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Have all races experienced reductions in complication rates following total hip arthroplasty? A NSQIP analysis between 2011 and 2019

Daniel Grits¹ · Christian J. Hecht II¹ · Alexander J. Acuña¹ · Robert J. Burkhart¹ · Atul F. Kamath¹

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Abstract

Introduction Despite numerous articles in the orthopedic literature evaluating racial and ethnic disparities, inequalities in total joint arthroplasty outcomes remain. While the National Surgical Quality Improvement (NSQIP) database has been previously utilized to highlight these disparities, no previous analysis has evaluated how the rate of various perioperative complications has changed over recent years when segregating by patient race. Specifically, we evaluated if all races have experienced decreases in (1) medical complications, (2) wound complications, (3) venous thromboembolism (VTE), and (4) readmission/reoperation rates following total hip arthroplasty (THA) over recent years?

Methods Current Procedural Terminology (CPT) code 27,130 (total hip arthroplasty) was utilized to identify all THA procedures conducted between 2011 and 2019. Patients were segregated according to race and various demographics were collected. Linear regression was utilized to evaluate changes in each complication rate between 2011 and 2019. A multivariate regression was then conducted for each complication to evaluate whether race independently was associated with each outcome.

Results Our analysis included a total of 212,091 patients undergoing primary THA. This included 182,681 (85.76%) White, 19,267 (9.04%) Black, 5928 (2.78%) Hispanic, and 4215 (1.98%) Asian patients. We found that for urinary tract infection (UTI), acute renal failure, superficial SSI, and readmission rates, White patients experienced significant reductions between 2011 and 2019. However, this was not consistent across all races. Black race was associated with a significantly increased risk of acute renal failure (OR: 2.03, 95% CI: 1.17–3.34; p = 0.008), renal insufficiency (OR: 2.33, 95% CI: 1.62–3.28; p < 0.001), deep vein thrombosis (DVT) (OR: 1.34, 95% CI: 1.07–1.66; p = 0.01), and pulmonary embolism (PE) (OR: 1.76, 95% CIL: 1.36–2.24; p < 0.001).

Conclusion Our analysis highlights specific complications for which further interventions are necessary to reduce inequalities across races. These include medical optimization, increased patient education, and continued efforts at understanding how social factors may impact-related care inequalities. Future study is needed to evaluate specific interventions that can be applied at the health systems level to ensure all patients undergoing THA receive the highest quality of care regardless of race.

Keywords National surgical quality improvement (NSQIP) \cdot Total hip arthroplasty (THA) \cdot Venous thromboembolism (VTE) \cdot Racial disparities \cdot Complications

Atul F. Kamath kamatha@ccf.org

Introduction

Although total hip arthroplasty (THA) continues to demonstrate efficacy in reducing pain caused by hip osteoarthritis (OA) while improving quality of life [1, 2], racial disparities in outcomes continue to be highlighted in the literature [3, 4]. Specifically, numerous institution-specific and large national database studies have found ethnic and racial disparities in the utilization of THA, post-operative complications, and discharge deposition [5–7]. In order to

¹ Department of Orthopaedic Surgery, Center for Hip Preservation, Orthopaedic and Rheumatologic Institute, Cleveland Clinic Foundation, 9500 Euclid Ave, Mail code A41, Cleveland, OH 44195, USA

address these multifactorial issues, there has been a plethora of literature evaluating differences in outcomes across racial groups, as well as potential methods of addressing these disparities across healthcare settings [8–10]. However, recent evidence suggests that related inequalities continue to exist among contemporary cohorts [7, 11, 12].

Invented in 2004, the American College of Surgeons National Surgery Quality Improvement Program (ACS-NSQIP) sought to improve the quality of surgical care through the monitoring of various post-operative complications as well as how patient- and surgeon-specific factors influenced outcomes [13]. NSQIP is a publicly available, de-identified database that prospectively collects data on preoperative characteristics, comorbidities, surgical attributes, and 30 day outcomes from a random sample of patients undergoing major surgical procedures from over 700 participating hospitals. Using standardized definitions to ensure uniformity in reporting and periodically audited by independent reviewers in order to ensure its accuracy, NSQIP has been reported to be more accurate than administrative databases [13]. Since its advent, various studies have used this national data to evaluate how peri-operative THA outcomes vary based on race. However, there remains inconsistencies in the literature regarding the association of race with postoperative outcome inequalities partly due to variations in comorbidity assessment and utilized time frames [14-17]. Additionally, although recent analyses have utilized NSQIP to evaluate how outcomes for THA procedures as a whole have changed over recent years [18], no previous analysis has evaluated changes in complication rates while stratifying by race.

Therefore, in order to better understand the existing THA complication rates and how they have changed for various racial groups over contemporary time frames, we utilized the NSQIP database between 2011 and 2019. Specifically, we asked: have all races experienced decreases in (1) medical complications, (2) wound complications, (3) venous throm-boembolism (VTE), and (4) readmission/reoperation rates following THA over recent years?

Methods

Database

The ACS- NSQIP database provides risk-adjusted data which can be utilized to illuminate trends in procedure-specific outcomes, 30 day post-operative complications, and mortality from over 700 hospitals. In addition to regular database audits, each NSQIP participating institution has a certified reviewer who verifies the authenticity of the data obtained before inputting it to ensure high fidelity [19]. With the ability to identify procedures through Current Procedural Terminology (CPT) codes, over 150 patient- and procedure-specific variables are made available for each surgical procedure. This includes each patient's age, sex, race, and comorbidity burden. Given its potential to help identify and subsequently address specific domains for quality improvement, numerous studies have utilized NSQIP to evaluated perioperative THA outcomes [7, 14, 16, 17, 20–23].

Patient selection

CPT code 27,130 (total hip arthroplasty) was utilized to identify all THA procedures conducted between 2011 and 2019. This time frame was selected as readmissions were not coded until 2011 and 2019 was the most recent dataset available at the time of analysis. Patients were excluded if information regarding inputted race was not available. The following demographic variables were collected: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) class, anesthesia type, operative time, operative year, and modified Charlson Comorbidity Index (CCI).

Patient demographics

Our analysis included a total of 212,091 patients undergoing primary THA (Table 1). This included 182,681 (85.76%) White, 19,267 (9.04%) Black, 5928 (2.78%) Hispanic, and 4215 (1.98%) Asian patients.

Outcomes evaluated

Based on the available outcomes provided in NSQIP and the Hip Society's standardized complication list [24, 25], we evaluated medical complications, wound complications, VTE, and readmissions/reoperations. Medical complications included myocardial infarction (MI), renal insufficiency, urinary tract infection (UTI), and acute renal failure. VTE included rates of pulmonary embolism (PE) and deep vein thrombosis (DVT). Wound complications captured wound dehiscence, superficial surgical site infection (SSI), and deep SSI.

Statistical analysis

Linear regression was utilized to evaluate changes in each complication rate between 2011 and 2019. A multivariate regression was then conducted for each complication to evaluate whether race independently was associated with each outcome. These models included each patient's age, sex, BMI, ASA class, anesthesia type, operative time, operative year, and modified CCI to generate Odds Ratios (ORs) with their respective 95% Confidence Intervals (95% CIs). All statistical analyses were conducted in R version 4.0.3

Variable	Asian, $N = 4215^1$	Black, $N = 19,267^1$	Hispanic, $N = 5928^1$	White, $N = 182,681^{1}$
Age category				
18–29	51/4215 (1.2%)	310/19,267 (1.6%)	104/5928 (1.8%)	684/182,681 (0.4%)
30–39	116/4215 (2.8%)	617/19,267 (3.2%)	259/5928 (4.4%)	2369/182,681 (1.3%)
40-49	276/4215 (6.5%)	2198/19,267 (11%)	661/5928 (11%)	9830/182,681 (5.4%)
50–59	830/4215 (20%)	5784/19,267 (30%)	1503/5928 (25%)	37,449/182,681 (20%)
60–69	1,425/4215 (34%)	6304/19,267 (33%)	1782/5928 (30%)	63,946/182,681 (35%)
70–79	1,040/4215 (25%)	3151/19,267 (16%)	1177/5928 (20%)	48,278/182,681 (26%)
80–89	431/4215 (10%)	844/19,267 (4.4%)	396/5928 (6.7%)	18,485/182,681 (10%)
90+	46/4215 (1.1%)	59/19,267 (0.3%)	46/5928 (0.8%)	1640/182,681 (0.9%)
Sex				
Female	2697/4214 (64%)	10,230/19,267 (53%)	3173/5928 (54%)	100,930/182,672 (55%)
BMI	27.34 (5.67)	31.61 (6.74)	30.53 (5.90)	30.15 (6.31)
ASA physical classificat	ion system			
1-No disturb	240/4215 (5.7%)	349/19,267 (1.8%)	183/5928 (3.1%)	5,733/182,681 (3.1%)
2-Mild disturb	2,468/4215 (59%)	8730/19,267 (45%)	3,177/5928 (54%)	97,395/182,681 (53%)
3-Severe disturb	1,451/4215 (34%)	9673/19,267 (50%)	2,443/5928 (41%)	75,839/182,681 (42%)
4-Life threat	52/4215 (1.2%)	509/19,267 (2.6%)	124/5928 (2.1%)	3,573/182,681 (2.0%)
5-Moribund	0/4215 (0%)	1/19,267 (<0.1%)	0/5928 (0%)	11/182,681 (<0.1%)
None assigned	4/4215 (<0.1%)	5/19,267 (<0.1%)	1/5928 (<0.1%)	130/182,681 (<0.1%)
Modified charlson como	rbidity index			
0–2	2598/4215 (62%)	14,114/19,267 (73%)	4103/5928 (69%)	107,515/182,681 (59%)
3–4	1550/4215 (37%)	4800/19,267 (25%)	1723/5928 (29%)	70,788/182,681 (39%)
5+	67/4215 (1.6%)	353/19,267 (1.8%)	102/5928 (1.7%)	4378/182,681 (2.4%)
Principal anesthesia tec				
Epidural	30/4215 (0.7%)	244/19,267 (1.3%)	35/5928 (0.6%)	1070/182,671 (0.6%)
General	1,965/4215 (47%)	11,523/19,267 (60%)	3,637/5928 (61%)	96,437/182,671 (53%)
Local	1/4215 (<0.1%)	4/19,267 (<0.1%)	0/5928 (0%)	40/182,671 (<0.1%)
MAC/IV sedation	349/4215 (8.3%)	2516/19,267 (13%)	580/5928 (9.8%)	21,681/182,671 (12%)
None	0/4215 (0%)	4/19,267 (<0.1%)	0/5928 (0%)	31/182,671 (<0.1%)
Other	2/4215 (<0.1%)	24/19,267 (0.1%)	2/5928 (<0.1%)	98/182,671 (<0.1%)
Regional	44/4215 (1.0%)	223/19,267 (1.2%)	61/5928 (1.0%)	3877/182,671 (2.1%)
Spinal	1,824/4215 (43%)	4724/19,267 (25%)	1,612/5928 (27%)	59,419/182,671 (33%)
Unknown	0/4215 (0%)	5/19,267 (<0.1%)	1/5928 (< 0.1%)	18/182,671 (<0.1%)
Operative time	101.52 (43.23)	104.46 (43.28)	103.21 (43.49)	92.67 (38.81)

Table 1 Characteristics of cohorts stratifying by patient radius
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 $^{1}n/N$ (%); mean (SD)

(R Project for Statistical Computing, Vienna, Austria). A p value < 0.05 was considered statistically significant.

Results

Medical complications

No changes in the rates of MI or renal insufficiency were demonstrated for all THA patients or when segregating by race (Table 2). There was a decrease in UTI rates demonstrated for the unsegregated THA cohort as well as for White, Hispanic, and Asian patients. However, no differences were seen for Black patients. Although THA patients as a whole did not experience a decrease in acute renal failure rates, White patients in isolation were found to have lower rates over the study period. On multivariate analysis, Black race was associated with a significantly increased risk of acute renal failure (OR: 2.03, 95% CI: 1.17–3.34; p = 0.008) as well as renal insufficiency (OR: 2.33, 95% CI: 1.62–3.28; p < 0.001) compared to other races (Table 3).

Wound complications

No changes in rates of deep SSI or wound dehiscence were found for THA patients collectively as well as when

Table 2	Changes in complication rates (as percentages) across races from 2011 to 2019
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Complications	Overall			White	White		Black		
	2011	2019	p value	2011	2019	p value	2011	2019	p value
Medical complications									
Myocardial infarction	0.003	0.002	0.142	0.002	0.002	0.402	0.007	< 0.001	0.208
Acute renal failure	0.001	< 0.001	0.186	< 0.001	< 0.001	0.046	0.004	< 0.001	0.529
Renal insufficiency	< 0.001	< 0.001	0.132	< 0.001	< 0.001	0.823	0.004	< 0.001	0.251
Urinary tract infection	0.01	0.008	0.029	0.01	0.008	0.036	0.017	0.006	0.076
Venous thromboembolism									
Deep vein thrombosis	0.004	0.004	0.042	0.004	0.004	0.069	0.007	0.004	0.118
Pulmonary embolism	0.003	0.003	0.667	0.002	0.003	0.915	0.007	0.004	0.675
Wound complications									
Deep SSI	0.002	< 0.001	0.175	0.002	< 0.001	0.348	0.056	0.001	0.076
Superficial SSI	0.01	0.002	< 0.001	0.01	0.002	0.002	0.011	0.002	0.003
Wound dehiscence	0.002	0.002	1	0.002	0.001	0.916	0.004	0.003	0.602
Readmission/reoperation									
Readmission	0.039	0.034	< 0.001	0.039	0.034	0.003	0.046	0.04	0.094
Reoperation	0.02	0.018	0.142	0.02	0.019	0.094	0.029	0.016	0.048
Complications	His	spanic				Asian			
	201	11	2019	p v	alue	2011	2	019	p value
Medical complications									
Myocardial infarction	0.0	1	0.002	0.9	17	0	0	.003	0.316
Acute renal failure	0		0	1		0	0		N/A
Renal insufficiency	0		< 0.001	0.9	08	0	0		0.333
Urinary tract infection	0.0	25	0.01	0.0	29	0.025	0	.01	0.048
Venous thromboembolism									
Deep vein thrombosis	0		0.004	0.3	48	0	0	.001	0.324
Pulmonary embolism	0		0.002	0.3	43	0	0	.003	1
Wound complications									
Deep SSI	0		0.001	1		0	0		0.205
Superficial SSI	0.0	3	0.003	0.1	18	0.008	0	.002	1
Wound dehiscence	0		0.002	0.1	36	0.008	0		1
Readmission/reoperation									
Readmission	0.0	25	0.029	0.9	17	0.033	0	.029	0.076
Reoperation	0		0.014	0.7	54	0.017	0	.01	0.754

segregating by race (Table 2). However, for superficial SSI, the combined cohort, as well as White and Black patients in isolation, were found to have significantly lower rates over the study period. This was not demonstrated for the other evaluated races. When controlling for various confounding variables, Black patients had a significantly lower risk of superficial SSI (OR: 0.62, 95% CI: 0.46–0.81; p < 0.001) (Table 3).

Venous thromboembolism

Although the overall cohort experienced a significant reduction in DVT rates between 2011 and 2019, no differences were noted for individual races (Table 2). Similarly, no differences in PE rates were seen across all cohorts. On multivariate analysis, Black race was associated with an increased risk of both DVT (OR: 1.34, 95% CI: 1.07–1.66; p=0.01) and PE (OR: 1.76, 95% CIL: 1.36–2.24; p < 0.001) (Table 3).

Readmissions/reoperations

Although the overall cohort experienced significant reductions in readmission rates, this was only seen for the segregated White cohort (Table 2). Although there was no difference in unplanned reoperation rates for all THAs, White patients experienced a significant reduction. Similarly, only Black patients were found to have a reduction

Outcome		Race				
		Black	Hispanic	Asian		
Medical complications						
Myocardial infarction	OR	0.77	0.85	0.58		
	95% CI	0.51, 1.11	0.42, 1.51	0.21, 1.26		
	p value	0.18	0.61	0.23		
Acute renal failure	OR	2.03	1.59	0		
	95% CI	1.17, 3.34	0.49, 3.84	N/A		
	p value	0.008	0.36	0.98		
Renal insufficiency	OR	2.33	0.78	0.8		
	95% CI	1.62, 3.28	0.24, 1.86	0.13, 2.51		
	p value	< 0.001	0.63	0.75		
Urinary tract infection	OR	0.92	1.22	1.18		
	95% CI	0.77, 1.10	0.92, 1.58	0.85, 1.60		
	p value	0.37	0.15	0.3		
Wound complications						
Deep SSI	OR	1.08	0.9	0.85		
-	95% CI	0.80, 1.43	0.48, 1.53	0.33, 1.74		
	p value	0.59	0.71	0.69		
Superficial SSI	OR	0.62	0.74	0.69		
1	95% CI	0.46, 0.81	0.44, 1.14	0.34, 1.22		
	p value	< 0.001	0.2	0.24		
Wound dehiscence	OR	1.04	1.25	0.73		
	95% CI	0.70, 1.50	0.62, 2.24	0.18, 1.92		
	p value	0.82	0.5	0.59		
Venous thromboemboli.	sm					
Deep vein thrombosis	OR	1.34	1.39	0.48		
-	95% CI	1.07, 1.66	0.94, 1.97	0.21, 0.93		
	p value	0.01	0.08	0.054		
Pulmonary embolism	OR	1.76	1.55	0.78		
	95% CI	1.36, 2.24	0.97, 2.35	0.33, 1.52		
	p value	< 0.001	0.051	0.51		
Readmission/reoperation	on					
Readmission	OR	1.07	0.91	0.75		
	95% CI	0.99, 1.16	0.78, 1.05	0.61, 0.91		
	p value	0.085	0.2	0.005		

Table 3 Multivariate regression for how race is associated with evaluated outcomes

in rates of any reoperation. Asian patients were found to have a significantly lower odds of readmission (OR: 0.75, 95% CI: 0.61–0.91; *p* = 0.005). Similarly, Black race was significantly associated with lower reoperation (OR: 0.88, 95% CI: 0.79–0.98; p = 0.026) rates (Table 3).

95% CI

p value

OR

Any reoperation

0.88

0.026

0.79, 0.98

0.82

0.051

0.66, 1.00

0.78

0.069

0.60, 1.01

Discussion

Despite numerous articles in the orthopedic literature evaluating racial and ethnic disparities, inequalities in total joint arthroplasty outcomes remain. While the NSQIP database has been previously utilized to highlight these disparities, no previous analysis has evaluated how the rate of various perioperative complications has changed over recent years when segregating by patient race. We found that for UTI, acute renal failure, superficial SSI, and readmission rates, White patients experienced significant reductions between 2011 and 2019. However, this was not consistent across all races. Additionally, we found that race was independently associated with an increased risk of acute renal failure, renal insufficiency, DVT, and PE for Black patients, decreased risk for superficial SSI and reoperation for Black patients, and decreased risk of readmission for Asian patients even after controlling for patient and procedure characteristics.

Limitations

Our analysis has some limitations. Since it has been suggested that the NSQIP database disproportionally collects data from academic hospitals, the rate of complications or other adverse events reported may be positively skewed. Additionally, NSQIP only follows patients for 30 days after surgery and therefore misses complications or death reported after that period. Although we suggest various etiologies behind the disparities demonstrated in our analysis, these issues likely remain multifaceted. Specifically, we are unable to control for structural inequalities or physician bias, both explicit and implicit, that may affect the incidence of perioperative outcomes. Related to this notion, as NSQIP does not provide data regarding each patient's socioeconomic status or geographic region, we are unable to control for factors such as social deprivation or other social determinants of health that may impact these outcomes, health literacy, or access to care. Furthermore, although we utilized the race coded for each patient in the NSQIP database, race and ethnicity remain multidimensional characteristics and therefore, we are unable to comment on outcomes for patients of mixed race or who identify across ethnic groups.

Medical complications

Although White, Hispanic, and Asian patients experienced reductions in UTI rates as well as reductions in the rate of acute renal failure for Whites, both of these were not demonstrated for Black patients. Furthermore, compared to White patients, Black patients had increased risk of acute renal failure and renal insufficiency when controlling for confounding variables. Globally beneficial approaches to reduce disparities in medical complications include increasing perioperative education and counseling [5, 16], improving health literacy about THA through individual and community-based programs [26–28], and attempting to address explicit and implicit bias [29] to subsequently improve patient trust [30]. However, more targeted approaches should focus on medically optimizing patients at risk for these complications. For example, as inadequate fluid resuscitation frequently may contribute to renal failure/insufficiency, more aggressive volume resuscitation may be employed for Black patients to help mitigate this complication risk. Similarly, orthopedic surgeons may consider limiting the use of indwelling catheters among all races given their potential to increase UTI risk [31].

Wound complications

We found that superficial SSI rates did not decreases for Hispanic or Asian patients. These findings have been similarly demonstrated in the literature when evaluating surgical site infection among cardiac surgery patients [32]. One possible explanation is that racial and ethnic minorities often have multiple co-morbidities including higher incidences of diabetes mellitus and chronic kidney disease that place them at a greater risk for SSI [33–35]. Furthermore, minority populations are less likely to be linked to a primary care provider that can adequately manage chronic health conditions [36, 37]. Patient comorbidity burden has also been identified as a significant risk factor for wound dehiscence [38]. Therefore, we believe continued efforts for reducing SSI and wound dehiscence should include appropriate education regarding surgical wound care and SSI prevention as well as close follow up in the postoperative period. Additionally, providers should assess whether a patient is linked to a primary care provider to ensure adequate management of comorbid conditions that may complicate wound healing.

Venous thromboembolism

Although the overall rate of DVT and PE did not significantly change over the study period for all cohorts, Black race was associated with significantly higher rates of both types of VTE on multivariate analysis. The former of these findings may be related to the relatively low rates of VTE demonstrated across all included years. Additionally, our finding regarding higher risks of VTE in Black patients reaffirms previous literature demonstrating higher DVT and PE rates among Black individuals for total joint arthroplasty (TJA) and orthopedic surgery as a whole [14, 21, 39, 40]. Various explanations, including a genetic predisposition or higher family history of thromboembolism have been suggested to contribute to these outcomes. Similarly, it has been suggested that Black patients may not receive VTE prophylaxis prescribed to them while in the inpatient setting [41]. However, as was recently reported from the International Consensus Meeting (ICM) on VTE, there is insufficient evidence in the literature to suggest that alternative chemoprophylaxis should be utilized for Black patients [40]. Therefore, we believe that continued efforts at reducing VTE among these patients should focus on appropriate patient education regarding the need and duration of VTE prophylaxis as well as strategies for ensuring adequate administration of and access to these medications [42–44].

Readmission/reoperation

While the overall and isolated White cohorts experienced reductions in readmissions over our study period, there were no changes seen for Black, Hispanic, and Asian patients. However, upon multivariate analysis, Asian patients had lower readmission rates while Blacks and Hispanics had no difference in rates compared to Whites. Consequently, for Black and Hispanic patients, factors other than race that are more common among these minorities may mediate these results. Our findings partly corroborate prior research documenting significant racial and ethnic disparities in readmission rates among the Medicare population. Several studies have demonstrated 30-day readmission rates for total hip arthroplasty, heart failure, and diabetes to be higher among Black patients [45–47]. While this issue is likely to be multifaceted, site of care has been identified as one possible explanation. Patients from predominately minority-severing hospitals have been found to have higher rates of readmission [45]. Furthermore, minority patients often encounter barriers to care such as poor social support, living in low-resource communities, limited English proficiency, health literacy, and mistrust in healthcare providers [48–50]. Therefore, addressing disparities in readmission rates will require intervention at both the system and provider-level. At the system-level, continued refinement of the Hospital Readmission Reduction Program (HRPP) regulated by the CMS is needed. While this program has had some success in reducing overall readmission rates [51, 52], our analysis has demonstrated the racial gap still persists. At the provider-level, targeted inventions that focus on education and social support may reduce readmission rates. Early screening and documentation of health literacy can ensure providers use appropriate terminology and discharge materials for the patient's educational level. Additionally, physicians should ensure patients are well connected to community resources that address the social determinants of health that disproportionately affect racial and ethnic minorities.

Conclusion

Racial disparities remain in outcomes following THA. Specifically, all races have not experienced comparable reductions in medical complication, readmission, and superficial SSI rates. Our analysis highlights specific complications for which further interventions are necessary to reduce inequalities across races. These include medical optimization, increased patient education, and continued efforts at understanding how social factors may impact-related care inequalities. Future study is needed to evaluate specific interventions that can be applied at the health systems level to ensure all patients undergoing THA receive the highest quality of care regardless of race. Specifically, these studies should explore methods of addressing SDOH as well as biases that may impact the provision of care as well as perioperative management.

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Declarations

Conflicts of interest A.F.K. reports the following disclosures: research support (Signature Orthopedics), paid presenter or speaker (DePuy Synthes and Zimmer Biomet), paid consultant (DePuy Synthes and Zimmer Biomet), stock or stock options (Zimmer Biomet, Johnson & Johnson, and Procter & Gamble), IP royalties (Innomed), and board or committee member (AAOS, AAHKS, and Anterior Hip Foundation). D.G., C.J.H., A.J.A., and R.J.B. have nothing to disclose.

Ethical approval We certify that our analysis complies with the ethical standards of our institution as well as laws related to research conducted in the USA.

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