

Low Rates of Reporting and Analyzing Race and Ethnicity in Hand Surgery Randomized Controlled Trials: A Systematic Review

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Abstract

Purpose: Sociodemographic factors have been shown to influence musculoskeletal health. However, little is known regarding the frequency of reporting and analysis of certain sociodemographic variables (e.g., age, sex, height, weight, body mass index (BMI), race, and ethnicity) in randomized clinical trials (RCTs) pertaining to hand surgery. The purpose of this study was to assess the rate of reporting and analysis of these variables in RCTs published in the *Journal of Hand Surgery (JHS)*.

Methods: A systematic review was conducted of RCTs published in JHS between 2015 and 2021. For each study, we determined whether the following sociodemographic variables were reported and/or analyzed: age, sex, height, weight, BMI, race, and ethnicity. Frequencies were reported by year and as a cumulative total. Studies were evaluated using the Cochrane risk-of-bias tool.

Results: A total of 45 RCTs met inclusion criteria, with about half (53.3%) originating from the United States. Age (97.8%) and sex (91.1%) were the most frequently reported sociodemographic variables, followed by race (17.8%), BMI (11.1%), and ethnicity (8.9%). Age (17.8%) was the most frequently analyzed variable, followed by sex (13.3%), and race (4.4%); the remaining variables were not analyzed in any study.

Conclusions: While age and sex are reported at a high rate, only about 1 in 4 RCTs published in JHS report either race or ethnicity. All sociodemographic variables were infrequently included as part of statistical analysis. The significance of these findings should be recognized and used to interpret and enhance the methodology of future RCTs.

Introduction

The influence of race and ethnicity on healthcare disparity is well-recognized within the medical community and has become a growing focus within the orthopedic literature¹⁻⁷. The influence of race and ethnicity on postoperative outcomes following joint and spine surgery has been particularly elucidated. Adelani et al. retrospectively reviewed postoperative complications in 585,269 patients who underwent hip and knee arthroplasty. Within this study, Black patients experienced increased rates of surgical site infection (SSI), deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, stroke, and death, even when controlling for medical comorbidities⁵. In a separate retrospective review of 4,803 patients, Sanford et al. found that Native American race was found to be an independent risk factor for SSI following cervical

fusion and decompression laminectomy, whereas African American race was found to be an independent risk factor for SSI and PE after decompression laminectomy and DVT after lumbar fusion². Alosch et al. screened over 100 million hospital discharge records from 1992 and 2005 and found 965,600 anterior cervical spine procedures. The authors similarly found that minorities had lower rates of surgery and that Black patients had significantly higher odds of dying while in the hospital⁶. Racial and ethnic differences in outcomes, decision-making, and other aspects in hand surgery itself further illustrate the health disparities within the field⁸⁻¹³.

Despite racial differences in health outcomes within the orthopedic literature, many randomized controlled trials (RCTs) fail to report race and ethnicity^{14,15}. Several reasons for this observation have been postulated, such as the belief that reporting these factors is not clinically relevant and a lack of emphasis to report by medical journals¹⁵. However, according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for transparent reporting of clinical trials, all sociodemographic information should be provided in the initial description of a study population¹⁶. Similarly, the National Institutes of Health (NIH) guidelines require that minority patients be included in NIH-funded research and suggest that race and ethnicity be collected even in cases where previous research has demonstrated no effect of these variables on the outcomes of an intervention¹⁵.

It is important to identify racial and ethnic differences within orthopedic studies so that further analyses may elucidate the underlying causes of differential health outcomes. While some studies have assessed the reporting and analysis of sociodemographic variables across orthopedic subspecialty areas, none have focused on hand surgery specifically. The *Journal of Hand Surgery (American Volume)* (JHS) is a premier journal in this field with the largest number of RCTs on PubMed search relative to similar journals. For this reason, the purpose of our study was to assess the rate of reporting and analysis of sociodemographic variables (e.g., age, sex, height, weight, body mass index (BMI), race, and ethnicity) in RCTs published in JHS from 2015 to 2021. We hypothesize that age and sex will be reported and analyzed at the highest frequency compared to the other sociodemographic variables.

Methods

Search Strategy

The Preferred Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were used to conduct this systematic review¹⁷ (Supplementary Table 1). This review was not prospectively registered. An advanced search on PubMed was conducted to identify all RCTs published in JHS from 2015 to 2021. Search terms included “randomized

control trial” and “randomized controlled trial.” Search results were screened to confirm use of an RCT design.

Inclusion and Exclusion Criteria

All RCTs published in JHS between 2015 and 2021 on human subjects were included. We chose this span of years to reflect continuity with previous orthopedic studies on this topic, which included data from 2015 to their respective dates of publication^{14,15}. Longitudinal analysis and previous follow-ups of clinical trials published prior to 2015 were included. Exclusion criteria were non-RCTs, basic science studies, meeting abstracts, responses to authors, letters to the editor, and withdrawn studies.

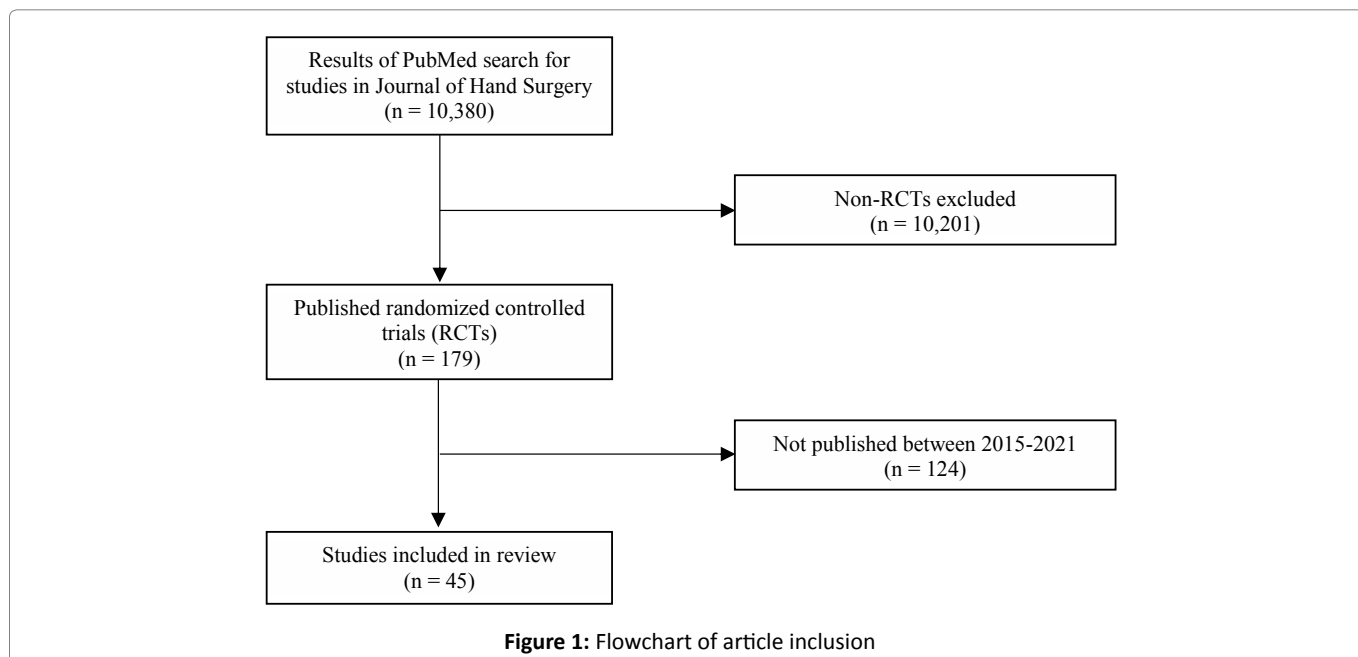
Data Collection

Eligible studies were assessed independently by two reviewers to determine whether the following sociodemographic variables were reported and/or analyzed: age, sex, height, weight, BMI, race, and ethnicity. Any discrepancy was resolved by consensus agreement with a senior author.

Data collection was based on the methodology reported by Griffin et al.¹⁴. A variable was considered reported if the mean or median with or without standard deviation/quartiles was provided for continuous variables (age, height, weight, BMI) or if a percentage of the study population was provided for categorical variables (sex, race, ethnicity). Comparing baseline demographics between treatment groups or between treatment and control groups was considered reporting but not analysis. A statement that all patients were of one race or ethnicity was considered adequate for reporting.

A variable was considered analyzed if statistical analysis was performed on the variable relative to the study's outcomes of interest. The evaluation of outcomes based on sociodemographic subgroups was considered analysis. If a variable was found not to be analyzed throughout the included papers, this indicated that no figure or table was included with the variable as part of a sub-analysis, no mention of an analysis with respect to the variable was found throughout the Methods or other sections within the study, nor were any conclusions drawn regarding the sociodemographic variable's impact on analyzed outcomes.

Race was defined using the following categories: White, African-American/Black, Asian/Pacific Islander, Native American, or other/unknown race. Ethnicity, which is defined as a subset of race, was defined as Hispanic or non-Hispanic¹⁸. Sex and gender were assessed as the same variable for the purpose of this study, as distinction between these terms is often interchangeable within the literature¹⁹. Each study's country of origin was also recorded, with the institution of the senior author considered the country of origin when authors from multiple countries contributed to a study.



Risk-of-Bias Assessment

The revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0) was used to assess each included study as “high risk,” “low risk,” or with “some concerns,” of bias. This tool evaluates the methodology of each study by scoring the following categories: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, selection of the reported result, and overall bias²⁰. Studies were assessed based on adherence to intention-to-treat analysis as this statistical method allows for optimal comparison between treatment groups and minimizes sources of bias²¹.

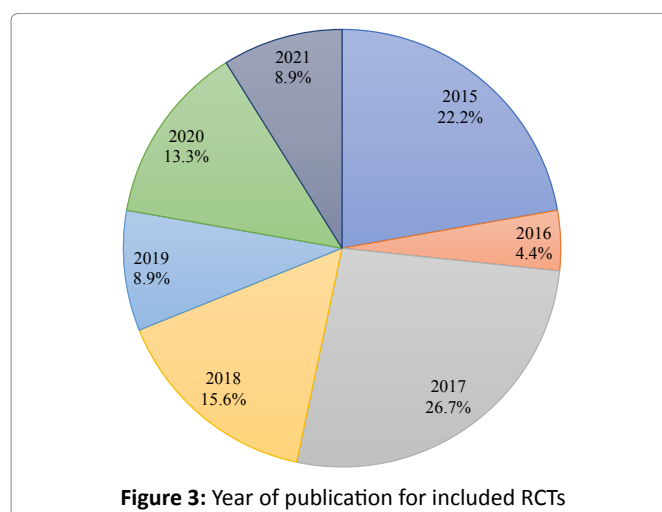
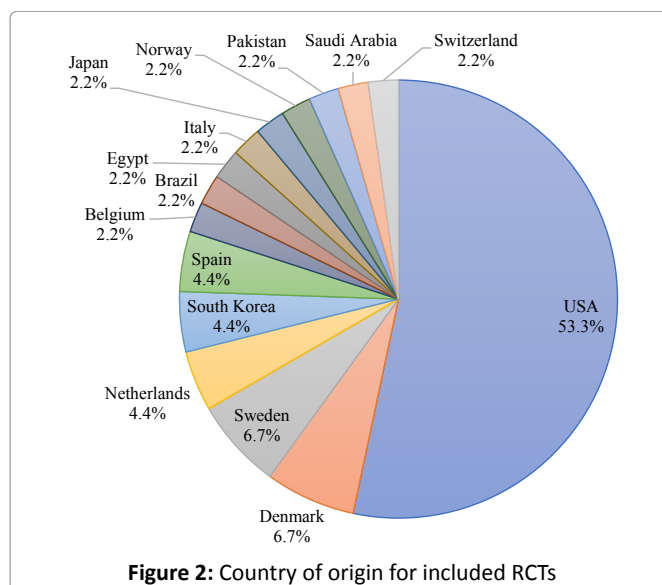
Results

Search Results

A total of 10,380 studies published in JHS were initially screened. 179 RCTs were identified, of which 45 met inclusion criteria and were included in the final review (Figure 1). Studies originating from 15 countries were included, the most common of which were the United States (53.3%), Denmark (6.7%), and Sweden (6.7%) (Figure 2). Most RCTs included in this review were published in 2017 (26.7%) and fewest were published in 2016 (4.4%) (Figure 3). Supplementary Table 2 compiles all included studies and illustrates data collected from each article.

Reporting of Sociodemographic Variables

Of the 45 included studies, 44 reported age (97.8%), 41 reported sex (91.1%), eight reported race (17.8%), five reported BMI (11.1%), four reported ethnicity (8.9%), one reported height (2.2%), and one reported weight (2.2%) (Figure 4).



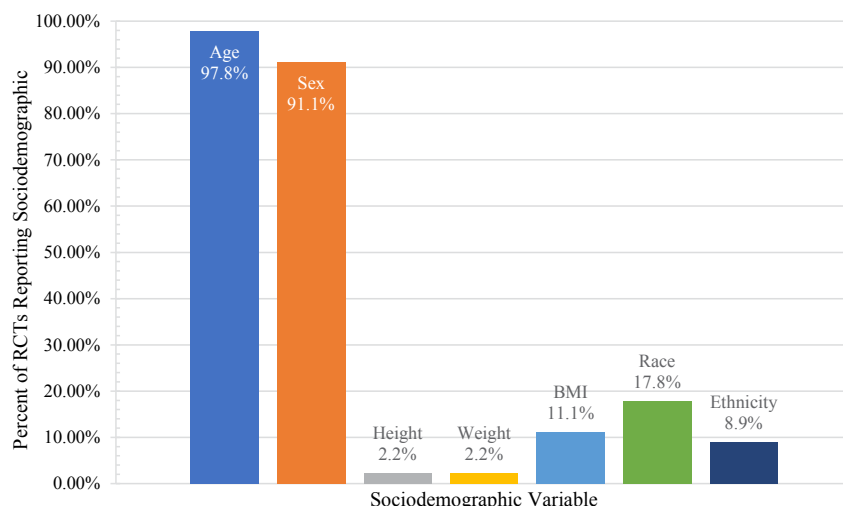


Figure 4: Proportion of studies reporting sociodemographic variables

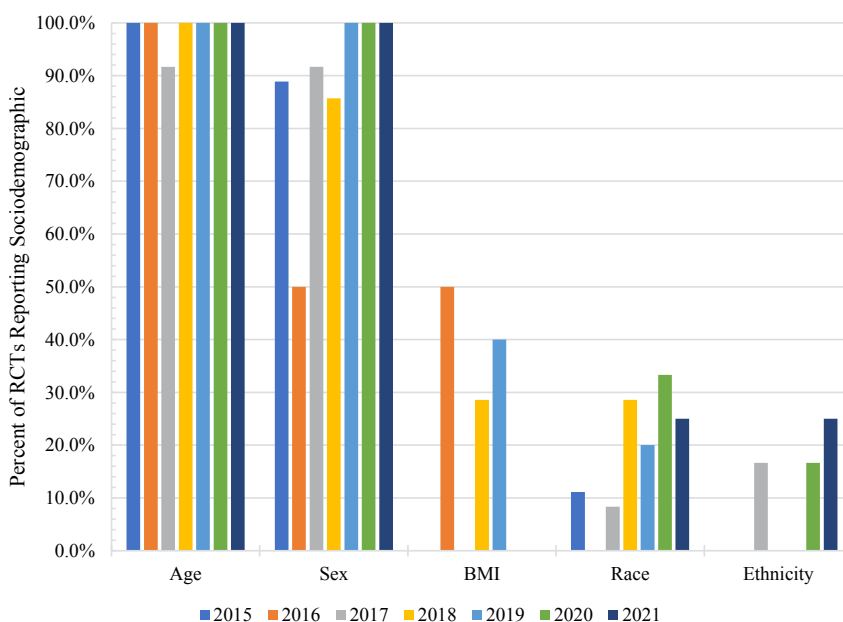


Figure 5: Proportion of studies reporting sociodemographic variables separated by year of publication

Sociodemographic reporting trended upward with time (Figure 5). Age and sex were reported at a high rate for each year of the study period, with both variables being reported in all studies since 2019. The reporting of race was variable year to year but trended upward with time, from 11.1% in 2015 to 25% in 2021. Ethnicity was only reported in 2017 (16.7%), 2020 (16.7%), and most frequently in 2021 (25%), and no specific trends could be observed. The proportions of sociodemographic reporting by year can be found in Supplementary Table 3.

Analysis of Sociodemographic Variables

The most analyzed sociodemographic variable was age (n=8; 17.8%), followed by sex (n=6; 13.3%) and race (n=2; 4.4%) (Figure 6). No studies analyzed weight, height, BMI, or ethnicity. No specific trends

could be observed for the analysis of the variables when separated by year of publication (Figure 7). The proportions of sociodemographic analysis by year can be found in Supplementary Table 4. Figure data is also summarized in Supplementary Table 5 to allow for accurate, additional interpretation of the provided figures.

Risk of Bias

“Selection of the reported result” had the least bias, with 95.6% of studies in this category classified as low risk (Figure 8). Most studies (>84%) had low levels of bias with respect to “deviations from intended outcomes,” “missing outcome data,” and their “randomization process.” “Measurement of the outcome” revealed some concerns for bias in 31.1% of studies.

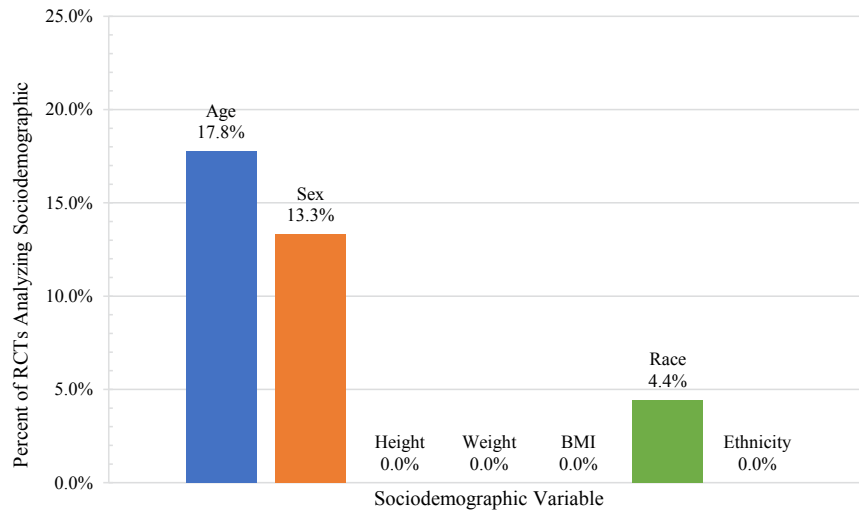


Figure 6: Proportion of studies analyzing sociodemographic variables

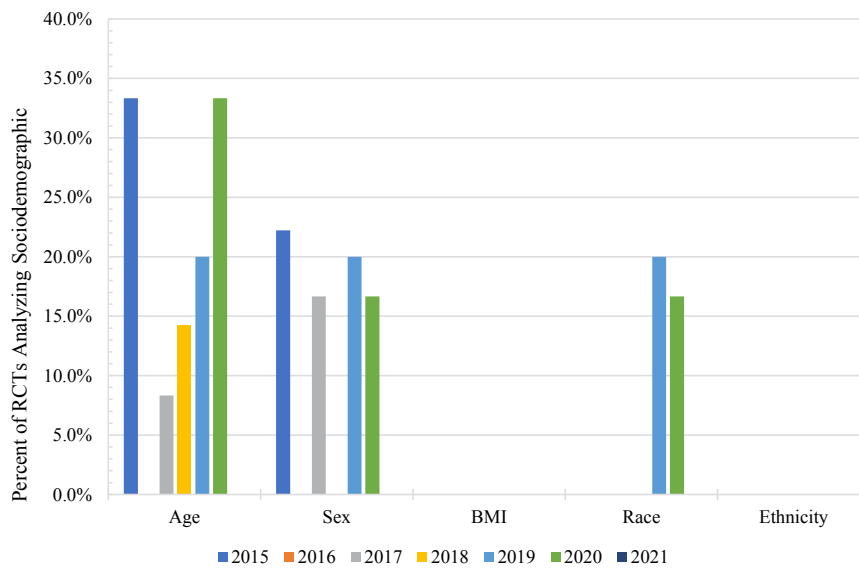


Figure 7: Proportion of studies analyzing sociodemographic variables separated by year of publication

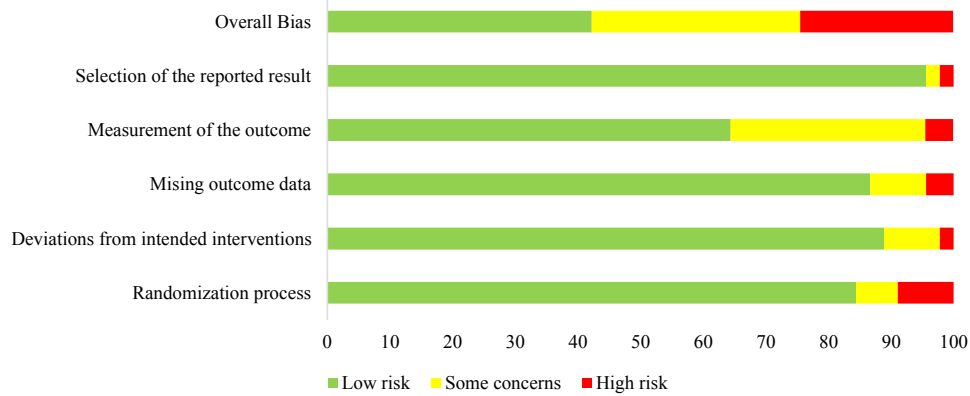


Figure 8: Bias assessment of included studies using the Cochrane risk-of-bias tool

Discussion

The primary purpose of this study was to evaluate the frequency of reporting and analyzing of several sociodemographic variables in hand surgery RCTs published in JHS between 2015 and 2021. Age and sex were the most reported demographics and were presented in nearly every study. Interestingly, race was reported in about one of six studies, while ethnicity was reported half as often. Height and weight were most infrequently reported but included through BMI in more than 10% of studies. Despite high rates of reporting, age was included within the statistical analysis of only 17.8% of studies, followed by sex in 13.3%, and race in 4.4%. There was no analysis of ethnicity, height, weight, or BMI throughout the seven-year period.

A recent systematic review investigated the rates at which randomized controlled trials published in 10 orthopedic journals between 2015 and 2019 reported and analyzed these same sociodemographic variables¹⁵. Of 482 total articles, only 7.3% reported race and 3.1% reported ethnicity. Analysis by race (1.2%) and ethnicity (0.2%) were much less frequent. Within this same study, articles were further subdivided into subspecialty categories. Of the 12 articles pertaining to hand surgery, 8.3% reported race and no studies reported ethnicity; each of these studies failed to perform analysis of these demographics. Interestingly, we found that RCTs published in JHS over a similar period reported race (17.8%) and ethnicity (8.9%) at much higher frequencies. These findings imply that rates of sociodemographic reporting may vary amongst RCTs of different orthopedic journals even if they pertain to the same orthopedic domain. Further study of specialty-specific journals should be performed to increase the power of these results and more accurately identify the rate of reporting and analysis of sociodemographic variables¹⁴.

In reviewing the racial and ethnic demographics of included publications within our study, we found there to be great diversity but inconsistent reporting of included patients²²⁻²⁹. For example, of the eight RCTs that reported race, half provided data on the number of White versus non-White patients^{22,24-26} only, while half provided data on a larger variety of subgroups including White, Black, Asian, Native American, and Pacific Islander patients^{23,27-29}. Only three studies reported ethnicity by including the percentage of Hispanic patients within their study populations^{23,28,29}, while one study commented on the 'ethnic homogeneity' of its study population³⁰. Regarding analysis of race and ethnicity, only two of the 45 studies (4.4%) within this review analyzed outcomes based on race, and none analyzed outcomes based on ethnicity.

As discussed previously, race has been shown to impact joint and spine surgery in the field of orthopaedic

surgery^{2,5,6}. However, other studies have explored the effect of race and ethnicity on the outcomes, decision-making, and other aspects of hand surgery. In a retrospective review of 92,921 patients with carpal tunnel syndrome, Brodeur et al. found that Black and Asian patients were less likely to undergo surgery compared to White patients. Similarly, the authors showed that patients of Hispanic ethnicity had decreased odds of surgery compared to patients of non-Hispanic ethnicity³¹. Mahmoudi et al. retrospectively reviewed 13,129 patients with traumatic digit amputation and found that Black patients were less likely than White patients to undergo replantation procedures³². In a separate analysis of over 31,000 trigger finger patients by Brodeur et al., Asian, African American, and other minority patients were less likely to undergo surgery relative to White patients⁹. Squitieri et al. similarly showed that Black and Hispanic children underwent attempted reimplantation of an amputated finger at significantly lower rates than their White counterparts, even after controlling for potential confounding factors¹¹. Following a brachial plexus injury, Bucknor et al. found that Black patients are more likely to be treated in the emergency department as opposed to an elective, outpatient setting and are also less likely to receive supported discharge compared to White patients¹². Walsh et al. found that Black and Hispanic patients show worse functional outcomes and report higher levels of pain following a distal radius fracture relative to White patients¹⁰ while a review by Khetpal et al. revealed many outcomes affected by various sociodemographic variables, including race¹³.

These studies illustrate the disparities in treatment rate and outcomes, among other factors, that are associated with the race and ethnicity of the patient. By highlighting these findings, we hope to emphasize the presence of these health inequities and stress the importance of analyzing—or at least reporting—these sociodemographic variables for future RCTs. Because race and ethnicity have been shown to affect patient decision-making and outcomes and may affect access to healthcare or the biases that patients experience, study outcomes should take into account these potential moderating factors. Not only can this reveal other yet-undiscovered health inequities, but it can also lead to treatments optimized for the patient's race and prevent complications disproportionately affecting particular minorities.

While race was infrequently reported and analyzed even less often, age was the most frequently analyzed sociodemographic variable in our review. Many of the included studies show that age, like race, can impact outcomes, decision-making, and other aspects in hand surgery. In a mixed-methods study by Zhuang et al., participants were asked to choose between receiving carpal tunnel release (expensive) or orthosis wear

(inexpensive) for hypothetical carpal tunnel symptoms after either receiving or not receiving cost information regarding the procedure. After stratifying the participants based on age, the younger subgroup was more inclined to choose surgery despite exposure to cost information when compared to the older subgroup²³. Valdes et al. investigated whether there was a difference in postoperative outcomes following volar plate fixation for distal radius fractures in patients randomized to home (unsupervised) vs. therapist-supervised hand therapy. Overall, there were no statistically significant differences in self-evaluation scores, extremity motion, pain, or grip strength. However, older subjects had poorer grip and self-evaluation scores at 12 weeks and reported less pain when compared to younger subjects³³. Finally, Chung et al. studied the predictors of outcomes 12 months following distal radius fractures. The authors found that increasing age was associated with lower Michigan Hand Questionnaire scores, implying that older patients with distal radius fractures may expect poorer outcomes when compared to those of younger age²⁷.

These findings show that outcomes of hand surgery RCTs can be heavily influenced by age. Differences based on other sociodemographic variables may be elucidated with increased reporting and analysis. Researchers should focus on the identification of health disparity so that clinicians can more effectively counsel patients before and after treatment.

The conclusions of our study may be limited by the small sample size of RCTs that met the inclusion criteria. Though all RCTs between 2015 and 2021 published in JHS were included, additional years of data collection or inclusion of other study types – such as highly powered cohort studies¹⁵ – may help to reveal racial and ethnic differences. Similarly, only papers published in JHS were included in this study; future studies should explore these sociodemographic trends in other hand surgery journals. As JHS is based in the United States, there may be some bias in the rate of publishing of studies submitted from the journal's home country, potentially skewing the geographical distribution of recent hand literature. Studies published in non-US-based hand surgery journals can be evaluated in future studies to explore this possible bias. In addition, there are a variety of socioeconomic factors associated with patient race and ethnicity that may influence study outcomes and never be adequately considered^{34,35}. As such, the effect of biological versus social factors on health outcomes remains difficult. Finally, included studies may have forgone the evaluation of race or ethnicity if these differences were known to have negligible effect on the intervention. Future reviews can select studies associated with topics known to exhibit notable health differences amongst these variables.

Conclusions

The present review of RCTs published in JHS between 2015 and 2021 found that the sociodemographic variables of age and sex were reported at high rates. Conversely, race was less commonly reported, and ethnicity was rarely reported. Each variable was infrequently included as part of statistical analysis. Because outcomes of hand surgery RCTs can be heavily influenced by race and age and may be further moderated by other sociodemographic variables, both reporting and analysis of these variables is crucial to ensure accurate and comprehensive study conclusions. The significance of these findings should be recognized and used to interpret and enhance the methodology of future RCTs.

Conflict of Interest

The Authors declare that there is no conflict of interest.

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Supplementary Data

Supplementary Table 1: PRISMA guidelines checklist

Section and Topic	Item #	Checklist item	Location where item is reported (Lines)
TITLE			
Title	1	Identify the report as a systematic review.	1-2
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	6-11
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	34-60
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	62-71
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	85-90
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	78-79
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	79-81
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	94-121
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	94-121
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	94-121
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	99-121
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	125-131
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	99-105
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	94-121
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	99-121
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	99-121, 137-172
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	99, 125-126
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	107-121
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	109-113, 117-121, 129-131
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	125-131
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	99

Section and Topic	Item #	Checklist item	Location where item is reported (Lines)
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	137-138, 297
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	137-138, 297
Study characteristics	17	Cite each included study and present its characteristics.	328
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	169-172, 308
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	137-165, 308
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	137-165, 300-306
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	169-172, 308
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	169-172, 308
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	169-172, 308
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	169-172, 308
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	176-260
	23b	Discuss any limitations of the evidence included in the review.	262-276
	23c	Discuss any limitations of the review processes used.	262-276
	23d	Discuss implications of the results for practice, policy, and future research.	280-287
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	78
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	78
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	78, N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	293-294
Competing interests	26	Declare any competing interests of review authors.	292
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	336-339

Supplementary Table 2: Quantification of sociodemographic variables of interest in the included studies

Author	Year	Country of Origin	Frequency of Reporting							Frequency of Analysis						
			Age	Sex	Height	Weight	BMI	Race	Ethnicity	Age	Sex	Height	Weight	BMI	Race	Ethnicity
Alter et al. ³⁶	2017	USA	X	X												
Alter et al. ³⁷	2017	USA	X	X												
Badalamente et al. ³⁸	2015	USA	X	X						X	X					
Bashir et al. ³⁹	2015	Pakistan	X	X												
Boriani et al. ⁴⁰	2017	Italy	X	X												
Cantero-Téllez et al. ⁴¹	2015	Spain	X	X												
Chung et al. ²⁷	2019	USA	X	X				X		X	X				X	
Curtin et al. ²⁸	2017	USA	X	X				X	X							
Dailey et al. ⁴²	2018	USA	X	X			X									
Dale et al. ⁴³	2020	USA	X	X												
De Moraes et al. ⁴⁴	2021	Brazil	X	X												
Earp et al. ⁴⁵	2017	USA	X	X												
El-Saeed et al. ⁴⁶	2019	Egypt	X	X												
Franko et al. ⁴⁷	2017	USA	X	X							X					
Hansen et al. ⁴⁸	2017	Denmark	X	X												
Hegazy et al. ⁴⁹	2021	Saudi Arabia	X	X												
Hutchison et al. ⁵⁰	2018	USA	X							X						
Ilyas et al. ⁵¹	2018	USA	X	X												
Keulen et al. ⁵²	2018	USA	X	X				X								
Kleiss et al. ⁵³	2020	USA	X	X				X		X	X				X	
Landgren et al. ⁵⁴	2017	Sweden	X	X												
Logli et al. ⁵⁵	2018	USA	X	X			X									
Marks et al. ⁵⁶	2017	Switzerland	X	X												
Martínez-Catalán et al. ⁵⁷	2020	Spain	X	X												
Nishiwaki et al. ⁵⁸	2021	Japan	X	X												
Plate et al. ⁵⁹	2015	USA	X	X												
Roe et al. ⁶⁰	2021	USA	X	X				X	X							
Roh et al. ⁶¹	2015	South Korea	X	X												
Roh et al. ⁶²	2019	South Korea	X	X			X									
Saving et al. ⁶³	2019	Sweden	X	X												
Schwartzberger et al. ⁶⁴	2017	USA	X	X						X	X					
Selles et al. ⁶⁵	2020	Netherlands	X	X												
Skov et al. ³⁰	2017	Denmark	X	X					X							
Soberón et al. ⁶⁶	2016	USA	X				X									
Sørensen et al. ⁶⁷	2020	Denmark	X	X												
Spekreijse et al. ⁶⁸	2015	Netherlands	X													
Strömberg et al. ⁶⁷	2016	Sweden	X	X												
Tsolias et al. ⁶⁹	2018	Belgium	X	X	X	X										
Tyser et al. ²²	2015	USA	X	X				X		X	X					
Valdes et al. ⁷⁰	2015	USA	X	X						X						
Wasterlain et al. ⁷¹	2017	USA														
Weinheimer et al. ⁷²	2019	USA	X	X			X									
Wilkens et al. ⁷³	2018	USA	X	X				X								
Williksen et al. ⁷⁴	2015	Norway	X	X												
Zhuang et al. ⁷⁵	2020	USA	X	X				X	X	X						
	Total	Count	44	41	1	1	5	8	4	8	6	0	0	0	2	0
	(n=45)	%	97.80%	91.10%	2.20%	2.20%	11.10%	17.80%	8.90%	17.80%	13.30%	0.00%	0.00%	0.00%	4.40%	0.00%

“X” indicates presence of the indicated variable.

Supplementary Table 3: Proportion of studies reporting sociodemographic variables by year

Year	Age	Sex	BMI	Race	Ethnicity
2015	100.0%	88.9%	0.0%	11.1%	0.0%
2016	100.0%	50.0%	50.0%	0.0%	0.0%
2017	91.7%	91.7%	0.0%	8.3%	16.7%
2018	100.0%	85.7%	28.6%	28.6%	0.0%
2019	100.0%	100.0%	40.0%	20.0%	0.0%
2020	100.0%	100.0%	0.0%	33.3%	16.7%
2021	100.0%	100.0%	0.0%	25.0%	25.0%

Supplementary Table 4: Proportion of studies analyzing sociodemographic variables by year

Year	Age	Sex	BMI	Race	Ethnicity
2015	33.3%	22.2%	0.0%	0.0%	0.0%
2016	0.0%	0.0%	0.0%	0.0%	0.0%
2017	8.3%	16.7%	0.0%	0.0%	0.0%
2018	14.3%	0.0%	0.0%	0.0%	0.0%
2019	20.0%	20.0%	0.0%	20.0%	0.0%
2020	33.3%	16.7%	0.0%	16.7%	0.0%
2021	0.0%	0.0%	0.0%	0.0%	0.0%

Supplementary Table 5: Data for provided figures

a) RCT Country of Origin data. b) RCT Year of Publication data. c) Sociodemographic variable reporting. d) Sociodemographic variable analyzing.

a		b		c						d					
Countries	Count	Years	Count	Sociodemographic Reporting						Sociodemographic Analysis					
					Age	Sex	BMI	Race	Ethnicity		Age	Sex	BMI	Race	Ethnicity
USA	24	2015	10	2015	9	8	0	1	0	2015	3	2	0	0	0
Denmark	3	2016	2	2016	2	1	1	0	0	2016	0	0	0	0	0
Sweden	3	2017	12	2017	11	11	0	1	2	2017	1	2	0	0	0
Netherlands	2	2018	7	2018	7	6	2	2	0	2018	1	0	0	0	0
South Korea	2	2019	4	2019	5	5	2	1	0	2019	1	1	0	1	0
Spain	2	2020	6	2020	6	6	0	2	1	2020	2	1	0	1	0
Belgium	1	2021	4	2021	4	4	0	1	1	2021	0	0	0	0	0
Brazil	1														
Egypt	1														
Italy	1														
Japan	1														
Norway	1														
Pakistan	1														
Saudi Arabia	1														
Switzerland	1														