REVIEW ARTICLE

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PREVALENCE OF PERIPHERAL ARTERIAL DISEASE IN PEOPLE WITH DIABETES MELLITUS: SYSTEMATIC REVIEW AND METHANALYSIS

PREVALÊNCIA DE DOENÇA ARTERIAL PERIFÉRICA EM PESSOAS COM DIABETES MELLITUS: REVISÃO SISTEMÁTICA E METANÁLISE

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ABSTRACT

Aim: To estimate the prevalence of Peripheral Arterial Disease in individuals with Diabetes Mellitus using evidence from the literature. **Method:** Systematic review and meta-analysis, carried out by two independent researchers, in national and international databases. The review protocol followed PRISMA recommendations and was registered in the International Prospective Register of Systematic Reviews (PROSPERO). Articles published in the last five years were included, and the methodological quality was assessed using the instrument proposed by The Joanna Briggs Institute, which assesses prevalence studies. In the meta-analysis, the random effects model was used, as well as analyzes to investigate heterogeneity. **Results:** 2408 studies were analyzed, which, after applying the eligibility criteria, totaled 14 articles, all of which performed the ankle-arm index test for the diagnosis of Peripheral Arterial Disease. The total sample consisted of 9335 people, prevalence of 6.30% of PAD, and the heterogeneity of the study was $I^2 = 97\%$. In the analysis of subgroups, women, people with more than 5 years of diabetes, hypertension and obesity had a higher prevalence of peripheral arterial disease. **Conclusion:** This study demonstrates that the prevalence of Peripheral Artery Disease among diabetic patients is relevant, especially among women. The ankle-arm index test is widely indicated and useful for the assessment of diabetic patients and early diagnosis of Peripheral Arterial Disease and may contribute to the prevention of wounds and amputation, providing a better quality of life.

Key words: Peripheral Arterial Disease; Diabetes Mellitus; Prevalence; Ankle Brachial Index; Nursing Care.

RESUMO

Objetivo: Estimar a prevalência da Doença Arterial Periférica em indivíduos com Diabetes Mellitus por meio de evidências da literatura. **Método:** Revisão sistemática e metanálise, realizadas por dois pesquisadores independentes, em bases de dados nacionais e internacionais. O protocolo da revisão seguiu as recomendações PRISMA e foi registrado na base International Prospective Register of Systematic Reviews (PROSPERO). Foram incluídos artigos publicados nos últimos cinco anos, e a qualidade metodológica foi avaliada através do instrumento proposto pelo The Joanna Briggs Institute, que avalia estudos de prevalência. Na metanálise utilizou-se o modelo de efeitos randômicos, assim como análises para investigação de heterogeneidade. **Resultados**: Foram analisados 2408 estudos, que, após aplicados os critérios de elegibilidade, totalizaram 14 artigos, no qual todos realizaram o teste do índice tornozelo-braço para o diagnóstico da Doença Arterial Periférica. A amostra total foi de 9335 pessoas, prevalência de 6.30% de DAP, e a heterogeneidade do estudo foi $I^2 = 97\%$. Na análise de subgrupos, as mulheres, pessoas com mais de 5 anos de diabetes, hipertensão e obesidade apresentaram maior prevalência de doença arterial periférica. **Conclusão:** Esse estudo demonstra que a prevalência da Doença Arterial Periférica entre os pacientes diabéticos é relevante, principalmente entre as mulheres. O teste do índice tornozelo-braço é amplamente indicado e útil para avaliação do paciente diabético e diagnóstico precoce da Doença Arterial Periférica e pode contribuir para a prevenção de feridas e amputação, proporcionado melhor qualidade vida.

Palavras-chave: Doença Arterial Periférica; Diabetes mellitus; Prevalência; Índice Tornozelo-Braço; Cuidados de Enfermagem.

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INTRODUCTION

Diabetes Mellitus (DM) is a disease of high morbidity and mortality, of multifactorial origin, characterized by persistent hyperglycemia, which causes systemic consequences1. More than 463 million people worldwide live with a diagnosis of DM, 90% of which is type 2[2]. DM often causes vascular complications, including Peripheral Arterial Disease (PAD), considered one of the causes for major lower limb amputations3. A PAD, when associated with neuropathy and foot ulceration, increases the risk of gangrene and limb amputation4.

PAD stands out for a gradual reduction in blood flow due to occlusive factors in arterial beds5. It is an atherosclerotic disease with more prevalence among the elderly and may be asymptomatic in the vast majority of cases, however, there is the potential to progress with clinical symptoms, such as lameness, and eventually lead to tissue necrosis6.

The diagnosis of PAD must include a thorough physical examination, which involves an investigation of clinical signs, such as the absence of peripheral pulses, arterial thrills and changes in the skin of the affected limb, in addition to verifying the severity of the vascular obstruction, specified by the ankle-brachial index (ITB) 7. The ABI is efficient for the detection of peripheral blood flow obstruction in the lower limbs and for the diagnosis of PAD, which is given by the relationship between the systolic blood pressure in the posterior or pedios tibial artery and the systolic pressure in the brachial artery8 .

The use of the ITB for the diagnosis of PAD is low-cost, non-invasive and easy to operate by any healthcare professional, including a trained and trained nurse. This assessment can be performed at the time of the consultation, and important information can be provided for clinical practice in Primary Health Care (PHC) 9. Thus, early diagnosis is extremely important, as it allows for prior treatment, in order to avoid complications10.

Thus, in order for health professionals to act preventively in PHC, there is a need to investigate the prevalence of this pathology in this specific population in the literature, since it is a common condition, subject to early assessment and intervention.

Thereby, it is possible to build a foundation for prevention measures and minimize complications of PAD.

Given the above, therefore, this study aims to estimate the prevalence of Peripheral Arterial Disease in individuals with Diabetes Mellitus through a systematic review with meta-analysis.

METHODS

It consists of a systematic review study with meta-analysis elaborated and written according to the PRISMA (Preferred

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Reporting Items for Systematic Reviews and Meta-Analyzes) recommendations, in order to mitigate the risk of bias. The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the number CRD42020196384.

The research question included the criteria established by the acronym PICo, being considered: P – Adult individuals; I – Prevalence of Peripheral Arterial Disease; Co – Individuals with Type 2 Diabetes Mellitus. Thus, this research sought to answer the following question: What is the prevalence of Peripheral Arterial Disease in individuals with Type 2 Diabetes Mellitus?

Original articles were included in the sample, cross-sectional studies, which investigated the prevalence of PAD in adult patients with type 2 DM; studies published in the last 5 years, in English, Portuguese and Spanish, with full text available. Studies that dealt with PAD but that the target population were not adult diabetic patients were excluded. Furthermore, the authors chose to exclude theses, dissertations and monographs.

Regarding the sources of information and search strategies, the selection of studies was performed in the following databases: Medical Literature Analysis and Retrieval System Online (MEDLINE), consulted by the US National Library of Medicine National Institute of Health (PubMed), Cumulative Index to Nursing & Allied Health Literature (CINAHL) and SCOPUS, using the Journal Portal of the Coordination for the Improvement of Higher Education Personnel (CAPES). In addition to these, the Nursing Database (BDENF), the Latin American and Caribbean Literature on Health Sciences (LILACS), the Spanish Bibliographic Index of Health Sciences (IBECS) and the Caribbean Literature in Health Sciences (MEDCARIB), which were examined through the Virtual Health Library (VHL).

The selection of studies was carried out between December 2019 and May 2020, and for the search in the databases, the following descriptors were combined: Ankle Brachial Index, Peripheral Arterial Disease, Diabetes Mellitus, in Portuguese, English and Spanish. The descriptors classified were those controlled and available by the Medical Subject Headings (MeSH) and Health Sciences Descriptors (DeCS).

According to the eligibility criteria, two authors independently selected the studies and evaluated the titles and abstracts. Then, the selected studies were analyzed in full, in which disagreements were resolved by consensus. To extract data from the studies, an Excel spreadsheet was created, and the variables of interest to the study were recorded: authors, year of publication, place of publication, prevalence of PAD, sample with PAD, total sample, sex, age, duration DM, SAH, dyslipidemia, BMI, smoking, presented symptoms and diagnostic method.

Regarding the assessment of the methodological quality of the included

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studies, the instrument used to assess the quality of prevalence studies was proposed by The Joanna Briggs Institute – JBI, with adaptations. The following criteria were adopted: 1) Was the sample appropriate to address the target population?; 2) Were study participants properly sampled?; 3) Was the sample size adequate?; 4) Were the subjects and environment described in detail?; 5) Was the data analysis conducted with sufficient coverage based on the sample?; 6) Were valid methods used to identify the disease?; 7) Was the condition measured in a standard and reliable way for all participants?; 8) Was there an adequate statistical analysis?; 9) Was the response rate adequate?. For each criterion met, the study received a point, in which the quality assessment was not used as an exclusion criterion for the articles.

The outcome analyzed in this study was Peripheral Arterial Disease (PAD), with the adoption of a 95% confidence interval. The forest plot and funnel graph were analyzed using the R software, version 3.6.2.

The assessment of heterogeneity between studies was measured by the Cochran Q test, which is based on the chi-square, in which a p-value less than 0.05 considers present heterogeneity. The I2 analysis was performed to test the degree of heterogeneity, and it was also evaluated through the analysis of subgroups (gender, duration of DM, hypertension, obesity and smoking). The funnel plot and the Egger test assessed the presence of publication bias among the studies that comprised the sample.

RESULTS

After a thorough analysis, the search strategy retrieved 2408 studies, of which 2295 did not meet the inclusion criteria, totaling 113 articles, which after being screened, remained a total of 14 articles included in the review and meta-analysis for meeting the eligibility criteria. Details of the selection process are illustrated in Figure 1.

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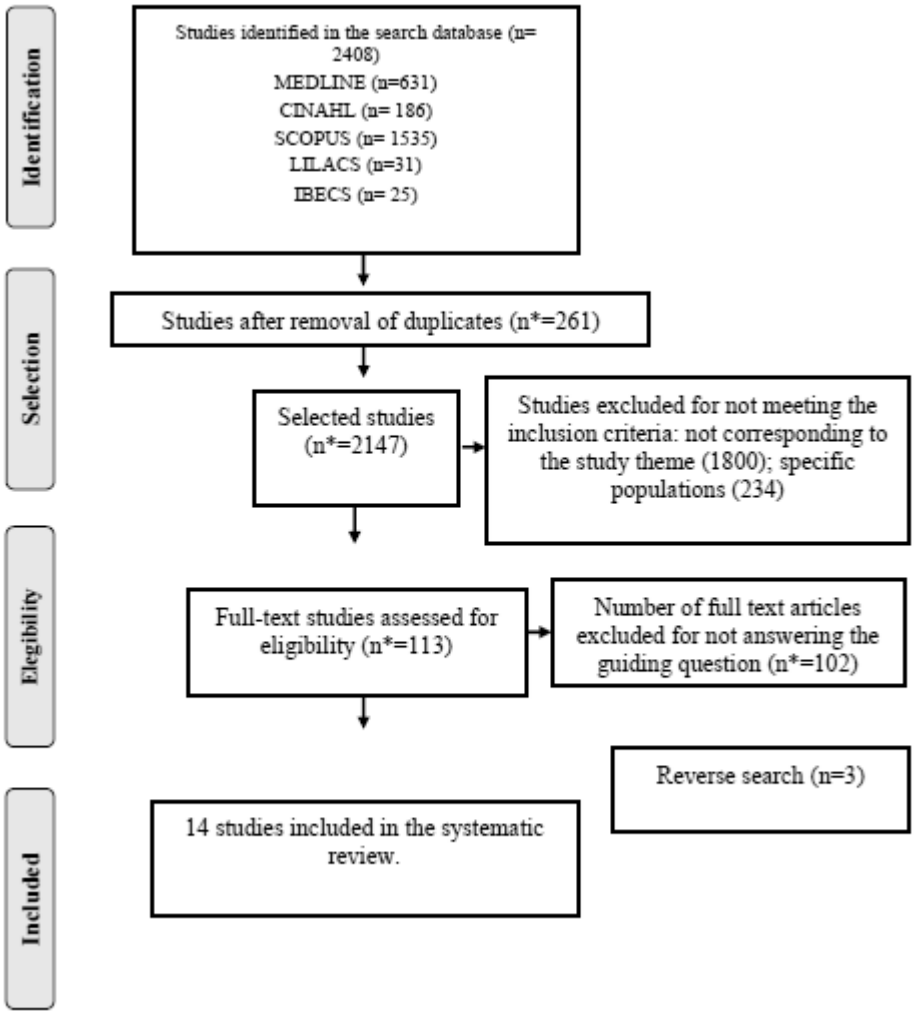
Figure 1 – Process of identification and inclusion of studies in the databases, Campina Grande, PB, Brazil, 2020



Source: The authors

When considering the studies included in the analysis, it was observed that India was the country with the highest number of publications on the prevalence of PAD in people with type 2 DM, totaling 28.5%, whose years of greatest publications were 2014 and 2019, both with 28.5%. In addition, in total, approximately 9335 people with type 2 DM were evaluated in the studies that comprised the sample. The diagnostic method applied in all studies was the ABI, which used the value <0.9 as PAD as a parameter, considered a strategy effective in the early diagnosis of PAD, shown in Table 1.

Table 1 - Characteristics of the studies included in the systematic review on the prevalence of PAD in people with type II DM. Campina Grande, PB, Brazil, 2020.

Author	Year	Place	Total Sample	Age group	Quality score	Diagnostic method	Pattern used

Arora et al[26]	2019	India	317	≥ 30	8	ITB	<1,00
Felício et al[27]	2019	Brazil	711	≥ 30	9	ITB	≤ 0,9
Yuan et al[28]	2019	China	1018	Average 58,59	9	ITB	<0,9
Weerarathna et al[29]	2019	Sri Lanka	2423	≥ 18	9	ITB	≤ 0,9
Shukla et al1[15]	2018	India	200	Average 57	9	ITB	≤ 0,9
Moreira et al[5]	2017	Brazil	249	≥ 18	9	ITB	≤ 0,9
Amissah; Antiri[18]	2016	Gana	200	≥ 20	8	ITB	≤ 0,9
Garg et al[13]	2016	India	67	≥ 30	8	ITB	≤ 0,9
Li et al[30]	2016	China	1028	Average 62	9	ITB	<0,9
Sales et al[31]	2015	Brazil	73	Average 55,7	9	ITB	≤ 0,9
Monterroso et al[32]	2014	Spain	251	≥ 50	9	ITB	≤ 0,9

Continue

Continuation – **Table 1.**

Author	**Year**	**Place**	**Total Sample**	**Age group**	**Quality score**	**Diagnostic method**	**Pattern used**
Okello et al[33]	2014	Uganda	229	≥ 50	9	ITB	≤ 0,9
Pinaya et al[34]	2014	Bolivia	76	-	8	ITB	<0,9
Eschol et al[12]	2014	India	2493	≥ 20	8	ITB	≤ 0,9

Source: The authors

It is observed, in the figure below, figure 2, that, referring to the population analyzed, a prevalence of PAD of 6.30% was estimated (95%CI = 3.21 – 11.99).

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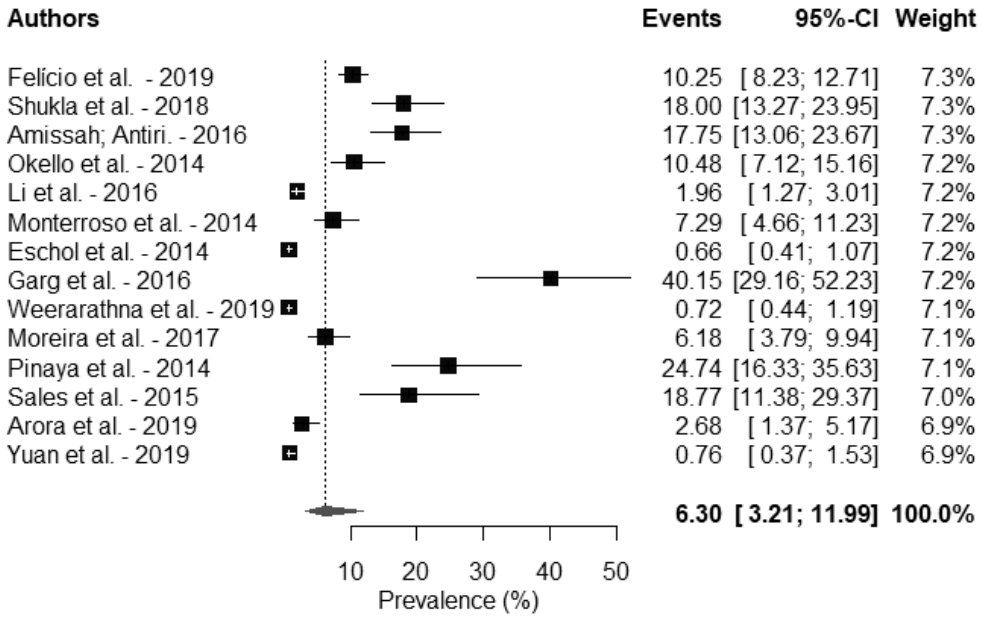
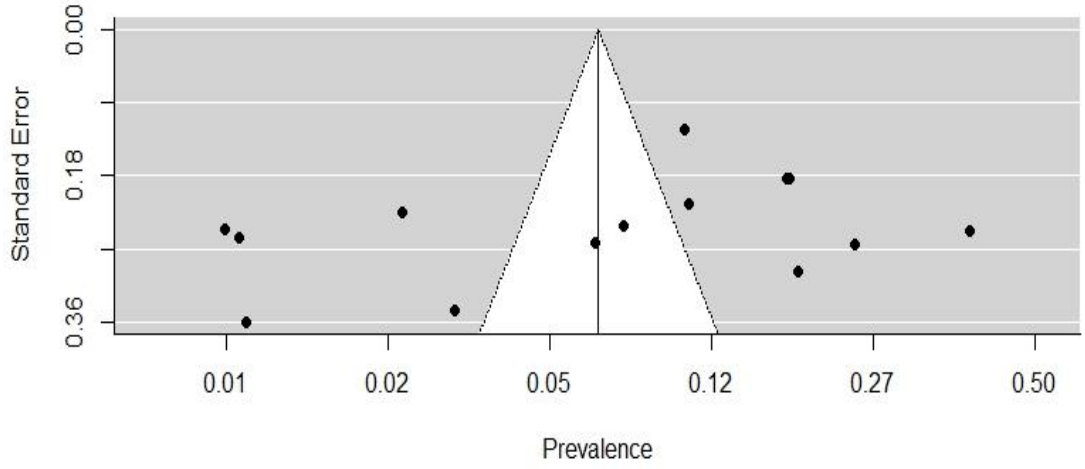
Figure 2 - Forest plot chart of Peripheral Arterial Disease prevalence among the analyzed studies. Campina Grande, PB, Brazil, 2020.



Source: The authors

The figure 3 Represents the funnel plot, which also displays data on the prevalence of PAD, according to the standard error, showing asymmetry between the evaluated studies. Such evidence is confirmed by the Egger Test (p=0.13), which shows a non-significant value, indicating that there is no bias between publications.

Figure 3 - Funnel chart for the distribution of the prevalence of Peripheral Arterial Disease, according to the manuscripts investigated. Campina Grande, PB, Brazil, 2020.



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Source: The authors

In the analysis of subgroups, there is a higher prevalence of PAD among the female population (20.4%). Furthermore, it was possible to identify a correlation between the duration of DM and PAD, in which 16.7% had DM between 5 – 10 years and 16.3% had it for more than 10 years. Furthermore, it is clear that smoking was not evidenced as a factor related to the development of PAD among the studies in the sample.

In order to analyze the possible causes of heterogeneity among the included studies, subgroup analyzes were performed, as described in Table 2. It is observed that the articles presented data regarding the absence of obesity, showing a homogeneity confirmed by I2 = 0.0 %. The other analyzes showed a high heterogeneity, however, they did not demonstrate the causes for the divergences between the data studied.

Table 2 - Distribution of the prevalence of peripheral arterial disease by subgroups. Campina Grande, PB, Brazil, 2020.

Subgroups	**Number of studies ****	**Total of participants**	**Prevalence (%)**	**IC95%**	**I2 (%)**	**p-value***
Gender						
Female	10	3515	20,4	15,6-26,4	92,0	<0,01
Male	10	4479	18,8	14,3-24,3	91,0	<0,01
Duration of DM						
5 - 10 years	6	6394	16,7	13,7-20,1	87,0	<0,01
Over 10 years	3	1469	16,3	4,8-42,8	98,0	<0,01
Hipertension						
Yes	7	3162	13,1	9,0-18,6	95,0	<0,01
No	7	2143	11,8	7,6-18,8	86,0	<0,01
Tabagism						
Yes	7	1050	2,5	1,7-3,7	69,0	<0,01
No	7	4244	18,3	13,4-24,4	93,0	<0,01
Obesity						
Yes	3	316	10,2	5,7-17,6	77,0	0,01
No	3	251	18,4	14,1-23,8	0,0	0,46

*Chi-square test; No.: Number; CI: Confidence Interval; DM: Diabetes Mellitus.
** In the analysis of subgroups, only studies that brought the association of the variable with PAD were included, so the sum does not necessarily give 14 studies.

Source: The authors

DISCUSSION

Understood as a challenge for patients and health team professionals in PHC, PAD requires specific care for prevention, identification of signs and symptoms and etiological factors. In this sense, the importance of early detection through the ABI is highlighted, considered an important indicator of PAD in its asymptomatic phase11.

In the present study, a prevalence of 6.30% of PAD was found in patients with type 2 DM. A lower prevalence of 0.66% was found in one study (95%CI 0.40 – 1.07) 12, while a considerably higher prevalence of 40.15 % was obtained in another study (95%CI 29.16 – 52.23) 13. This high variability of PAD prevalence found in the literature can be explained by the different research sites, by concentrating people with different types of complications, by the age of the participants, time elapsed before diagnosis and types of tests used for diagnosis.

Although not a high prevalence (6.3%), the result presented has a relevant clinical value due to the high morbidity and mortality of the disease. It also demonstrates the important association between PAD and DM, related to the duration of DM, systemic arterial hypertension (SAH), smoking and obesity, considered risk factors for cardiovascular events. These results corroborate published studies 6,14 that demonstrated that the main risk factors for the development of PAD would be DM, smoking, SAH and obesity. It is justified that such factors deteriorate the vascular endothelium and stimulate an inflammatory reaction in the vessel wall.

A high heterogeneity (I^2 = 97%) was identified between the studies, which can be explained by the inequalities between the selected articles, indicated by the Egger Test (p=0.13). Furthermore, the heterogeneity can be justified by the differences in the scenario of the included studies, the sample difference, as well as the defined time frame.

In the present study, a relationship between gender and the prevalence of PAD was observed, in which a greater number of women (24%) had the disease. This result converges with other studies that observed a higher prevalence of PAD among women, considered to be the most important predictor of the pathology 12,15. This is justified by the fact that women in menopause have a decrease in estrogen production, which contributes to the atherosclerotic process, due to changes in the vascular wall, causing a greater cardiovascular risk, which can be aggravated by other comorbidities16.

With regard to the duration of DM, the data show that the prevalence of PAD is directly proportional to its course, and

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represents an important risk factor for the worsening of the disease. In this study, it is demonstrated that the predominance of PAD was greater among people who had more than five years of DM. This result was also found in other studies that demonstrate that DM complications occur after five years of diagnosis17. In a study carried out in India15, it was identified that the prevalence of PAD was significantly higher in patients with diabetes for a longer period. Thus, it can be stated that PAD progresses more quickly in people with DM, and its prevalence increases with advancing age and duration of diabetes [13,18].

Still on cardiovascular complications, it is known that SAH is associated with vascular diseases and arteriosclerotic complications, and this study found a higher prevalence of SAH in people with PAD. Another study demonstrated that there is an association between SAH and high mortality rates in patients with PAD19, as was also evidenced by a study carried out in Brazil, that there was a significant correlation between PAD and hypertension, in which, in its sample , 83.5% of patients had both comorbidities5. In the selection of articles included in this review, 50% of the studies showed this risk factor associated with PAD.

In the present study, there was a low number of smokers, which can be explained by the low rate of smokers in the included sample and by the greater awareness of people over the years regarding the risks of smoking. However, it is known that smoking is associated with numerous diseases and is considered the risk factor that most contributes to the development of PAD, as well as being related to the progression and acceleration of acute arterial occlusions14. This result corroborates another study that demonstrated the association between smoking and PAD20. This association can be explained by the fact that smoking directly damages the vascular endothelium, causing structural damage and endothelial dysfunction. In turn, it is essential that diabetic patients stop smoking, considering that it is one of the measures that has the greatest impact in reducing the risk of complications21.

By analyzing the samples studied in each article, it was found that three of the selected studies addressed obesity as a risk factor for the development of PAD. It is known that obesity increases the risk of metabolic syndrome, which is linked to several clinical conditions and risk factors for the development of cardiovascular diseases. It was previously demonstrated by other studies that obesity was the most prevalent risk factor, being considered an independent factor for the development of cardiovascular diseases22. In addition, obesity was shown to be present in another study, affecting more than 75% of the population evaluated23. According to the Brazilian Society of Diabetes24, most individuals living with type

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2 DM are obese, thus, this population is more vulnerable to the development of PAD.

In addition, this injury represents a relevant economic impact on the health system, as it demands a high cost to control and treat complications. Among them, PAD, associated with DM, increases the risk of amputations, impairing the quality of life of individuals with the pathology, as well as overloading the health system25.

Thus, it is understood that the role of the PHC team in assisting the individual with DM is essential, considering that it contributes to the planning of health promotion and disease prevention actions, in addition to acting directly in care. Health education stands out as an important factor for the prevention and treatment of complications arising from DM. By performing the ABI, it is possible to identify early PAD in its asymptomatic phase, in order to minimize the morbidity and mortality of the complication. In addition, Primary Health Care is highlighted as a place for monitoring the patient with DM, and in this scenario the identification of risk factors, blood glucose levels and monitoring of health care of the population, aiming to identify and minimize the factors of risk for the development of complications26.

The limitations of this systematic review study refer to the variability of the articles included and the scenarios of each research, covering the sample difference, different time frames and heterogeneous populations. Another limitation is the number of studies retrieved, which can be justified by the temporal filter applied.

Despite the limitations, this study can contribute both to the academic environment and to the qualification of actions in Primary Health Care. By identifying the prevalence of PAD among individuals with DM, through the ABI, and the association between risk factors pathology, the study can favor the planning of public policies and strategies, in order to minimize the complications of DM, as well as the costs generated by the treatment of complications.

CONCLUSION

This study demonstrates that the prevalence of PAD among diabetic patients is relevant, especially among women. Despite the challenges observed, it is believed that this study represents an initial effort to systematize information on the diagnosis of PAD, the main indicator of difficult-to-heal wounds and amputation in diabetic patients. It was found that the ABI is widely indicated and useful for the assessment of patients with DM and that it can be performed by health professionals, including nurses, trained and trained and can contribute to the prevention of diseases in this population, providing better quality of life for individuals and minimizing costs related to hospitalization and treatment of possible complications.

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The results also suggest that there are gaps between risk factors and PAD in relation to age that need to be investigated in this population of diabetics. It is also suggested that new studies should present, in addition to strict design, an adequate sample size that allows a statistical comparison between the variables and application of standardized instruments to monitor the results in the long term. It is considered that other studies of this nature will make it possible to identify groups of diabetics at higher risk for the development of PAD, and to plan health promotion and intervention actions aimed fundamentally at maintaining and improving the quality of health care for this group of patients.

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