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Ambulatory blood pressure monitoring and vascular complications in patients with type 1 diabetes mellitus – Systematic review and meta-analysis of observational studies

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ABSTRACT

Aims: This study aimed to evaluate the role of the 24-Hour Ambulatory Blood Pressure Monitoring (ABPM) as a possible predictor of vascular outcomes in office normotensive people with type 1 diabetes mellitus (T1DM).
Methods: This is a systematic review including cohort studies from the Embase, PubMed/Medline, and Web of Science databases on people with T1DM undergoing ABPM and subsequent evaluation of vascular complications. Measurements of difference (MD) were obtained using random effect model *meta*-analysis.
Results: We found 364 articles and 49 duplicates. Seven studies were included, comprising 635 participants aged 25.8 ± 6.2 years. Most (57.5 %) were men, mean duration of diabetes was 11.8 ± 5.3 years, mean glycated hemoglobin level among participants was 8.5 % ± 1.6 %, and mean follow-up time was 4.2 years. Lower night systolic blood pressure MD − 4.37 mmHg ($p = 0.0009$) and night diastolic blood pressure MD − 3.97 mmHg ($p < 0.0001$) were associated with lower incidence of albuminuria. People with T1DM who presented no beginning or progression of retinopathy were those with lower night diastolic blood pressure MD − 3.62 mmHg ($p = 0.042$), diurnal diastolic blood pressure MD − 2.69 mmHg ($p = 0.0138$), and 24-hour diastolic blood pressure MD − 3.65 mmHg ($p = 0.037$).
Conclusion: Small mean differences in blood pressure parameters, as measured by ABPM, between people with T1DM are associated with a lower incidence or risk of progression of nephropathy and retinopathy.

1. Introduction

Approximately one third of people with type 1 diabetes mellitus (T1DM) has systemic arterial hypertension, a well-established risk factor for micro and macrovascular complications in this population. [1] Despite this, there are no high-quality studies to guide blood pressure (BP) control in people with T1DM. The American Diabetes Association's (ADA) guideline, known as Standards of Care in Diabetes—2024 defined BP levels > 130/80 mmHg as systemic arterial hypertension (SAH) in people with T1DM, recommending an individualized control target, extrapolating the results of studies with people with type 2 diabetes mellitus (T2DM). [2–4] In agreement, the American Heart Association (AHA) also recommends starting drug treatment when BP values above 130/80 mmHg are persistently found in people with diabetes. [5].

BP changes are common in people with T1DM and may indicate the risk of developing or progressing complications. However, office BP measurements alone may not identify early changes. [6] The 24-Hour Ambulatory Blood Pressure Monitoring (ABPM) offers information on more parameters and BP patterns, allowing better assessment of BP, in addition to better prediction of long-term cardiovascular outcomes. [5,7].

We conducted a systematic review with *meta*-analysis of cohort studies to evaluate possible differences in BP parameters, as measured by ABPM, between people with T1DM and normal BP who did and did

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not progress to micro- or macrovascular complications. We hypothesized that these parameters could be predictors of a greater risk of developing these complications.

2. Methods

This study was conducted following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) and the Meta-Analyses and Systematic Reviews of Observational Studies (MOOSE) guidelines. [8,9].

The review was registered in the International Prospective Register of Systematic Reviews (PROSPERO) – CRD42022312038.

2.1. Study selection

This systematic review included cohort studies from the Embase, Pubmed/Medline, and Web of Science databases dated until November 2023 on people with T1DM undergoing ABPM, with subsequent evaluation of micro and macrovascular complications. Studies with people with T1DM, whose patients were undergoing ABPM, had follow-up with assessment of vascular outcomes, and used a cohort design were included.

Medical Subject Headings (MeSH) terms were used in combination, including 'Diabetes Mellitus, Type 1,' 'Blood Pressure Monitoring, Ambulatory,' and several terms for micro- and macrovascular complications. Further description of the employed strategy is described in the Appendix A.

We excluded articles that did not describe the type of diabetes, included people with T2DM, did not include ABPM, and/or adopted a cross-sectional design. There were no language restrictions.

Moreover, references from included articles were manually searched.

The authors of unavailable articles and those with partially available data were contacted.

2.2. Data extraction

Literature searches were performed by two independent reviewers (MCH, EFP). Data extraction into standardized Excel tables was also performed by two independent reviewers (MCH, VHL). Disagreements were solved by a third reviewer (TCR).

Corresponding authors of studies with unavailable data were emailed.

ABPM devices included the portable oscillometric recorder Spacelabs 90,202 (Poulsen) [10], Spacelabs 90,207 (Lovshin, Lurbe, Mateo-Gavira, Rodrigues) [11–14], 02 Meditech (Lengyel) [15], and Novacor DiaSys Integra II (Marcovecchio) [16]. During the day, BP measurements were obtained automatically at intervals of 15 min (Lengyel, Rodrigues) [14,15], 20 min (Poulsen, Lurbe, Mateo-Gavira, Lovshin) [10,13,14], and 30 min (Marcovecchio) [16]. During the night, BP measurements were obtained every 30 min (Lurbe, Lengyel, Mateo-Gavira, Rodrigues) [12–15], 50 min (Lovshin) [11], and one hour (Marcovecchio, Poulsen) [10,16].

Glomerular filtration rate (GFR) was measured using the single injection technique of 51Cr-labeled EDTA (Rodrigues) [14], using the Cockcroft–Gault formula (Mateo-Gavira) [13], or from cystatin C measurements, following Larsson and colleagues equations (Lovshin) [11]. Serum creatinine was measured by the Jaffe kinetic reaction (Lengyel) [15]. In total, three studies did not present data on creatinine or GFR (Lurbe, Marcovecchio and Poulsen) [10,12,16].

Urinary albumin excretion (UAE) was expressed as geometric mean of three overnight samples collected within a week (Poulsen) [10], three 24-hour urine samples (Lengyel, Mateo-Gavira) [13,15], and two 24-hour urine samples (Lurbe) [12]. Urinary albumin/creatinine ratio (ACR) was calculated from spot urine samples and evaluated by radioimmunoassay in a study (Lovhsin) [11] and from three morning urine samples using the double antibody ELISA method (Marcovecchio) [16]. Only one study used the 24-hour urinary albumin excretion rate by immunoturbidimetry (Rodrigues) [14]. To measure UAE, Poulsen and Lengyel [10,15] used a radioimmunoassay, Mateo-Gavira [13] used an immunoturbidometric assay, and Lurbe [12] used a nephelometric assay. In all studies, patients were normoalbuminuric in the initial assessment, with progressors being defined as those who presented, in the follow-up, UAE $>$ 20 mcg/min (Poulsen) [10], $>$30 mg/24 h confirmed in two measurements (Lurbe, Lengyel, Mateo- Gavira) [12,13,15], and ACR $>$ 30 mg/g in men and $>$ 35.4 mg/g in women (equivalent to an overnight albumin excretion rate of 20–200 mcg/min) (Marcovecchio) [16]. Lovshin [11] defined as progressors people with T1DM who presented hyperfiltration at the end of follow-up, defined as GFR $>$ 133 ml/min/1.73 m^2.

The presence of diabetic retinopathy (DR) was evaluated and classified by the same ophthalmologist using direct and indirect ophthalmoscopy after mydriasis (Rodrigues) [14] and TopCon camera without mydriasis (Mateo-Gavira) [13]. People with T1DM who presented the onset of DR or progressed in the classification stage from their baseline were considered to be Progressors.

2.3. Quality of studies

The quality of included studies was assessed by two independent reviewers (MCH, VHL) using the validated Newcastle-Ottawa scale assessment for risk of bias between reviewers and authors of cohort studies (Appendix B).

2.4. Statistical analysis

Statistical analysis was performed with the R Studio software version 2023.06.0 with the "meta," "readxl," and "metafor" packages. Results were expressed as difference measurement (MD) in mmHg.

Heterogeneity between studies was determined by the I square test (I^2).

Random effects models were used for *meta*-analyses.

3. Results

We found 364 articles (Embase: 187, Lilacs: 3, PubMed: 111, Web of Science: 63), 49 of which were duplicates. After analyzing titles and abstracts, 24 articles remained for complete reading. Of these, six met the inclusion criteria. Then, one more article was found by manual search in the references of those included (Fig. 1). Therefore, we included seven studies, comprising 635 participants, mean age of 25.8 $\pm$ 6.2 years, 57.5 % men, mean diabetes duration of 11.8 $\pm$ 5.3 years, mean glycated hemoglobin (HbA1c) of 8.5 % $\pm$ 1.6 %, and mean follow-up time of 4.2 years. Table 1 contains the main information about the included articles and the results are presented graphically.

No studies were found evaluating macrovascular outcomes or neuropathy.

Fig. 2 describes the *meta*-analysis for the albuminuria outcome in relation to daytime systolic and diastolic BP levels. Non-progressor people with T1DM had almost 2 mmHg lower BP levels compared to Progressors (Fig. 2A), which is not a significant difference. Similar results were observed for daytime diastolic BP levels and albuminuria (Fig. 2B).

Lower nocturnal BP means were associated with a lower incidence of nephropathy: nocturnal systolic BP, with MD − 4.37 mmHg (95 %CI − 6.96; −1.79, p = 0.0009, I^2 30 %) and nocturnal diastolic BP, with MD − 3.97 mmHg (95 %CI − 5.85; −2.10, p $<$ 0.0001, I^2 0 %) (Fig. 3A and 3B respectively).

Both nocturnal systolic BP (MD − 3.36 mmHg [95 %CI − 6.71; −0.02, p = 0.049, I^2 63 %]) and nocturnal diastolic BP (MD − 2.88 mmHg [95 %CI − 5.23; −0.25, p = 0.0168, I^2 57 %]) remained significantly protective, but with high heterogeneity, when we added the

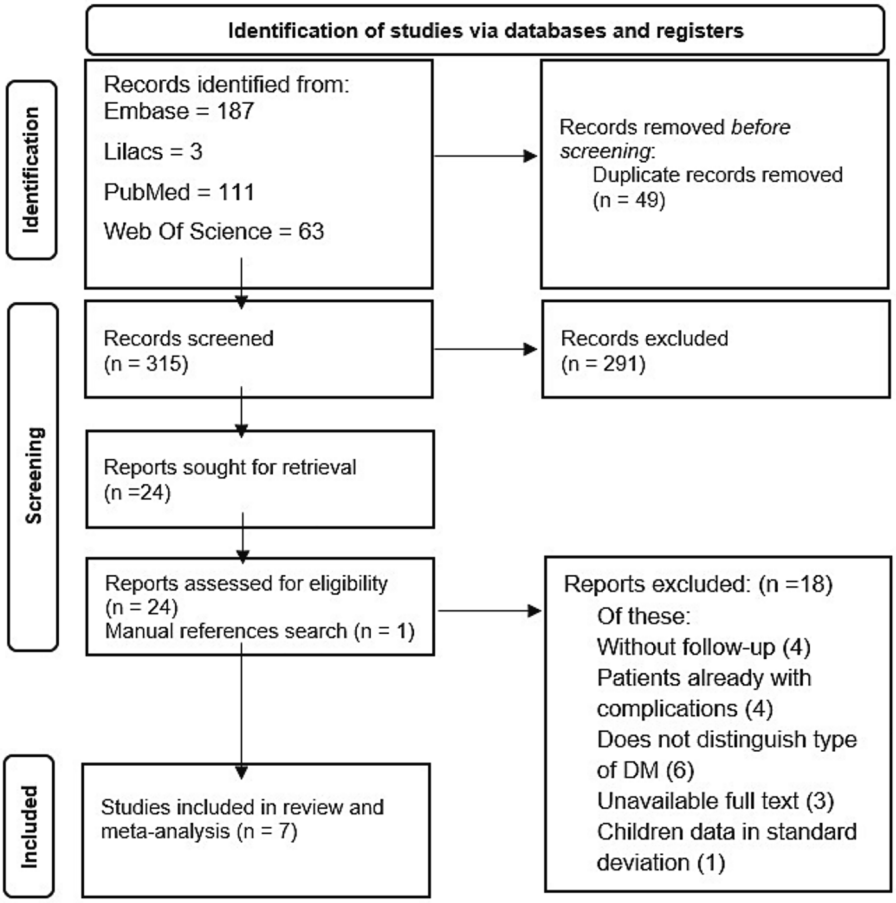

Fig. 1. Flow diagram of the search process and study selection.

Table 1
Characteristics of studies included in the *meta*-analysis.

Study	Year	N	Age	Men%	T1DM duration (years)	HbA1c%	GFR	Follow-up (years)
Poulsen	1994	44	33.9 (8)	68.8	19.75 (6.6)	8.6 (1.5)	NI	3
Lurbe	2002	75	19.75 (7.1)	65.7	10.4 (2)	9.9 (1.6)	NI	5
Lengyel	2003	83	37.4 (10.7)	71.2	17.1 (9.8)	8.6 (2)	NI	5
Rodrigues	2006	44	33.43 (7.44)	47.4	10.36 (6.3)	6.6 (1.8)	125.30 (22.9)	6
Marcovecchio	2009	250	15.3 (2)	56.8	6.2 (3.6)	9 (1.5)	NI	2
Mateo-Gavira	2016	85	27.9 (6.1)	38	12.3 (6.5)	7.9 (1.1)	123.8 (25.4)	7
Lovshin	2017	98	13.3 (2.1)	55	6.8 (2.7)	8.6 (1.3)	125 (23)	2
TOTAL		679	25.85 (3.2)	57.5	11.84 (5.3)	8.4 (1.5)	124.7 (23.8)	4.2

NI: not informed.

study that evaluated hyperfiltration (Lovshin) to the analysis of renal progression [11]. Daytime BP was not associated with renal outcomes.

When we excluded the study with HbA1c < 8 % (Mateo-Gavira) from the analysis of renal progression, the results were maintained, with nocturnal systolic BP (MD − 3.23 mmHg [95 %CI − 5.98; −0.48, p = 0.0212]) and nocturnal diastolic BP (MD − 3.61 mmHg [95 %CI − 5.61; −1.61, p = 0.0004]) significantly protective. [13].

Regarding the emergence or progression of retinopathy, we observed that people with T1DM who did not progress were those who had lower levels of nocturnal diastolic BP (MD − 3.62 mmHg [95 %CI − 7.18; −0.06, p = 0.042, I^2 0 %]) (Fig. 4A), daytime diastolic BP (MD −2.69 mmHg [95 %CI − 4.84; −0.55, p = 0.0138, I^2 0 %]) (Fig. 4B), and 24 h diastolic BP (MD − 3.65 mmHg [95 %CI − 6.56; −0.75, p = 0.037, I^2 0 %]) (Fig. 4C)—all of them without heterogeneity. Systolic BP was not associated with progression of retinopathy.

Better glycemic control was associated with protection against the development of albuminuria HbA1c (MD − 0.99 % [95 %CI − 1.48; −0.55, p < 0.0001, I^2 0 %]) and protection against the development or progression of retinopathy (MD − 2.36 % [95CI − 1.11; −0.25, p = 0.018, I^2 0 %]).

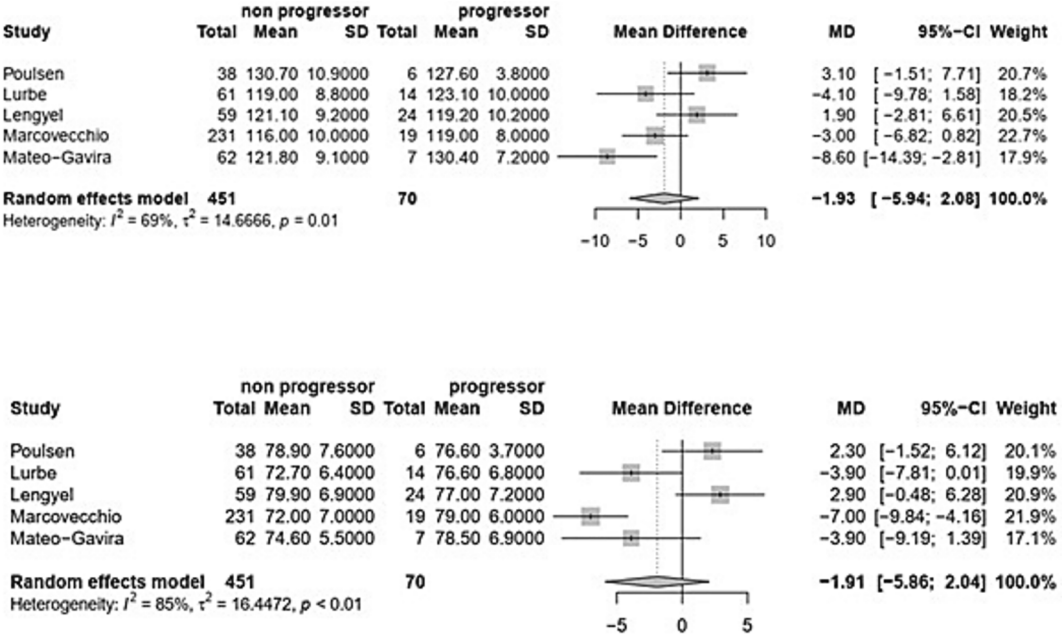

Fig. 2. Forest plot-albuminuria and diumal systolic blood pressure (2ª) and diumal diastolic blood pressure(2B).

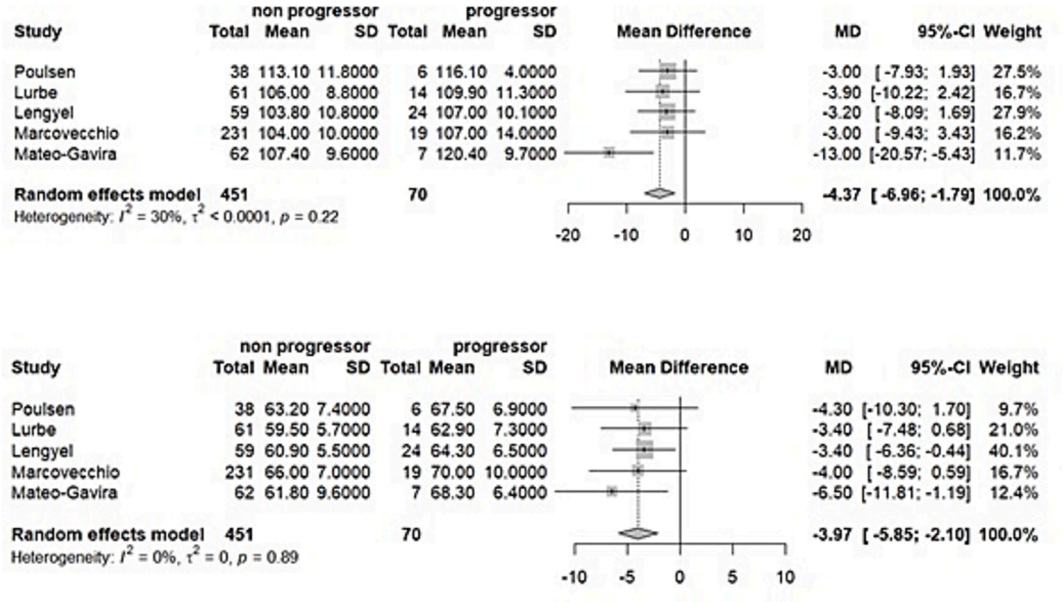

Fig. 3. Forest plot – Albuminuria and noctunal systolic BP(3ª) and nocturnal diastolic BP(3B).

No significant differences were found regarding T1DM duration and patient's age.

4. Discussion

In this systematic review with *meta*-analysis, we evaluated the mean differences in BP parameters, as measured by ABPM, between people with T1DM and normal BP who did and did not progress to microvascular complications. Increased nocturnal systolic and diastolic BP were associated with the emergence of albuminuria. Meanwhile, for retinopathy, only diastolic pressure measurements were predictors. We found no studies about neuropathy or cardiovascular outcomes.

Elevations of nocturnal systolic and diastolic BP have already been associated with the emergence of albuminuria in people with T1DM who are still normotensive in office evaluations. [12,13,15,17] Our data agree with the literature, but they are the product of prospective studies with follow-up of up to seven years. A cross-sectional study with 60 adolescents with T1DM identified significantly higher nocturnal systolic BP in those with increased albuminuria compared to normoalbuminuric individuals. [18] Nocturnal BP elevations have already been related to incipient glomerular changes in people with T1DM. [19].

In a prospective study with people with T1DM and normal BP who underwent ABPM at baseline and after seven years, there was a relationship between nocturnal systolic BP and the development of albuminuria. [13] A national database multicenter study in Germany and Austria with 2,150 children and adolescents showed a prevalence of 6.1 % persistent albuminuria, and this was significantly associated with higher levels of nocturnal diastolic BP. [17] Nocturnal BP elevations, even within the normal range, appear to be associated with a greater risk of developing nephropathy. [18] A Brazilian case-control study with

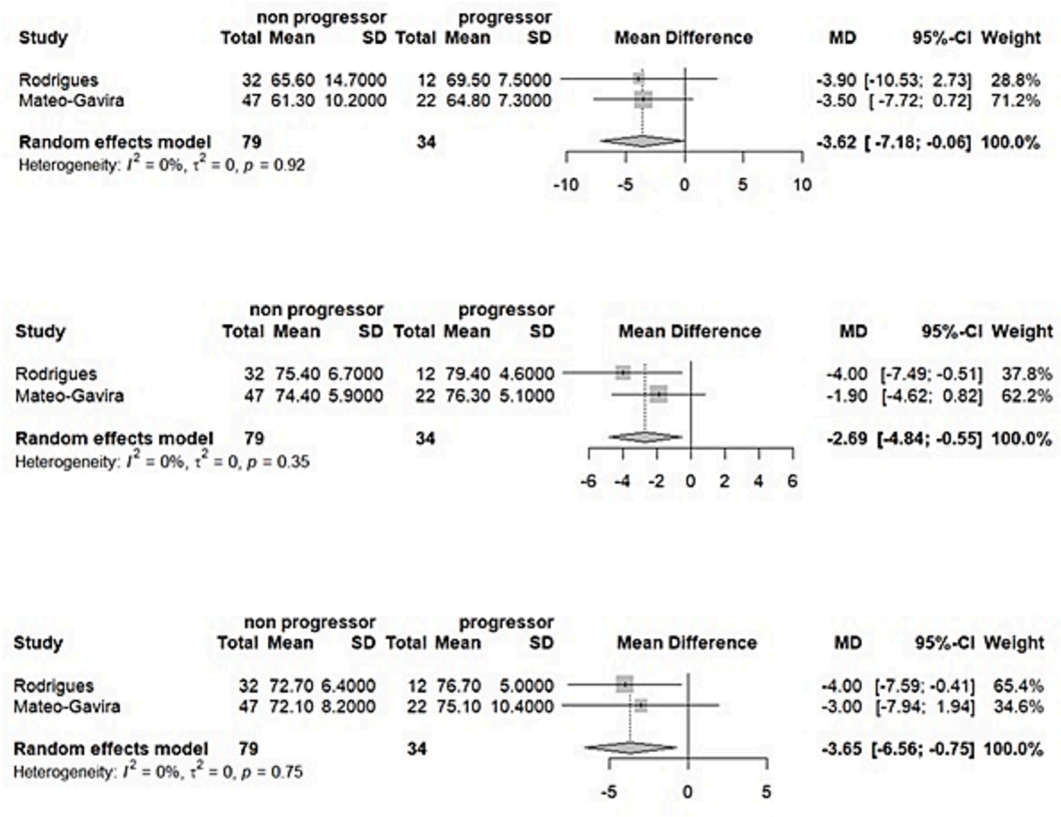

Fig. 4. Forest Plot – Retinopathy and nocturnal diastolic BP(4a), diurnal diastolic BP(4b) and 24 h diastolic BP(4C).

normotensive and normoalbuminuric people with T1DM and normotensive controls without diabetes showed higher nocturnal systolic and diastolic BP in people with T1DM, matched for gender and age. [20].

We did not find an association between daytime BP measurements and albuminuria, unlike previous studies. This may be due to the fact that we only included people with normal BP in office measurements. A cross-sectional study that evaluated 150 people with T1DM found a correlation between AUE and ABPM parameters, including 24-hour systolic and diastolic BP averages, as well as the percentage of systolic measurements > 140 mmHg and diastolic measurements ≥ 90 mmHg. [21].

When hyperfiltration was included in the analysis of renal outcomes, added to studies evaluating albuminuria, both nocturnal diastolic and nocturnal systolic BP remained significantly associated with kidney disease progression. A controlled cross-sectional study with normotensive and normoalbuminuric people with T1DM found an association between higher nocturnal diastolic BP and glomerular hyperfiltration. [22] We highlight that hyperfiltration would be an early phase of diabetic kidney disease, which precedes glomerular damage and albuminuria.

Albuminuria is caused by increased glomerular permeability and/or reduced reabsorption in the proximal convoluted tubules. [18] Its early identification can save the patient from loss of kidney function and the need for renal replacement therapy. A follow-up study of the DCCT/EDIC cohort found an association between systolic BP of 120 mmHg and reduced risk of albuminuria and incidence of diabetes kidney disease (DKD) at stage 3, compared with systolic BP in the range of 130 to 140 mmHg in office measurements. [23] Therefore, identifying people at risk of developing albuminuria allows intensifying the control of risk factors, the frequency of monitoring, and even the early introduction of nephroprotective therapies.

Regarding the emergence of retinopathy, we found an association only between elevations in diastolic BP, at day and night and within 24 h. This finding corroborates the 30-year follow-up cohort of the DCCT/EDIC, which identified higher mean diastolic BP as a risk factor for retinopathy and clinically significant macular edema. [19] Another cross-sectional study by our group found a prevalence of 23.3 % of nocturnal hypertension in normotensive people with T1DM, and this change was associated with retinopathy. [14] In a Spanish cohort with seven years of follow-up, nocturnal diastolic pressure was also associated with progression of retinopathy. [18].

In the presence of hyperglycemia, the autoregulatory adaptation of retinal vessels is inhibited. High BP increases intraluminal pressure, increasing capillary leakage and favoring the filtration of plasma proteins via the endothelium, causing retinal ischemia. [6,24] This could explain our finding that even small differences in diastolic BP in individuals with normal BP could translate into an increased risk of the onset or progression of retinopathy.

Although the relationship between BP elevation and mortality in people with T1DM is well established, we did not find cohort studies performing ABPM in normotensive patients with sufficient follow-up for macrovascular outcomes. Some studies have demonstrated an association between nocturnal hypertension and thickening of the carotid intima-media layer in children with T1DM and normal BP. [25,26] Recently, a prospective cohort of 654 persons with T1DM from the Steno Diabetes Center Copenhagen who underwent ABPM found an association between a 10 mmHg increase in nocturnal systolic BP and a pattern of non-dipping with all-cause mortality, a drop in GFR ≥ 30 %, end-stage renal disease, and composite renal outcome (all-cause mortality, decline in GFR ≥ 30 %, and/or end-stage renal disease). However, 19 % of patients already had previous cardiovascular disease and 24 % had office BP > 140/90 mmHg [27]. Therefore, this ABPM was a treatment evaluation for many persons who were either hypertensive or already had previous macrovascular disease. This study was not included in our analysis since it used a tonometric device similar to a wristwatch, different from the traditional ABPM of the other studies included here,

in addition to having included hypertensive people and people with vascular disease.

ABPM is the gold standard for diagnosing hypertension and assessing 24-hour BP, being superior to office measurements for predicting cardiovascular mortality. [28,29] However, there is no consensus on the definition of normal ABPM values in individuals with T1DM. [30] A Swedish population-based cohort study that followed 36,303 people with T1DM for 3.3 years found lower adjusted mortality rates in people with diastolic BP from 60 to 69 mmHg and systolic BP from 130 to 139 mmHg. [31] Except for the International Society for Pediatric and Adolescent Diabetes, which recommends the use of ABPM to diagnose hypertension in children with diabetes, no other organization recommends routine use of the device in people with T1DM. [32] Unfortunately, there is a lack of clinical trials to define diagnostic values and therapeutic BP targets that are more appropriate for people with T1DM.

As expected, worse glycemic control was associated with the emergence of microvascular complications. [33–35].

The findings of our *meta*-analysis are in line with previous observational studies. [17,18,20,22,23,36,37] However, we found few studies monitoring people with T1DM after performing ABPM and subsequent evaluation of complications. Furthermore, studies usually present a limited number of participants. As patient follow-up times varied between studies, we were unable to define the progression time of complications. Only three studies reported the prevalence of non-dippers in their populations. [11,13,16] No data regarding postural hypotension were reported. Surprisingly, three studies did not report creatinine or GFR, but all reported absence of renal disease at initial assessment.

We identified only two studies evaluating DR and different methods were used for measurement: Rodrigues [14] performed direct and indirect ophthalmoscopy after mydriasis and Mateo-Gavira [13] used a TopCon camera without mydriasis.

As one of the strengths of our study, we highlight the prospective nature of the included studies and the finding of ABPM parameters related to the development of nephropathy and the onset/progression of retinopathy in people with T1DM who are still normotensive. Additionally, the heterogeneity of our findings was low, contrary to what is expected in meta-analyses of observational studies.

All 24-h ABPM devices used in studies are validated, except for the Novacor DiaSys Integra II, which we did not find a validation study. Only three different brands of monitors were used, with similar protocols, except Marcovecchio who used higher intervals of measurement. In addition, the intervals of measurement were all within what is advocated by the last guideline of the European Society of Cardiology. [38].

Indications for performing ABPM include assessments of white coat hypertension, masked hypertension, treatment in people using antihypertensives, abnormal 24-hour BP pattern (daytime, postprandial, nocturnal hypertension, and nocturnal drop), and resistant hypertension. [39] The AHA includes diabetes mellitus as a risk factor for masked hypertension and suspected nocturnal hypertension. [5].

5. Conclusion

Even small mean differences in BP parameters assessed in ABPM between people with T1DM and normal BP who have and have not progressed to microvascular complications are associated with a lower incidence or lower risk of progression of these complications.

More quality studies are needed to determine BP cutoff points that can support clinical practice and ABPM recommendations in this population.

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CRediT authorship contribution statement

Mariana Costa Hoffmeister: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Vinicius Hammel Lovison:** Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Methodology, Investigation, Formal analysis, Data curation. **Eduardo Priesnitz Friedrich:** Writing – original draft, Software, Resources, Methodology, Investigation, Formal analysis, Data curation. **Ticiana da Costa Rodrigues:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2024.111873.

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