically recruit a diverse population of patients.

Our regression modeling allowed us to analyze and understand how the geographic location of a study might have influenced variation in the race of women recruited. First, surprisingly, an increase in a region's census breakdown by race/ethnicity did not correlate with an absolute increase in trial representation for that particular race/ethnicity. The one exception was from Black women, where an increase the census proportion of Black people correlated with a higher trial proportion of Black participants. Translation of consent forms and recruiting patients in other languages could increase enrollment among other racial groups which may include recent immigrants to the US and who might not speak English.

Furthermore, higher census proportions of Black, Hispanic and Asian persons were actually correlated with lower representation (a greater difference between the repost study demographics and census data) in a study from that region. This means that Caucasians are actually overrepresented in SUI research studies. These two findings together suggest that minority groups are not necessarily better represented in trials from regions where that particular minority group is better represented. There are several reasons why simply conducting research in a diverse city is not enough to improve representation in clinical research. Mistrust and fear of the medical community among minority patients is well documented.¹⁷ Other barriers may include language, cultural, and lack of leisure time for working patients. These findings suggest that

Table 2. Comparison of reported study and census demographic data of the nine US studies reporting race

Study		Subject Characteristics			
		Non-Hispanic White	Black	Hispanic	Asian
1	Reported data	79%	3%	12%	0%
	Average census data	53%	17%	22%	8%
	Absolute difference	26%	14%	10%	8%
2	Reported data	100%	0%	0%	0%
	Average census data	26%	9%	49%	15%
	Absolute difference	74%	9%	49%	15%
3	Reported data	71%	7%	14%	1%
	Average census data	50%	22%	19%	8%
	Absolute difference	21%	15%	5%	7%
4	Reported data	87%	6%	0%	0%
	Average census data	50%	23%	19%	7%
	Absolute difference	37%	17%	19%	7%
5	Reported data	90%	5%	3%	0%
	Average census data	57%	20%	14%	7%
	Absolute difference	33%	15%	11%	7%
6	Reported data	96%	1%	0%	3%
	Average census data	68%	16%	8%	7%
	Absolute difference	28%	15%	8%	4%
7	Reported data	75%	6%	11%	0%
	Average census data	54%	17%	21%	7%
	Absolute difference	21%	11%	10%	7%
8	Reported data	79%	3%	12%	0%
	Average census data	55%	18%	18%	7%
	Absolute difference	24%	15%	6%	7%
9	Reported data	76%	0%	0%	0%
	Average census data	55%	19%	18%	7%
	Absolute difference	21%	19%	18%	7%
Total average difference		32%	14%	15%	8%

researchers need to be intentional about designing their studies and recruitment strategies to maximize diverse representation.

Although prevalence studies have identified weekly incontinence to be highest among Hispanic women (36%), the cited guideline studies only included 7% of Hispanic women in the data.⁷ Khan et al identified language and cultural norms as barriers for Latina women seeking urinary incontinence care.¹⁸ If it is challenging for Latinas to establish care at baseline, these barriers likely also make research participation difficult. Additionally, none of the studies reported using non-English language questionnaires, even though 75% of the questionnaires that were used in the studies have been validated in Spanish. The available validated Spanish questionnaires include: Patient Global Impression of Improvement (PGI-

I), Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Medical, Epidemiologic, and Social Aspects of Aging Urinary Incontinence Questionnaire (MESA), Pelvic Floor Distress Inventory (PFDI), and Pelvic Floor Impact Questionnaire (PFIQ) surveys. One-third of all Hispanics in the US are monolingual Spanish speakers and 57% are older Hispanic women, who are at high risk for SUI and are likely not represented in the SUI literature reviewed.¹⁹ We previously identified Latina and non-Hispanic women as being more likely than Black and Asian women to undergo a sling surgery when analyzing Medicare claims, yet these women remain underrepresented in clinical outcome studies.⁸

Prior analysis of the Office of Statewide Health Planning and Development from the State of California administrative database for women undergoing a mid-urethral slings procedure found that Black race and Medicaid insurance status were independently associated with an increased risk of a 30-day adverse event.²⁰ Black women only represented 4% of the participants in the cited SUI studies reporting race.

Racial disparities have been recognized in the management of other benign female urologic conditions such as OAB and pelvic organ prolapse. A prior similar study found poor diverse racial representation in studies used to develop the 2019 AUA/SUFU OAB treatment guideline.¹⁰ Additionally, Syan et al identified Asians as having the lowest usage rate of oral agents, and non-White race as being associated with a lower rate of advanced therapy

Table 3. Correlation between regional census proportion race/ethnicity and reported study proportion of race and ethnicity*

Race/Ethnicity	Effect (95% CI)	P value
White (Non-Hispanic)	-0.24 (-0.88; 0.41)	.492
Black	0.46 (0.10; 0.81)	.041
Hispanic	-0.07 (-0.47; 0.34)	.762
Asian	-0.06 (-0.35; 0.22)	.677

* Effect is from simple linear regression models where the independent variable is the proportion of the census data made up of that particular Race/Ethnicity and the dependent variable is the study proportion made up of that Race/Ethnicity.

Table 4. Correlation of difference between regional census proportion race/ethnicity and reported study proportion of race and ethnicity and regional census proportion race/ethnicity*

Race/Ethnicity	Effect (95% CI)	P value
Black	−0.56 (−0.90; −0.19)	.020
Hispanic	−1.07 (−1.47; −0.66)	.001
Asian	−1.06 (−1.35; −0.78)	<.001

* Effect is from simple linear regression models where the independent variable is the proportion of the census population made up of the particular race/ethnicity and the dependent variable is the difference between the study proportion of a particular Race/Ethnicity and the proportion of the census data's population made up of that particular Race/Ethnicity.

(onabotulinumtoxinA, sacral neuromodulation, percutaneous tibial nerve stimulation) use for the management of OAB.²¹ Likewise, Cardenas-Trowers et al analyzed pelvic organ prolapse and patient race association using the American College of Surgeons National Surgical Quality Improvement Program database.²² They discovered that apical suspension procedures are less often performed for Hispanic women, and Black women and other minority women are more likely to undergo an obliterative procedure for treatment of their high grade prolapse.²²

Although our article highlights an important topic that can be easily overlooked, it is not a comprehensive review of all published SUI clinical studies as we only reviewed the cited studies used to develop the AUA/SUFU SUI guideline. Another limitation of this study is our analysis of multicenter data, as studies did not report the specific proportion of patients recruited by individual sites and we did not contact authors for this information. Also, some of the research sites are large tertiary centers and may have patients from various counties. Furthermore, although we found that the publicly available average census data was consistent over the 10-year period using our methods, it may underestimate racial representation. We hope that our efforts increase awareness of the current SUI research engagement disparities and encourage academic urologists to prioritize scholarly work that equitably represents our patients. Understandably, there may be recruitment challenges beyond the immediate actions of researchers to increase diversity. However, the published literature should highlight these shortcomings and their implications.

CONCLUSION

SUI is a highly prevalent condition that disproportionately impacts non-White populations. However, the studies used to develop the AUA/SUFU guidelines failed to include research participants that proportionately match the patients we treat. Overall, non-Hispanic women were overrepresented, while other groups of women were underrepresented and completely excluded in the case of AIAN women. Possible solutions to help improve the representation of diverse participants include actively recruiting underrepresented patients in research studies,

crafting research materials in a variety of languages, enforcing racial recruitment thresholds, requiring reporting of racial/ethnic data, and building organizational partnerships with historically marginalized communities. Additionally, including diverse expert panel members in the development of future AUA/SUFU guideline recommendations will better allow for representation of different perspectives and will better match our patient populations.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2021.08.038>.

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