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DIABETES AS A RISK FACTOR FOR INCIDENT PERIPHERAL ARTERIAL DISEASE IN WOMEN COMPARED TO MEN: A SYSTEMATIC PROSPECTIVE STUDY AT TERTIARY CARE HOSPITAL FROM NORTH INDIA

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ABSTRACT

Previous meta-analyses have suggested that diabetes confers a greater excess risk of coronary heart disease(CHD), stroke, vascular dementia and heart failure in women compared to men. While the underlying mechanism that explains such greater excess risk is unknown. In the current analysis, we hypothesized that we would find a similar sex difference in the relationship between diabetes and peripheral arterial disease (PAD).We conducted a prospective study to find out correlation of Type2-DM(T2-DM)and Peripheral vascular disease(PVD)and higher incident PVD in women than men We conducted present study at tertiary care hospital;UP University of Medical Sciences(UPUMS), India. All participants were enrolled in Medical OPD(MOPD)of UPUMS,India and study was carried out prospectively at this single centred tertiary care hospital We recruited and did periodic assessment and review for 09 years wef Apr2008 to2017 The relative risk (RR), and its variability, for incident PAD associated with diabetes in both sexes was evaluated. We excluded those participants who were not adjusted at least for age and in which participants had pre-existing PAD. Random-effects Prospective analyses with inverse variance weighting were used to obtain summary sex-specific RRs and the women: men ratio of RRs for PAD. The Newcastle–Ottawa scale was used to assess study quality 20712participants (49.8% women), were included in this study. The relative risk for incident PAD associated with diabetes compared with no diabetes was 1.96 (95% CI 1.29–2.63) in women and 1.84 (95% CI 1.29–2.86) in men, after adjusting for potential confounders. The multiple-adjusted RR ratio was 1.05 (95% CI 0.90–1.22), with virtually no heterogeneity between studies ($I^2 = 0\%$). studies scored 6–8, on the Newcastle–Ottawa scale of 0–9, indicating good quality.there was no sex-specific relative risk Consistent with other studies, we found evidence that diabetes is an independent risk factor for PAD. However, in contrast to similar studies of other types of cardiovascular disease, we did not find evidence that diabetes confers a greater excess risk in women compared to men for PAD. More research is needed to explain this sex differential between PAD and other forms of CVD, in the sequelae of diabetes. In addition, we found that very few studies reported the sex-specific relative risk for the association between diabetes and PAD, adding to existing evidence for the need for improved reporting of sex-disaggregated results in cardiovascular disease research.

KEYWORDS: Type2-DM, Peripheral vascular disease, Cardiovaschlar Risk.

INTRODUCTION

Cardiovascular disease (CVD) is a leading cause of morbidity and mortality for women and men globally. Peripheral arterial disease (PAD), which in the context of this review refers to atherosclerotic occlusive disease of the lower extremities, is a manifestation of CVD with similar morbidity, mortality, and health economic costs as coronary heart disease and stroke.[1,21] While PAD has long been considered a man's disease,[3] contemporary data show that in low and middle income countries the

prevalence of PAD in women and men is approximately equal, while in wealthier countries the prevalence of PAD is slightly higher in women than in men.[2,3,4] Moreover, data from the Global Burden of Disease study showed that women, compared to men, experienced a greater increase in PAD-related death (1.64 Additional years of life lost in women versus 0.53 in men) and disability (1.0 additional disability adjusted-life years lost in women versus 0.51 in men) between 1990 and 2010.[5,6,7]

Women tend to seek medical attention at more advanced stages of PAD than men, which is reflected in their higher mortality rates and adverse outcomes, including critical limb ischemia and limb loss.[2,3,6] 2,3,6The misconception that PAD is a predominantly found in men,[3] as well as the fact that women have higher rates of subclinical, asymptomatic, and atypical (according to standard criteria) PAD.[2,3,6] might account for these delays.

Responding to the lack of timely support that women with PAD receive, in 2011 the American Heart Association (AHA) and the Vascular Disease Foundation (VDF) issued a joint "call to action" that urges healthcare professionals to promptly screen women at-risk of PAD, even when asymptomatic, and to develop women-specific public health messaging about this disease.[1] The major risk factors for PAD are well-established and include advanced age, tobacco use, and diabetes.[3] However, nearly a decade later, it is unknown whether any of these risk factors differentially increase the risk of PAD in women compared to men. Given that PAD risk is closely associated to age, that the population is ageing globally, and that women tend to live longer than men (at a rate that is expected to be sustained) there is an immediate need to address challenges in diagnosis and successful management of PAD in women.[7]

Research by this team and others has provided strong evidence that, while women have lower risk for CVD overall, diabetes confers an excess relative risk in women for the onset of CVDs, including coronary heart disease, stroke, heart failure, and vascular dementia.[8,9,10,11,12,132,14,15] that partially erases this female "biological advantage.[14,15,16] The reasons for this advantage in women without diabetes compared to men of the same age are not entirely clear, but likely the result of multifactorial contributions including the protective effect of estrogen/harmful effect of testosterone, differences in cardiovascular risk factors, and sex differences.[18,19] in the diagnosis and treatment of diabetes and cardiovascular disease.

In order to ensure the accuracy of, and to potentially improve, current screening recommendations, risk factor calculation, and prevalence estimation of PAD, it is necessary to investigate if the sex-specific excess risk for diabetes extends to this disease. Understanding the interplay between sex, diabetes, and PAD-onset is particularly important given the women with intermittent claudication and diabetes have greater excess risk of coronary heart disease, stroke, and heart failure than men with these same co-morbidities Although four previous reports have suggested that women with diabetes have greater excess risk for PAD than men, these reports have been speculative, based on findings of a small number of studies where only subjects with diabetes, or only participants with PAD, were included.[6,7,17,24] We thus conducted a systematic review with meta-analysis of prospective cohort studies to establish more conclusively whether women with diabetes have a greater excess risk for PAD compared to their male counterparts, independent of other variables.

METHODS

we hypothesized that we would find a similar sex difference in the relationship between diabetes and peripheral arterial disease (PAD).We conducted a prospective study to find out correlation of Type2-DM(T2-DM)and Peripheral vascular disease(PVD)and higher incident PVD in women than men We conducted present study at tertiary care hospital;UP University of Medical Sciences(UPUMS),India.All participants were enrolled in Medical OPD(MOPD)of UPUMS, India and study was carried out prospectively at this single centred tertiary care hospital We recruited and did periodic assessment and review for 09 years wef Apr2008 to2017 The relative risk (RR), and its variability, for incident PAD associated with diabetes in both sexes was evaluated. We excluded those participants who were not adjusted at least for age and in which participants had pre-existing PAD. Random-effects Prospective analyses with inverse variance weighting were used to obtain summary sex-specific RRs and the women: men ratio of RRs for PAD. The Newcastle–Ottawa scale was used to assess study quality 20712 participants (49.8% women), were included in this study. The relative risk for incident PAD associated with diabetes compared with no diabetes was 1.96 (95% CI 1.29–2.63) in women and 1.84 (95% CI 1.29–2.86) in men, after adjusting for potential confounders. The multiple-adjusted RR ratio was 1.05 (95% CI 0.90–1.22), with virtually no heterogeneity between studies ($I^2 = 0\%$). studies scored 6–8, on the Newcastle–Ottawa scale of 0–9, indicating good quality.there was no sex-specific relative risk Consistent with other studies, we found evidence that diabetes is an independent risk factor for PAD. However, in contrast to similar studies of other types of cardiovascular disease, we did not find evidence that diabetes confers a greater excess risk in women compared to men for PAD.

Study selection and data extraction

Population-based studies were included if they provided relative risks (RRs), or equivalents, together with their 95% confidence intervals (CIs), directly or indirectly, for the associations between diabetes and PAD in women and men separately (16). Studies were included regardless of how they determined a diagnosis of diabetes in patients, and both type 1 and type 2 patients

were included in the analysis. Similarly, we did not eliminate studies based on how they defined incident PAD. Studies were excluded if they did not at least adjust for age, if they included patients with baseline PAD, or if they were conducted predominantly in patients with an underlying health condition. In cases where the published article did not report the RR separately for women and men, authors were emailed for additional information. In the primary analysis, only prospective studies were included; cross-sectional studies were added to the sensitivity analysis. For the primary analysis, two independent investigators (AZC and IHYC) screened studies by title and abstract and extracted the data; they resolved any discrepancies by mutual consent. A modified version of the Newcastle–Ottawa Quality assessment scale.[20] was used to evaluate the methodological rigor of all included studies
Statistical analyses.

The main endpoint was incident PAD. For each study, we obtained the sex-specific RRs for PAD, comparing individuals with diabetes versus individuals without diabetes, and their corresponding 95% confidence intervals (CIs), through extraction from the published manuscripts or personal communication with the study authors. We then used these to calculate the women-to-men ratio of RRs (RRR) and their 95% CIs Studies varied in how they detected incident PAD, and in the variables used in these multiple-adjusted estimates; where more than one multiple adjustment was carried out, we chose that with the most covariates.

The main metric was the multiple-adjusted pooled RRR, with its 95% CI. After natural log transformation of study-specific RRs and RRRs, random-effects meta-analysis was used to calculate pooled estimates for the maximally-adjusted sex-specific RRs and the RRR. The inverse of the variance of the log RR, and of the log RRR, were used to weight studies. The I^2 statistic was used to estimate the percentage of variability among studies attributable to between-study heterogeneity, and we also reported the p-values for Cochran's Q test for homogeneity. The small number of eligible studies precluded assessment of publication bias. Random effects meta-regression was used to explore heterogeneity across studies according to estimated average age at censoring (mean age at baseline plus mean follow-up time). A sensitivity analysis was also conducted where we also calculated the RRR for cross-sectional studies. All analyses were performed using R software, version 3.6.1 (R Project for Statistical Computing).[22] P-values < 0.05 were considered significant.

RESULTS

Of the 4158 unique articles identified through the systematic search for the primary analysis, 93 met the criteria for full-text review the remainder were discarded based on the lack of relevance of the title and/or abstract. Of these, seven articles met our inclusion criteria, providing data from seven unique cohorts, totaling 2,071,260 participants (49.8% women) (Table 1). All studies were published in English and were conducted in high-income, western countries. We did not identify any relevant abstracts or unpublished work. In studies that reported the average age of participants, the range was 45 to 72 years. Across studies, the average duration of follow-up ranged from 5 to 20 years. In the six studies that reported the number of baseline diabetes cases by sex, 46.5% of patients were female. There were 16,434 incident cases of PAD; in the five studies that reported incident cases by sex, 52.3% of patients with PAD were women. Studies were of good quality, all scoring between 6 and 8 of a possible maximum 9 points on the Newcastle–Ottawa scale In women, the overall multivariable adjusted summary RR for incident PAD associated with diabetes, compared with no diabetes, was 1.96 (95% CI 1.37–2.86), compared to 1.84 (95% CI 1.29–2.63) in men The statistic was 92.6% in women and 94.0% in men, indicating substantial between-study heterogeneity. For comparative purposes, age-only adjusted RRs for women and men were 2.74 (95% CI 1.72–4.39) and 2.51 (95% CI 1.63–3.84), respectively; the I^2 statistic was 92.0% in women and 90.5% in men (Additional file 4: Fig. S1). Results did not change meaningfully when we removed Shah et al.[27] from the analysis.

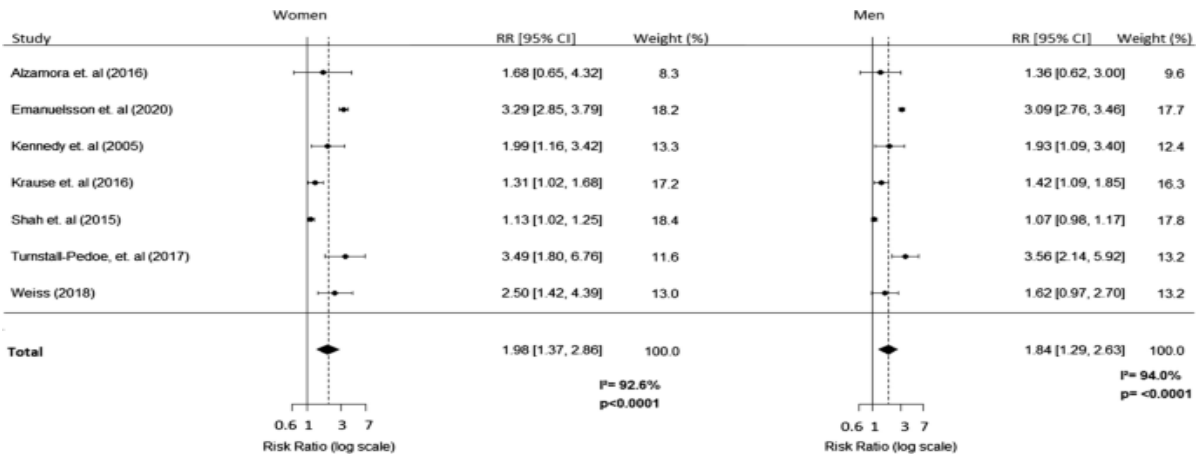

Fig. 1:

Multiple-adjusted pooled relative risks (RRs) for incident PAD, comparing individuals with diabetes with those without diabetes. Results for women and men are reported separately

The pooled multiple-adjusted women-to-men RRR for incident PAD was 1.05 (95% CI 0.90–1.22) age-only adjusted RRR (women: men) was 1.07 (95% CI 0.94–1.22) (Additional file 6: Fig. S3). The I^2 statistic in both cases was 0%, indicating virtually no between-study heterogeneity in the measurement of the male to female ratio. Repeating this analysis without Shah et alwhich contributed 93% of the study subjects, did not meaningfully change the results (Additional file 7: Fig S4). There was no evidence that age at censoring had any effect on the RRR (estimated regression slope of − 0.002 (standard error 0.005)).

DISCUSSION

Our meta-analysis of six prospective studies with over 2 million individuals provides evidence that diabetes is an independent risk factor for PAD in both sexes, associated with an excess risk of PAD of 96% and 84% in women and men, respectively, and thus, similar in women and men. This contradicts previous reports that speculated that a female disadvantage in the relationship between diabetes and PAD existed Furthermore, the absence of a sex difference was consistent across all included prospective studies. Exclusion of the Shah et al cohort, which contributed 93% of the individuals in our analysis, did not meaningfully change these results Encouragingly, we found that, in each of the included studies, at least 50% of participants were women, even though historically women have been poorly represented in studies concerning PAD.[36]

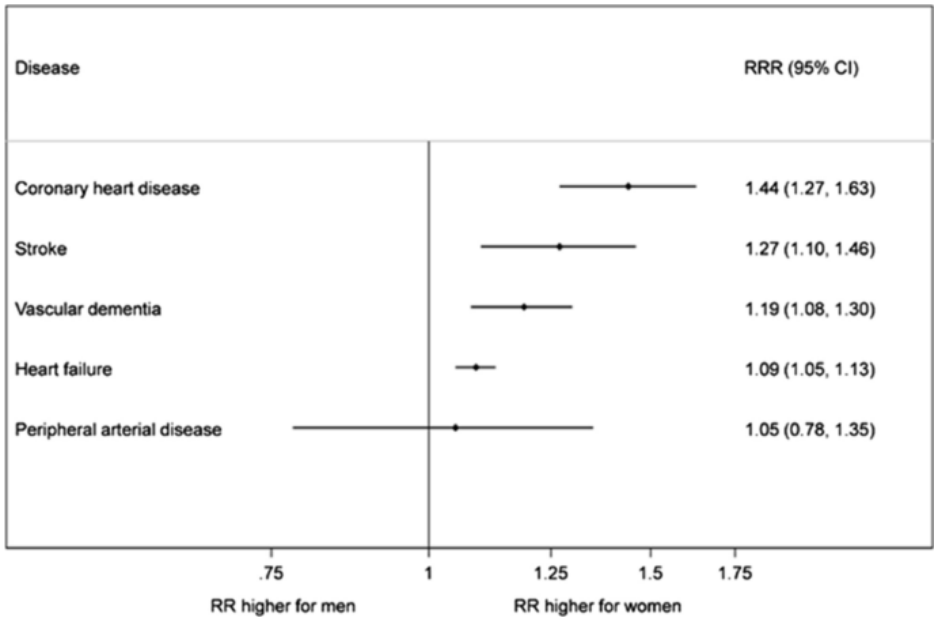

Fig. 2:

Multiple-adjusted ratio of women: men relative risks (RRRs) for incident coronary heart disease stroke vascular dementia,heart failure and PAD, comparing individuals with diabetes to those without diabetes.

Given that the underlying mechanism by which diabetes might confer this greater excess risk to women for other incident cardiovascular diseases is still unknown,[38] it is challenging to explain why we do not see a sex-specific effect for the relationship between diabetes and PAD, which is also a type of cardiovascular disease. However, one possible explanation lies in the finding that the more pronounced increase in relative risk for CVD events in women with diabetes compared to men appears, in part, to reflect the lower disease risk in women compared with men without diabetes PAD is unusual among atherosclerotic diseases in that its prevalence is slightly higher in women than in men throughout much of the lifecourse,which may be partially explained by the effect of average shorter height in women on ankle blood pressure[40,41,42,43] The natural advantage that the absence of diabetes confers in women compared to men may have been attenuated by factors such as height that increase PAD risk in women more than men overall, and that were not adjusted for in our analysis. It follows that the relative risk for women with diabetes versus without is not as pronounced as it is in other atherosclerotic diseases, which in turn attenuates the relative risk ratio between men and women.

CONCLUSION

Though few studies reported sex-specific results, we found evidence that diabetes is an independent risk factor for PAD in both women and men, highlighting the need for prevention and management strategies to reduce the risk of PAD onset in all individuals with diabetes. However, diabetes does not appear to confer a significantly greater relative risk of incident PAD in

women compared to men. These findings have implications for risk factor control, PAD screening, public health messaging, and modelling the future burden of PAD. More research is needed to determine the mechanisms responsible for sex differences in diabetes-related cardiovascular risk, and why these differences are not apparent for PAD.

Abbreviations

CVD
Cardiovascular disease

CIs
Confidence intervals

PAD
Peripheral arterial disease/peripheral vascular disease

RRR
Relative risk ratio

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Ethical clearance-Taken from University

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