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ORIGINAL ARTICLE

Inclusion and reporting by age, sex, and ethnicity in clinical studies of high-risk medical devices approved in the European Union

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Introduction Adequate inclusion and representation of patients in clinical studies is critical for the generalizability of research findings. The aim of this analysis was to determine inclusion and reporting by age, sex, and ethnicity in clinical studies of high-risk medical devices (orthopaedic, diabetes, and cardiovascular) approved in the European Union.

Methods This is an analysis of data from three co-ordinated systematic reviews of clinical evidence for high-risk medical devices. This analysis includes 641 studies, reporting on more than 1.9 million patients treated with high-risk orthopaedic, diabetes, and cardiovascular medical devices. The main outcomes were the proportions of studies providing data on the age, sex, and ethnicity of participants, and the performance of stratified analyses based on these factors.

Results The majority (>90%) of studies in all three device categories (orthopaedics, diabetes, and cardiovascular) provided data on the age and sex of participants, but only a minority (<10%) provided information on ethnicity. Female patients comprised over half of the patients in the included orthopaedic and diabetes device studies, but <40% of patients in the included cardiovascular device studies ($P < 0.001$). A minority of studies performed analyses stratified by age (14.6%) or sex (10.4%), although those were more frequently reported in randomized studies.

Conclusions Almost all studies in this analysis provided demographic data on age and sex, but only a small minority had analysed whether these factors had any impact on device performance. Very few studies provided information on the ethnicity of study participants. Cardiovascular device studies enrolled a lower proportion of female patients in comparison to orthopaedic and diabetes device studies.

Study registration Cardiovascular device systematic review: PROSPERO (CRD42022308593). Diabetes device systematic review: PROSPERO (CRD42022366871). Orthopaedic device systematic review: open science framework (https://osf.io/6gmyx).

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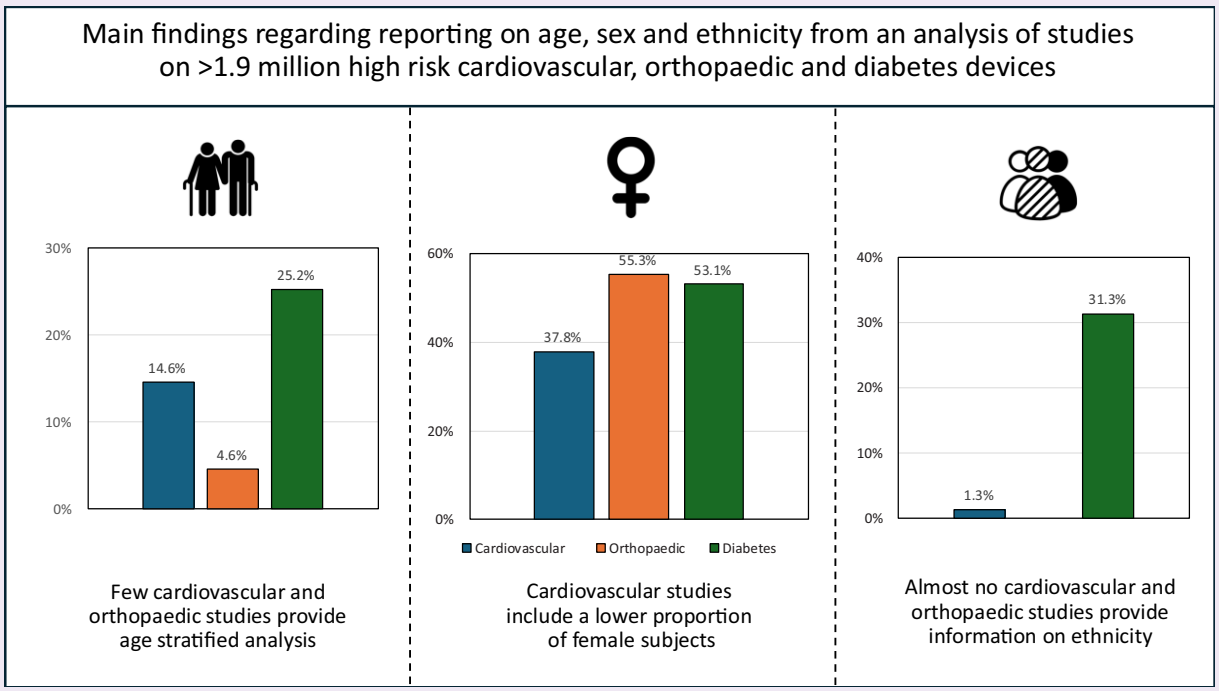
Graphical Abstract



Keywords Medical devices • Heart valves • TAVI • Clinical research

Key Learning Points

What is already known:

- Adequate inclusion and representation of patients in clinical studies is critical for the generalizability of research findings. There is evidence that some high-risk medical devices perform differently in different populations, so it is important for studies of devices to assess their performance in these subgroups.

What this study adds:

- While the majority of studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices approved in the European Union (EU) provide demographic data on the age and sex of participants, only a minority of these studies provided information on participant ethnicity. Few studies performed stratified analysis as per age and sex. Cardiovascular device studies enrolled a lower proportion of female patients in comparison to orthopaedic and diabetes device studies. These results suggest that the studies of high-risk medical devices identified in this systematic review do not adequately provide data on the age, sex, and ethnicity of the studied participants. In addition, they suggest that female patients are under-represented in cardiovascular device trials.

Introduction

Adequate inclusion and representation of patients in clinical studies is critical for the generalizability of research findings. Inclusion refers to patients from different groups being enrolled in clinical research studies, whereas representation means that the study subjects reflect the population in which the treatment will be used in clinical practice.[1] Potential subgroups of interest in this regard include those stratified by age, sex, and ethnicity.[2] There is evidence that some high-risk medical devices perform differently in different populations, so it is important that studies of high-risk medical devices assess their performance in these subgroups.[3–7]

In this analysis, we assessed inclusion and reporting by the age, sex, and ethnicity of participants in studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices approved in the EU. The study aimed to determine the proportions of studies providing data and performing stratified analyses based on these factors.

Methods

Coordinating Research and Evidence for Medical Devices (CORE-MD) was an EU Horizon 2020 project that aimed to review methodologies for the clinical evaluation of high-risk medical devices and recommend new designs to set an appropriate balance between innovation, safety, and clinical effectiveness.[8] Systematic reviews of orthopaedic, diabetes, and cardiovascular devices were performed according to pre-specified protocols, which are available on the website of the CORE-MD project

(www.core-md.eu) and summarized later. For this secondary analysis, their findings were combined into a single database of studies of high-risk medical devices.

Orthopaedic devices

A systematic review of the medical literature was performed for a random selection of 30 hip and knee implants used as intended for primary joint replacement.[9] Sources for the random selection were the Orthopaedic Data Evaluation Panel (ODEP) list and implant lists from current annual reports of European national arthroplasty registries. For the selected 30 implants, all peer-reviewed clinical investigations published in English, French, or German within 10 years before, and up to 20 years after, regulatory approval (date of CE-marking) were considered eligible and were identified through Embase, PubMed, or Web of Science. Studies were included if they reported clinical investigations as defined by Article 2 (45) of the EU Medical Device Regulation 2017/745. They were considered to have been *undertaken to assess the safety or performance of a device* if they: (i) specifically aimed to assess the device in question using at least one of the safety and performance outcomes of interest (defined later) and (ii) presented outcomes as per device. The outcomes of interest were: all-cause revision, assessed at a specific time point; assessment of implant migration or periprosthetic osteolysis on imaging (recognized surrogate markers for implant failure); patient-reported outcomes; and frequency of post-operative orthopaedic complications relevant to arthroplasty. Case reports and series, case–control studies, registry-based cohorts, cohort studies, and randomized controlled trials (RCTs) were considered for inclusion. From the studies finally included, data were extracted on study characteristics, methodologies, outcomes, measures to prevent bias, and the timing of clinical investigations.

Devices for diabetes

A systematic review of the medical literature was performed by searching Embase (Elsevier), Medline All (Ovid), Cochrane Library (Wiley), Science Citation Index Expanded, and Emerging Sources Citation Index (Web of Science), to identify interventional and observational studies that evaluated the efficacy and/or safety of high-risk medical devices for the management of diabetes.[10,11] No language or publication date limits were applied. Animal studies were excluded. The medical devices for diabetes management considered as having a high risk were implantable continuous glucose monitoring systems, implantable pumps, and automated insulin delivery devices. For the included studies, data were extracted on study characteristics, methodologies, outcomes, and measures to prevent bias.

Cardiovascular devices

A systematic review was performed to identify published studies of prospective design evaluating 71 high-risk cardiovascular devices in seven different classes (bioresorbable coronary scaffolds, left atrial appendage occlusion devices, transcatheter aortic valve implantation systems, transcatheter mitral valve repair/replacement systems, surgical aortic and mitral heart valves, leadless pacemakers, and subcutaneous implantable cardioverter defibrillators).[12] The search time span covered 20 years (2000–21). Details of study design, patient population, intervention(s), and primary outcome(s) were summarized and assessed with respect to the timing of the corresponding CE-mark approval. Medline (Ovid), Embase (Ovid), and the Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley) were searched with device-sensitive search algorithms and each iteration of specific devices was considered separately. Trials of any prospective design (whether non-randomized or randomized clinical trials) in humans were considered for inclusion. RCTs that aimed to investigate other medical interventions in patients who received one of the medical devices of interest in the absence of randomization/clinical investigation on a device level were excluded. Case reports including case series, compassionate use reports, reviews, systematic reviews, meta-analyses, and expert opinion documents were also excluded. No language restrictions were applied.

Statistical methods

For this analysis of data from the three systematic reviews, information was jointly considered from all eligible studies in the high-risk orthopaedics, diabetes, and cardiovascular medical device categories. This included the reporting of distributions according to age, sex, and ethnicity, and the performance of analyses according to stratification by age, sex, and ethnicity. Using descriptive statistics, the study characteristics were summarized for each category separately. Nominal data were summarized using counts with percentages. Studies included in each category (orthopaedics, cardiovascular, and diabetes) were also analysed separately for randomized and non-randomized studies. Cross-tabulations were used to evaluate differences in characteristics between device types and between randomized and non-randomized studies. The comparisons between independent groups of studies were performed with Fisher's exact test or the χ^2 test for categorical data of unpaired samples. Given that multiple comparisons were performed, we used the Bonferroni correction to control for the possibility of type 1 error. The adjusted significance level was calculated as $P < 0.00625$ (0.05/8).

Results

A total of 641 studies were included in this analysis, of which 19.3% (124) were randomized and 80.7% (517) non-randomized. Of these, 23.6% related to orthopaedic devices, 28.4% to diabetes devices, and 48.0% to cardiovascular devices (*Table 1*). A total of 1 976 370 devices/patients were included in these studies.

Inclusion and reporting by age

A summary metric for age, either the mean or median age of the study population, was reported in the majority of orthopaedic (91.4%), diabetes (94.5%), and cardiovascular (100%) studies. A minority of the analyses were restricted to specific age groups (4.6% of orthopaedic, 24.7% of diabetes, and 0% of cardiovascular device studies). Analyses stratified by age group were performed more frequently in the diabetes (25.2%) and cardiovascular (14.6%) device studies than in the orthopaedic (4.6%) device studies (*Table 1* and *Figure 1*).

Inclusion and reporting by sex

The sex distribution was reported in the majority of orthopaedic (91.4%), diabetes (91.8%), and cardiovascular (98.7%) device studies. Female patients comprised over half of the patients in the orthopaedic (55.3%) and diabetes (53.1%) device studies, but only 37.8% of patients in the cardiovascular device studies ($P < 0.001$). Analyses restricted to one sex were performed in a minority of studies in all three device categories (5.3% of orthopaedic, 1.6% of diabetes, and 0.7% of cardiovascular device studies). Analyses stratified by sex were performed in the minority of studies in all three categories (6.0% of orthopaedic, 12.6% of diabetes, and 10.4% of cardiovascular device studies) (*Table 1* and *Figure 1*).

Information on ethnicity of participants

Information on the ethnicity of participants was provided in 0% of orthopaedic, 31.3% of diabetes, and 1.3% of cardiovascular device studies ($P < 0.001$).

Comparison of randomized vs. non-randomized studies

Analyses stratified by age group were performed more frequently in randomized studies (*Table 2*). The proportion of female patients was lower in the randomized compared with the non-randomized studies

Table 1 Inclusion and reporting by age and sex in studies of high-risk medical devices

Category and number of studies	Total (*N* = 641)	Orthopaedic (*N* = 151)	Diabetes (*N* = 182)	Cardiovascular (*N* = 308)	*P* value
Number of devices/patients included	1 976 370	1 814 953	64 310	97 107	—
Mean or median age reported, *n* (%)	618 (96.4)	138 (91.4)	172 (94.5)	308 (100)	<0.001
Analyses restricted to specific age group, *n* (%)	52 (8.1)	7 (4.6)	45 (24.7)	0 (0)	<0.001
Analyses stratified by age group, *n* (%)	98 (15.3)	7 (4.6)	46 (25.2)	45 (14.6)	<0.001
Sex distribution reported, *n* (%)	609 (95.0)	138 (91.4)	167 (91.8)	304 (98.7)	<0.001
Female subjects, *n* (%)	1 074 524 (54.4)	1 003 669 (55.3)	34 149 (53.1)	36 706 (37.8)	<0.001
Analyses restricted to sex, *n* (%)	13 (2.0)	8 (5.3)	3 (1.6)	2 (0.7)	0.004
Analyses stratified by sex, *n* (%)	64 (10.0)	9 (6.0)	23 (12.6)	32 (10.4)	0.12
Information on ethnicity of participants provided, *n* (%)	61 (9.5)	0 (0.0)	57 (31.3)	4 (1.3)	<0.001

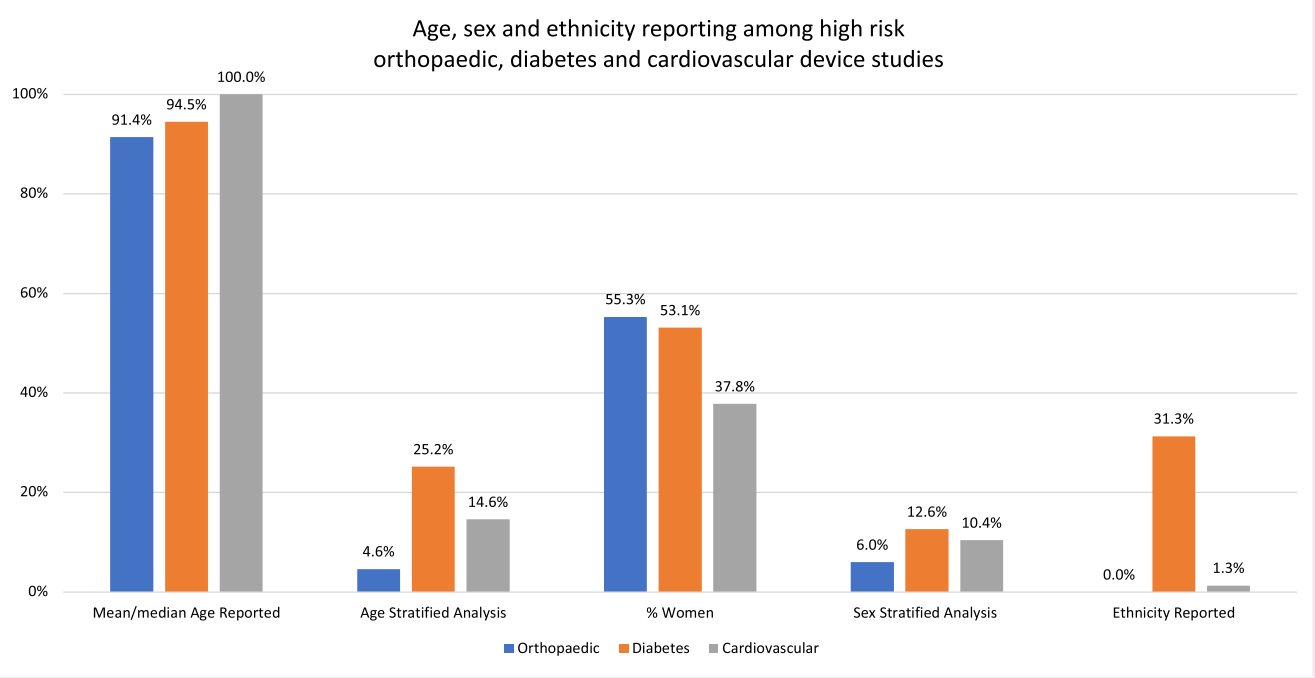


Figure 1 Inclusion and reporting by age, sex, and ethnicity in clinical studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices approved in the European Union.

(38.3% vs. 54.4%, $P < 0.001$), whereas analyses stratified by sex were performed more frequently in randomized studies (22.6% vs. 7.0%, $P < 0.001$). Information on the ethnicity of participants was provided more frequently in randomized in comparison to non-randomized studies (16.9% vs. 7.7%, $P = 0.002$). These data are summarized in *Table 2* and *Figure 2*. Further information on the results in the orthopaedic, diabetes, and cardiovascular device categories as per study randomization is provided in Supplementary material online, *Tables S1–S3*.

Discussion

This analysis of data from patients treated with >1.9 million high-risk medical devices has demonstrated that:

1. Virtually all studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices reported demographic data on the age and sex of the participants.
2. Almost no studies of high-risk orthopaedic and cardiovascular medical devices included information on the ethnicity of the included participants, although this was more frequently provided in randomized studies.
3. A lower proportion of patients in the cardiovascular device studies were female in comparison to the orthopaedic and diabetes device studies.
4. A minority of studies of high-risk medical devices performed age- and sex-stratified analyses, although this was more frequently provided in randomized studies.

In recent years, there has been increasing recognition of the importance of promoting the inclusion and representation of underserved groups in clinical trials.[13,14] Female, elderly, and 'minority' ethnic

Table 2 Comparison of randomized vs. non-randomized studies

	All studies (*N* = 641)	Randomized studies (*N* = 124)	Non-randomized studies (*N* = 517)	*P* value
Number of devices/patients included	1 938 952	35 890	1 940 480	–
Age				
Mean or median age reported, *n* (%)	618 (96.4)	124 (100.0)	494 (95.5)	0.01
Analyses restricted to specific age group, *n* (%)	52 (8.1)	14 (11.3)	38 (7.4)	0.15
Analyses stratified by age group, *n* (%)	98 (15.3)	29 (23.4)	69 (13.3)	0.008
Sex				
Sex distribution reported, *n* (%)	609 (95.0)	121 (97.6)	488 (94.4)	0.17
Women, *n* (%)	1 074 524 (54.4)	13 728 (38.3)	1 055 609 (54.4)	<0.001
Analyses restricted to sex, *n* (%)	13 (2.0)	2 (1.6)	11 (2.1)	0.70
Analyses stratified by sex, *n* (%)	64 (10.0)	28 (22.6)	36 (7.0)	<0.001
Ethnicity				
Information on ethnicity of participants provided, *n* (%)	61 (9.5)	21 (16.9)	40 (7.7)	0.002

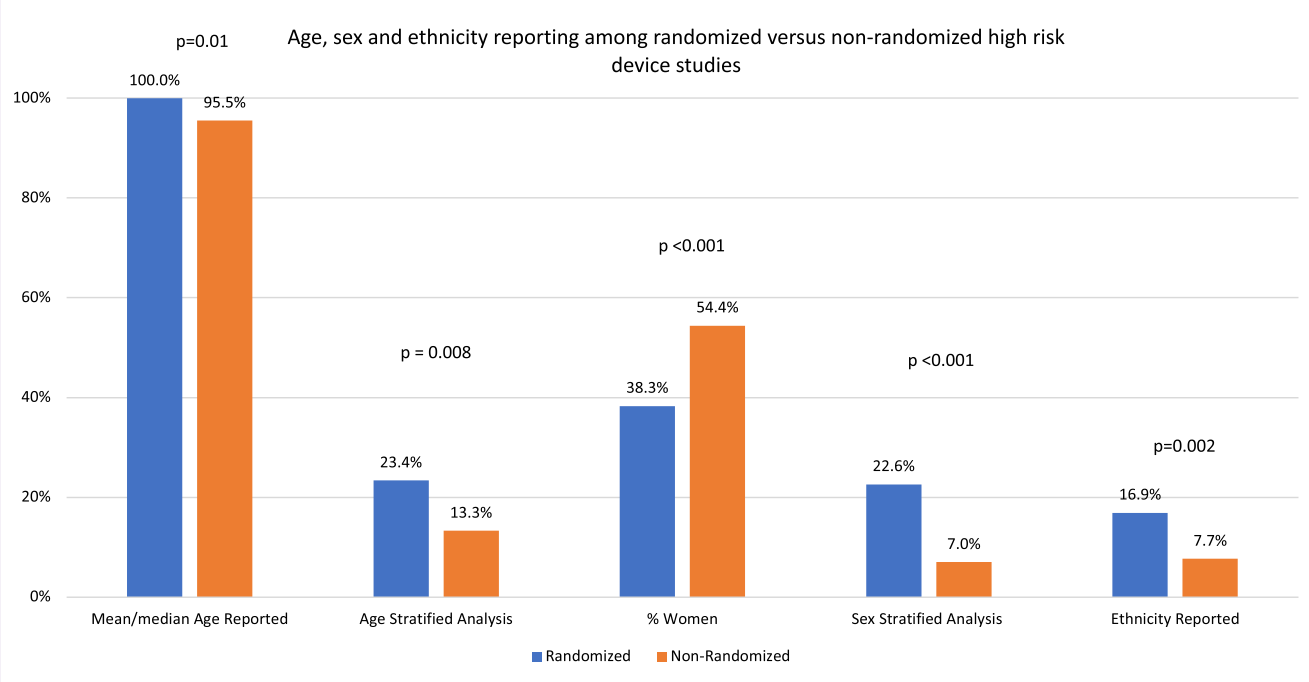


Figure 2 Inclusion and reporting by age, sex, and ethnicity in randomized vs. non-randomized clinical studies of high-risk medical devices approved in the European Union.

groups tend to be under-represented in randomized clinical trials.[15–20] From a global perspective, it is also important to recognize that ethnic groups that are sometimes referred to as 'minority' groups in western populations (where the majority of clinical trials are conducted) may actually be majorities in the global population. The fact that medical devices have not been adequately tested in these ethnic groups may lead to exacerbations in health inequalities. A review of this issue has recently been commissioned by the Health Secretary in the UK.[21]

When medical devices perform differently in different populations, this has the potential to impact on treatment decisions and subsequent clinical care.[22] It is notable that a minority of studies included in our analysis provided information on the ethnicity of participants. This means that it is not possible to assess whether or not the devices in question have been assessed adequately in different ethnic groups. This may have important real-world consequences. For example, outcomes after surgical aortic valve replacement have been reported to be worse in black patients, who were also noted to be under-represented in clinical trials of these devices in comparison to their prevalence in the population.[4]

Subgroup analysis is often performed in clinical trials. Notwithstanding its inherent limitations, it can be useful to explore

heterogeneity of treatment effects.[23] However, it has been reported that few subgroup analyses are available for high-risk medical devices reviewed by the FDA.[24] In our study, the relatively low proportion of sex-stratified analyses in the orthopaedic and diabetes device categories was notable, a finding that was observed in both randomized and non-randomized studies. This is concerning as several studies have reported that device performance can vary according to sex. For example, metal-on-metal hip implant complications (adverse local tissue reaction, dislocation, aseptic loosening, and revision) have been reported to occur more commonly in women than in men.[3] Similarly, female patients have been reported to have an increased risk of complications after isolated aortic/mitral valve surgery.[5] In the cardiovascular device category, age- and sex-stratified analyses were included more often in reports from randomized studies (see Supplementary material online, *Table S3*), but still in a minority overall. Our results highlight the importance of analysing and presenting the results of high-risk medical device studies according to age, sex, and ethnicity. This would provide important insights with respect to any heterogeneity of clinical outcomes or device performance.

Enrolling inclusive and representative populations should be a key goal for all clinical studies. Regulators, including the notified bodies in Europe, should mandate data on the age, sex, and ethnic breakdown of the populations in whom high-risk medical devices have been tested.[25] The performance of subgroup analysis based on age, gender, and ethnicity should also be mandated for all high-risk medical devices. This is recommended in standards and guidance published by medical device regulatory agencies.[26]

However, it must also be recognized that in some EU states there are restrictions on collecting and reporting data by ethnicity, which may represent a barrier to achieving this goal.

Overall, our analysis highlights that currently available studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices do not provide adequate insight into the performance of the investigated devices in patient populations according to age, sex, and ethnicity. The under-representation of certain patient groups in clinical research appears to be complex and multifactorial.[27] However, it is increasingly recognized that implicit or unconscious bias amongst research and clinical professionals may contribute to this.[28–30] Potential solutions to counteract this may include providing training for research staff at all levels in implicit bias, structural racism, sexism, and ageism. It has also been reported that female principal investigators (PIs) are more likely to enrol female patients.[31] Therefore, efforts to increase the number of female PIs and PIs from diverse racial and ethnic backgrounds may, in turn, increase the representativeness of patients recruited to clinical trials. Encouraging results have been reported from local and community actions to promote inclusive research recruitment, and this is another potential method of increasing rates of diverse recruitment.[32]

Limitations

The CORE-MD consortium restricted its analyses to available studies of high-risk devices; other documents may contain data on high-risk medical devices but were not publicly available. There was also some heterogeneity in the presentation of demographic data (e.g. means ± standard deviations and medians with interquartile ranges for age) amongst the studies included. There was also heterogeneity across the three systematic reviews regarding the included study designs, time restrictions for included studies, device selection, and selection of the relevant outcomes.

It is possible that certain groups may constitute a smaller proportion of trial populations but still be 'representative' of their proportion of the total prevalence of the disease. Given the variety of conditions treated by cardiovascular devices in our study, it would be difficult to determine whether the proportion of female patients in cardiovascular device trials is under-representative of their actual prevalence, or whether it accurately reflects a lower prevalence in women of indications for these devices. There was no gender bias, however, in the studies of devices used for orthopaedic conditions or diabetes. Our data are consistent with previous reports that women are under-represented in cardiovascular device trials.[33–35] A separate but important argument in favour of recruiting similar numbers of male and female subjects into cardiovascular device trials is that ideally the strength of evidence for using a device should be as strong for a device that is rarely used as for a device that is needed frequently, or for any device that may be used less often in women than in men. It will be more challenging to recruit into a study many patients with a rare condition or less frequent indication for a device, but the goal should always be to ensure that a study has sufficient statistical power for any key subgroups (such as either gender).

Given that multiple comparisons were performed, we acknowledge that the possibility of type 1 error may be increased. In order to counteract this, we employed the Bonferroni correction, which resulted in a P value of <0.00625 indicating significance.

Conclusions

While the majority of studies of high-risk orthopaedic, diabetes, and cardiovascular medical devices approved in the EU provide demographic data on the age and sex of participants, only a minority of these studies provided information on participant ethnicity. Few studies performed stratified analysis as per age and sex, although this was performed more frequently in randomized trials. Cardiovascular device studies enrolled a lower proportion of female patients in comparison to orthopaedic and diabetes device studies. These results suggest that the studies of high-risk medical devices identified in this systematic review do not adequately provide data on the age, sex, and ethnicity of the studied participants.

Supplementary material

Supplementary material is available at *European Heart Journal—Quality of Care and Clinical Outcomes* online.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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