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Estimating the True Prevalence of Diabetes in Patients with Stroke

Leonora Kona [1,*], Eleftherios Meletis [1], Georgios Mavraganis [2], Georgios Georgiopoulos [2,3,4,5], Olympia Lioupi [1], Evangelia Anifanti [1], Polychronis Kostoulas [1,†] and Konstantinos Pateras [1,†]

[1] Laboratory of Epidemiology, Applied Artificial Intelligence & Biostatistics, Faculty of Public and One Health, University of Thessaly, 431 00 Karditsa, Greece
[2] Department of Clinical Therapeutics, National and Kapodistrian University of Athens, 157 72 Athens, Greece
[3] Department of Physiology, School of Medicine, University of Patras, 265 04 Patras, Greece
[4] Institute of Cardiovascular Sciences, University College London (UCL), London WC1E 6BT, UK
[5] School of Biomedical Engineering and Imaging Sciences, St Thomas Hospital, King's College London, London WC2R 2LS, UK
* Correspondence: leonorakona@gmail.com
† These authors contributed equally to this work.

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Abstract: Aims: This study aims to investigate challenges associated with diabetes prevalence estimates in stroke survivors, focusing on the issue of misclassification bias in diagnostic tests, and to propose measures for improving the accuracy of these estimates. Methods: The study examines the inherent misclassification biases associated with the diagnostic tests, including Fasting Blood Glucose (FBG), Oral Glucose Tolerance Test (OGTT), and Hemoglobin A1c (HbA1c), commonly used to identify diabetes in stroke survivors. To address misclassification biases, three parameter Bayesian latent class models are applied to delineate true prevalence from the apparent prevalence reported in studies, using FBG, OGTT, HbA1c as standard diagnostic tests for diabetes. Results: The results revealed discrepancies between apparent and true prevalence of diabetes in stroke patients, highlighting the influence of the sensitivity and specificity of each diagnostic test on prevalence estimates. Conclusions: Correcting misclassification biases in diabetes diagnostic tests is crucial for accurate prevalence estimates in stroke survivors, which is necessary for proper diagnosis and patient care. The study underscores the need for future research to address data biases and uncertainties in diagnostic test measures, which will optimize the accuracy of diabetes diagnosis in this vulnerable population.

Keywords: diabetes; stroke; apparent prevalence; true prevalence; diagnostic test

1. Introduction

Stroke is defined as rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 h or longer, or leading to death, with no apparent cause other than of vascular origin [1]. In 2021, the number of new stroke cases worldwide increased to 11.9 million, representing a 70% rise since 1990, while the number of stroke survivors reached 93.8 million (an 86% increase). Stroke-related deaths also rose to 7.3 million (a 44% increase), making stroke the third leading cause of death globally, following ischaemic heart disease and COVID-19 [2]. There are two categories of stroke: (I) ischaemic and (II) haemorrhagic. Ischaemic stroke accounts for 80% of stroke cases and is caused by a blood clot blocking a blood vessel, which prevents blood flow to the brain. Haemorrhagic stroke accounts for 20% of strokes and is caused by a ruptured brain vessel [1]. When a vessel ruptures, blood flows through it, resulting in the interruption of blood supply to the brain tissue [3].

Diabetes mellitus is a prevalent health complication with significant social, public health and economic ramifications that increases the risk of stroke [4]. According to World Health Organization, diabetes affects 422 million people worldwide and is directly responsible for 1.5 million deaths per year. Diabetes is the leading cause of kidney failure, heart attacks, strokes, lower limb amputation and blindness [5]. Centers for Disease Control and Prevention reports state that screening for diabetes mellitus can be performed through a two-hour oral glucose tolerance test (OGTT) (≥200 mg/dl indicates diabetes), a hemoglobin A1c test (HbA1c) (≥6.5% [48 mmol/mol] indicates diabetes), a fasting plasma glucose test (FBG) (≥126 mg/dl indicates diabetes) or a random blood glucose test (≥200 mg/dl indicates diabetes) [6]. Several mechanisms associated with diabetes may also lead to stroke, including large artery atherosclerosis, cerebral small vessel disease, and cardiac embolism [7]. People with diabetes have a 1.5–2 times higher risk of stroke compared to people without diabetes, with risk increasing with diabetes duration [7]. Hyperglycemia is a significant risk factor for poor outcomes following stroke [8], which can result in higher mortality, worse neurological and functional results, longer hospital stay, higher readmission rates, and a higher risk of stroke recurrence [9]. A meta-analysis of 39 cohort studies found that the prevalence of diabetes in all stroke patients was 28% (95% CI 26–31) and higher in patients with ischaemic stroke (33%, 95% CI 28–38), in comparison to patients experiencing haemorrhagic stroke (26%, 95% CI 19–33) [9]. Taking into consideration the aforementioned associations, secondary stroke prevention guidelines recommend screening for diabetes following a stroke [10].

Prevalence is frequently utilized for chronic illnesses, like diabetes, that have a lengthy duration and an ambiguous beginning date [11]. The prevalence estimates of diabetes and stroke disease vary, mainly attributed to the method of diagnosis of diabetes, stroke disease, or the type of prevalence estimate undertaken [12]. As expected, diagnostic tests are inherently imperfect, meaning that they may yield false-positive and false-negative results, thereby leading to a biased estimation of prevalence (Apparent Prevalence), which deviates from the true population value (True Prevalence). The results of a prevalence study are often overestimates or underestimates of the true disease prevalence, depending on the sensitivity and specificity of the imperfect diagnostic test used in a particular prevalence study [13]. The latter raises challenges as the imperfect sensitivity and specificity can lead to biased prevalence estimates, thereby influencing healthcare decisions and resource allocation.

Misclassification bias is a type of systematic error that occurs during the diagnostic process. It appears when someone is placed in a different category than the one in which they belong [14]. Misclassification bias can further contribute to inaccurate and biased estimates of disease prevalence. Despite its significance, misclassification bias in the prevalence of diabetes in stroke patients is indirectly present in studies and is not explicitly mentioned [15]. Additionally, while numerous studies examine the relationship between stroke and diabetes, diagnostic inaccuracies may distort the true prevalence of diabetes and its association with stroke outcomes [9].

In light of these research gaps, this study serves as a guide to estimating the true prevalence of diabetes in stroke patients using a Bayesian model that addresses misclassification bias. Specifically, it employs a statistical model that differentiates between apparent and true prevalence. The findings highlight broader implications for disease prevalence estimation.

2. **Material and Methods**

2.1. Study Selection

A scoping literature search was conducted using PubMed to identify articles on the prevalence of diabetes after stroke. The subject heading used to search and identify articles was: “prevalence” and “diabetes” and “stroke”. The article by Lau L et al. [9] was selected from this search. The article was chosen based on the following criteria: (a) it presents a meta-analysis consisting of several studies to find the prevalence of diabetes in people with stroke, (b) it consists of a wide variety of diagnostic tests. In particular, the thirty-nine studies selected for the meta-analysis included a clear definition of the diagnosis of diabetes, based on patient history, use of antidiabetic medications or biochemical diagnostic tests (OGTT, HbA1c, FBG or random plasma glucose test). Also, in the context of the selected article, a second meta-analysis of the prevalence of diabetes in people with stroke was performed in studies using only HbA1c as a diagnostic test for diabetes. This study will act as the pool to select candidate studies for misclassification bias correction within this manuscript.

Statistical analysis to estimate the true prevalence was performed in fifteen of the thirty-nine studies, containing the minimal information that allows the estimation of the true prevalence (Table 1). Specifically, two analyses were performed. In the first analysis, the true prevalence was estimated in studies that used only HbA1c as a diagnostic test for diabetes. In the second analysis, the true prevalence was estimated in studies that used OGTT and FBG diagnostic tests (Figures 1 and 2). The data collected from these studies are as follows: type of stroke, y (positives), n (sample size), reported apparent prevalence in the study, diagnostic test, sensitivity,

specificity, 95% confidence interval (CI) for sensitivity and specificity of each diagnostic test separately, based on which the parameters of the Beta prior distributions for sensitivity and specificity were then calculated (Table 1).

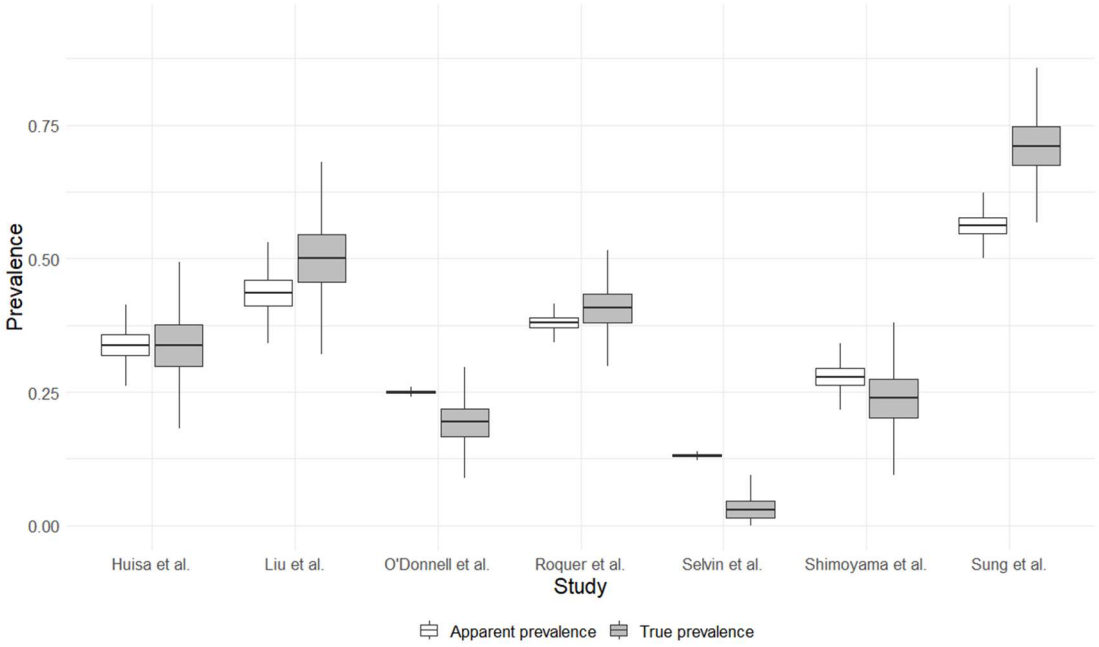

Figure 1. Box-plots showing the posterior prevalence of each study, of the meta-analysis by Lau L et al. [9], using HbA1c as the diagnostic test.

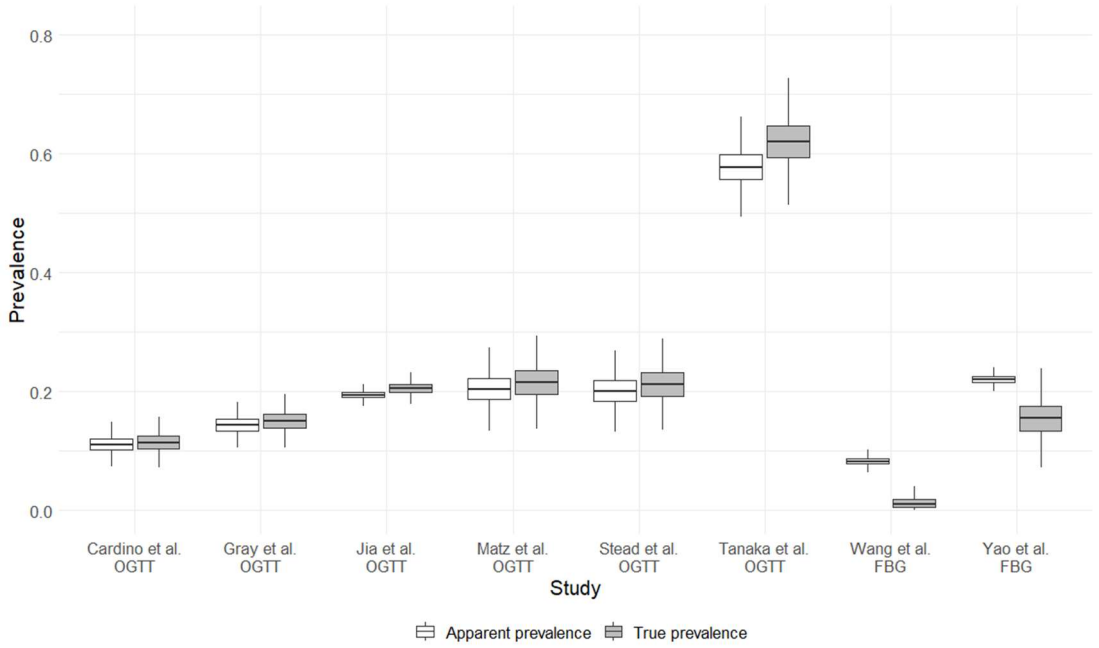

Figure 2. Box-plots with the posterior prevalence of each study, of the Lau L et al. [9] meta-analysis, using OGTT and FBG as the diagnostic tests.

2.2. Estimation of Apparent and True Prevalence

Models for both apparent and true prevalence were applied using JAGS—Just Another Gibbs Sampler [16]. Model specification to determine apparent prevalence involves: y individuals with a positive test in a sample of n randomly selected individuals of a single population. The y follows an approximate binomial distribution, where Ap is the apparent prevalence that is modelled using a prior Beta: Ap ~ Beta (a_{Ap}, b_{Ap}), where a_{Ap}, b_{Ap} are the parameters of the prior distribution Beta for Ap [17].

$$y \sim \text{Binomial}(Ap, n) \quad \text{(Model 1)}$$

The posterior distribution of the above model can be calculated analytically via Beta ($y + a_{Ap}$, $n - y + b_{Ap}$), where $y + a_{Ap}$ and $n - y + b_{Ap}$ are the parameters of the Beta posterior [16]. The lack of prior knowledge of the prevalence can be expressed by setting $a_{Ap} = b_{Ap} = 1$, a low-informative prior that is equivalent to the Uniform (0–1) distribution.

The apparent prevalence, with the sensitivity (Se) and specificity (Sp) of each test, could be used to approximate the true prevalence (Tp) [13]. The relationship between apparent and true prevalence of the disease is well known and is given by the equation:

$$Ap = Tp \times Se + (1 - Tp) \times (1 - Sp) \quad (1)$$

Therefore, in model 1, replacing Ap with Equation (1), gives:

$$y \sim \text{Binomial}(Tp \times Se + (1 - Tp) \times (1 - Sp), n) \quad \text{(Model 2)}$$

$$Tp \sim \text{Beta}(a_{Tp}, b_{Tp})$$

$$Se \sim \text{Beta}(a_{Se}, b_{Se})$$

$$Sp \sim \text{Beta}(a_{Sp}, b_{Sp})$$

where α_{Tp}, b_{Tp}, α_{Se}, b_{Se}, α_{Sp}, b_{Sp} are the parameters of the Beta prior distributions for Tp, Se, and Sp, respectively [17]. The parameters of interest are three (Tp, Se, Sp). In each application of the model to calculate Tp, we have one degree of freedom for each test separately. If the degrees of freedom of each test are too low, relative to the number of parameters, then the ability of the model to estimate the parameters is limited. Consequently, the model is not identifiable.

The lack of prior knowledge about the true prevalence can be expressed via a uniform shaped prior, thus we assume a low-informative Beta distribution for the main parameter of interest, the true prevalence. The hyperparameters of the Beta prior distributions for sensitivity and specificity should be placed informative value to avoid the model becoming non-identifiable. Thus, we can calculate parameters (α_{Se}, b_{Se}, α_{Sp} and b_{Sp}), based on available prior information and the use of the "PriorGen" package [18] of the statistical software R 4.1.1. "PriorGen" converts prior information into prior parameters for Beta distributions of the sensitivity and specificity of diagnostic tests. As a next step, sensitivity and specificity parameters are estimated for each test separately, based on the collected data of each diagnosis. Finally, Bayesian analysis provides a posterior distribution for the outcome of interest, the true prevalence.

For some diagnostic tests, such as the OGTT, no related evidence was found regarding the CI of sensitivity and specificity. Therefore, the calculation of the CI for sensitivity and specificity was performed, based on the formulas of Berkman ND et al. [19]. More specifically, the 95% CIs for sensitivity and specificity were calculated as:

$$95\%\ \text{confidence interval} = \text{sensitivity} \pm 1.96 \times \sqrt{\frac{\text{sensitivity} - (1 - \text{sensitivity})}{\text{n sensitivity}}} \quad (2)$$

$$95\%\ \text{confidence interval} = \text{specificity} \pm 1.96 \times \sqrt{\frac{\text{specificity} - (1 - \text{specificity})}{\text{n specificity}}} \quad (3)$$

where n sensitivity is the positive individuals of each diagnostic i.e., true positive and false negative (TP + FN), and n specificity is the negative individuals of each diagnostic i.e., true negative and false positive (TN + FP). We further expressed our prior ignorance of the uncertainty around estimates by increasing the CIs by 5%.

Table 1. Data collection from the 15 studies in the Lau L et al. [9]. All the studies can be found in the Supplementary Materials.

Study	Year	Type of Stroke	y/n	Reported Apparent Prevalence in the Study	Diagnostic Test	Se	Sp	95% CI (Se)	95% CI (Sp)	a (Se)	b (Se)	a (Sp)	b (Sp)
Shimoyama et al.	2014	Ischaemic	104/375	0.277	HbA1c	73.9%	87.2%	67.5–79.6%	81.5–91.5%	159.7	57.4	127.9	19.9
Huisa et al.	2013	Ischaemic	94 */279	0.34									
Roquer et al.	2015	Ischaemic	500 */1317	0.38 **									
Sung et al.	2017	Ischaemic	272/484	0.562									

O'Donnell et al.	2016	Both	3361 */13,447	0.25 **
Liu et al.	2015	Both	87/200	0.43
Selvin et al.	2005	Ischaemic	1635/12,521	0.13

Table 1. *Cont.*

Study	Year	Type of Stroke	y/n	Reported Apparent Prevalence in the Study	Diagnostic Test	Se	Sp	95% CI (Se)	95% CI (Sp)	a (Se)	b (Se)	a (Sp)	b (Sp)
Yao et al.	2016	Ischaemic	629/2862	0.22 **	FBG	82.3%	89.4%	74.1–88.6%	84.7–93%	101.7	23.3	160.6	20.1
Wang et al.	2015	Haemorrhagic	118/1438	0.082									
Tanaka et al.	2013	Ischaemic	140/242	0.52 **	OGTT	93%	100%	86–99.9%	99–100%	65.9	5	1072.8	5.3
Jia et al.	2012	Both	669 */3450	0.194									
Matz et al.	2006	Both	48/238	0.202									
Gray et al.	2004	Both	83/582	0.14									
Cardino et al.	2011	Both	55 */504	0.1132									
Stead et al.	2010	Haemorrhagic	47/237	0.198									

* y (Positives) was calculated based on the Prevalence in Meta-Analysis study and n (Total); ** Calculated based on y * (Positives) and n (Total); Se (Sensitivity), Sp (Specificity), CI (Confidence Interval); aSe, bSe, aSp, bSp are parameters of the Beta prior distributions for Se and Sp; HbA1c, FBG, OGTT data for Se, Sp, 95% CI (Se, Sp) were based on Kaur G et al. [20] and Aekplakorn et al. [21]; The study by Kaur G et al. [20] used the 75-g OGTT as the gold standard for diabetes diagnosis (HbA1c, FBG). The study by Aekplakorn et al. [21] evaluated the FPG and the 2-h postprandial OGTT but did not explicitly mention a "gold standard" for diagnosis in their study (OGTT).

3. Results

The data from fifteen studies collected are presented in detail in Table 1. Specifically, the seven studies using only HbA1c as a diagnostic test for diabetes mellitus in patients with stroke, consisted of five studies including only ischaemic stroke and two studies including both ischaemic and haemorrhagic stroke. Studies using FBG as a diagnostic test for diabetes mellitus consist of one study, involving only ischaemic stroke and one study, involving only haemorrhagic stroke. In addition, the studies using the OGTT as a diagnostic test for diabetes mellitus consist of four studies including both ischaemic and haemorrhagic stroke, one study including only ischaemic stroke, and one study including only haemorrhagic stroke.

The posterior distributions of the apparent and true prevalence of diabetes in people with stroke, using only HbA1c as a diagnostic test for diabetes are shown in Figure 1. In Figure 1, seven studies are presented, where the true prevalence may be higher than the apparent prevalence and vice versa. More specifically, in the study by Liu et al., the apparent prevalence is 43.6% (95% Credible Interval (CrI) 36.8–50.4%), while the true prevalence is 50.2% (95% CrI 37–63.6%). Furthermore, in the study by Sung et al., the apparent prevalence is 56.2% (95% CrI 51.8–60.5%), while the true prevalence is much higher. The same is the case with the study by Roquer et al., where the apparent prevalence is about 38% (95% CrI 35.3–40.5%), while the true prevalence is slightly higher. In contrast, in the studies by Shimoyama et al., O'Donnell et al. and Selvin et al., the apparent prevalence is higher than the true prevalence. Finally, in the study by Huisa et al., the apparent prevalence is equal to the true prevalence. A value for apparent prevalence is close to 33% (95% CrI 28.4–39.3%) and for true prevalence is close to 33% (95% CrI 22.5–45.5%).

Figure 2 shows the posterior distributions of the apparent and true prevalence of diabetes in stroke patients using OGTT and FBG as diagnostic tests. In Figure 2, eight studies are presented where the true prevalence deviates from the apparent prevalence. More specifically, in studies using the OGTT as a diagnostic test, the true prevalence is higher than the apparent prevalence. For example, in the study by Tanaka et al., the apparent prevalence is less than 57.9% (95% CrI 51.8–63.9%), while the true prevalence is about 62% (95% CrI 53.9–69.8%). In the study by Cardino et al., the apparent prevalence is about 11% (95% CrI 8.5–13.8%), while the true prevalence is slightly higher, with a value close to 11.4% (95% CrI 8.5–14.5%) (Figure 2). On the other hand, in studies where FBG is used as a diagnostic test, the true prevalence is lower than the apparent prevalence. For example, in the study by Yao et al., apparent prevalence reaches 22% (95% CrI 20.5–23.5%), while the true prevalence is 15.3% (95% CrI 8.8–21.3%). In the study of Wang et al., the apparent prevalence is 8.3% (95% CrI 6.8–9.7%), while the true prevalence is even lower (Figure 2).

4. Discussion

The results of this study demonstrate that apparent prevalence results can often be biased estimates of the true prevalence of diabetes in stroke patients. If the sensitivity and specificity of the corresponding diagnostic test are not considered, this can lead to underestimation or overestimation of apparent prevalence [13]. In general, a

diagnostic test with high sensitivity but low specificity is more likely to produce true positive results. Thus, if the true prevalence is lower than the apparent prevalence, it suggests that there is a higher number of false positives, leading to an overestimation of the apparent prevalence. On the other hand, if the true prevalence is higher than the apparent prevalence, this suggests that the test may have low sensitivity and high specificity, leading to an underestimation of the apparent prevalence.

A key factor influencing the accuracy of diabetes prevalence estimates is the choice of diagnostic test. Based on the literature, the HbA1c diagnostic test has low sensitivity, causing false negative results. On the other hand, while the high specificity of HbA1c successfully identifies individuals who do not have diabetes, there is still the potential for false positive results in a low proportion. FBG diagnostic test is a reliable test with high accuracy. FBG, like any test, does not have perfect sensitivity and specificity, thus, it may result in a small percentage of false negative and positive results, respectively. Finally, the OGTT diagnostic test has a very high specificity that successfully detects all individuals who do not have diabetes, while the sensitivity of the OGTT even though quite high, at the same time may show a small percentage of false negative results, thus explaining why the true prevalence is higher than the apparent prevalence (Figure 2).

Therefore, as expected, most diagnostic techniques used in the Lau L et al. [9] publication have non-perfect sensitivity and specificity that potentially introduce systematic misclassification and affecting clinical or research outcomes [14]. Clinical or research results are further affected in cases where the sensitivity or specificity is very low or high, as in the case of the OGTT diagnostic test, where the specificity is equal to 100%. In such cases, the Bayesian model for estimating the true prevalence can become uninformative, resulting in the model not giving accurate estimates and predictions. There is to date considerable heterogeneity in diagnostic tests for diabetes [9]. No pooled analysis, involving all studies and diagnostic tests, was performed to approximate the true prevalence of diabetes in stroke patients. We focused on studies clearly reapplying and reporting their diagnostic test, such as HbA1c, FBG, OGTT, as they all had appropriate public information that could aid towards the estimation of the true prevalence.

Beyond methodological concerns, misclassification bias has profound moral and clinical consequences. Misclassification can lead to incorrect diagnoses, potentially underestimating or overestimating the true prevalence of diabetes, which may affect patient care and resource allocation. It is crucial to ensure accurate diagnosis in order to provide appropriate treatment and minimize the risk of harm caused by misdiagnosis [22]. By employing models to correct these biases, the study emphasizes the responsibility of researchers to use methodologies that enhance the validity of their findings. The applied approach not only improves the reliability of prevalence estimates but also helps ensure that healthcare strategies are based on accurate data. The moral implications also include the need for transparency in reporting limitations and uncertainties, encouraging continuous improvement in diagnostic accuracy and evidence-based medical practices [23].

Another factor contributing to prevalence misclassification bias is stress hyperglycemia, which is a confounding factor that has the potential to overestimate the prevalence of diabetes in studies using glucose-based assays, such as FBG [9]. Stress-induced hyperglycemia is a phenomenon that occurs after any acute illness and is usually detected during hospital admission [24]. It can also occur in people with pre-existing diabetes. According to Lau L et al. [9], 50–70% of people who were hyperglycemic on admission to hospital, had normal OGTT results three or six months after stroke, suggesting that stress-induced hyperglycemia may be a temporary condition in a significant number of acute stroke patients. Although FBG is still a commonly measured glycemic parameter for the diagnosis of diabetes, its accuracy in acute stroke may be affected by stress hyperglycemia [9], which may lead to an overestimation of the apparent prevalence of diabetes in stroke patients (Figure 2).

We should note that, of the fifteen studies selected for inclusion in this study, the studies by Stead et al. [25], Cardino et al. [26], Matz et al. [27] and Gray et al. [28] specifically considered stress hyperglycemia as a factor influencing glucose levels. In contrast, the remaining eleven studies either did not address stress-induced hyperglycemia or referred to hyperglycemia in general terms without distinguishing between stress hyperglycemia and other forms of hyperglycemia. The inclusion or exclusion of this factor has significant implications for the accuracy of diabetes prevalence estimates in stroke patients. Studies that did not account for stress-induced hyperglycemia may have overestimated the prevalence of diabetes, as stress-induced glucose elevation is typically transient and not indicative of chronic diabetes.

This study does have certain limitations, primarily its partial reliance on data presented by Lau L et al. [9]. Also, in this study we assumed that the sensitivity and specificity of diagnostic tests (HbA1c, FBG, and OGTT) were consistent with those reported in studies identifying diabetes in the general population, these values may differ when applied to individuals who had a stroke. Stroke-induced factors, such as altered glucose metabolism and stress hyperglycemia may affect the performance of these tests, resulting in slightly higher sensitivity and slightly lower specificity. To account for this and that prior elicitation discrepancies due to differences in target population, the CIs of sensitivity and specificity of each diagnostic test were increased by 5%. Finally, for some

diagnostic tests, such as the OGTT, there was lack of available data that specifies the confidence intervals for sensitivity and specificity.

Subsequent investigations ought to tackle these constraints and go deeper into the previously described elements. As such, when collecting primary data, care should be taken to minimize the possibility of misclassification. This can be accomplished by carefully following the diagnostic guidelines, as well as by using more accurate instruments, comprehensive medical examination methods or tests with high sensitivity and specificity [14]. To ensure that results accurately reflect the true prevalence in the population, researchers should carefully consider these factors when designing and interpreting studies, as well as consider the quality of the data and statistical methods used in analyses.

In conclusion, the apparent prevalence may differ from the true prevalence of diabetes in stroke patients. Low sensitivity and specificity of diagnostic tests exert a significant impact on the true prevalence of diabetes. However, information on true prevalence is critical and vital. When better informed, health professionals can tailor these interventions to the specific needs of stroke patients. Therefore, the calculation of the true prevalence rate of diabetes will aid in the development of effective prevention and intervention measures.

Supplementary Materials

The following supporting information can be downloaded at: https://www.sciltp.com/journals/jcmde/articles/2505000597/s1

Author Contributions

L.K.: Methodology, Formal analysis, Investigation, Data Curation, Writing—Original Draft, Visualization, Project administration. E.M.: Validation, Writing—Review & Editing. G.M.: Writing—Review & Editing. G.G.: Writing—Review & Editing. O.L.: Writing—Review & Editing. E.A.: Writing—Review & Editing. P.K.: Writing—Review & Editing, Supervision. K.P.: Conceptualization, Validation, Data Curation, Writing—Review & Editing, Supervision, Project administration. All authors have read and agreed to the published version of the manuscript.

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Data Availability Statement

All data generated or analyzed are included in this manuscript and its references. Statistical analyses were conducted following the methodology described by Polychronis Kostoulas in The Hotline Project [29]. Analyses were performed using the R software (version 4.1.1.). All results are reported with 95% credible intervals (CrIs).

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Conflicts of Interest

The authors declare no conflict of interest.

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