

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

3.

4.

5.

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

Relationships not covered above.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

Grant: A grant from an entity, generally [but not always] paid to your organization

Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes **Pending:** The patent has been filed but not issued **Issued:** The patent has been issued by the agency

Licensed: The

patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent



ICMJE Form for Disclosure of Potential Conflicts of Interest

| Section 1. Identifying Inform | nation | |
|---|---|---|
| 1. Given Name (First Name) ZEFO KIYOSI | 2. Surname (Last Name) WIBOWO | 3. Date MARCH 14, 2022 |
| 4. Are you the corresponding author? | Yes V No | |
| 5. Manuscript Title The Relationship between Diabetes Distre | ss and hba1c Level in Type 2 Diabetes M | fellitus Therapy Patients: A Systematic Review |
| 6. Manuscript Identifying Number (if you ki | now it) | |
| | | |
| Section 2. The Work Under C | onsideration for Publication | |
| Did you or your institution at any time rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter | tive payment or services from a third part g but not limited to grants, data monitor est? Yes V No | rty (government, commercial, private foundation, etc.) for ring board, study design, manuscript preparation, |
| | | |
| Section 3. Relevant financial | activities outside the submitte | ed work. |
| Place a check in the appropriate boxes of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of inter | in the table to indicate whether you ibed in the instructions. Use one line port relationships that were presen est? Yes V No | have financial relationships (regardless of amount e for each entity; add as many lines as you need by t during the 36 months prior to publication . |
| | | |
| Section 4. Intellectual Prope | rty Patents & Copyrights | |

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes V No



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Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

Yes, the following relationships/conditions/circumstances are present (explain below):

V No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Evaluation and Feedback

Please visit <u>http://www.icmje.org/cgi-bin/feedback</u> to provide feedback on your experience with completing this form.

Contribution Details (to be ticked marked as applicable):



Commented [D1]: Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.



SONY WIBISONO <sony.wibisono@fk.unair.ac.id>

Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review ^{15 pesan}

Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> 5 Maret 2022 23.02 Kepada: zefo.kiyosi.wibowo-2018@fk.unair.ac.id, sony mudjanarko <sony.wibisono@fk.unair.ac.id>, khairina@fk.unair.ac.id Cc: I Gede Putu Supadmanaba <supadmanaba@gmail.com>, septiawansaputra3@gmail.com

Dear Authors,

Thank you for submitting your article entitled: "The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review"

Based on our author guidelines, Your article fulfilled the minimal required structure, https://www.balimedicaljournal.org/index.php/bmj/pages/view/authorguidlines In order to have a better-structured article, we suggest you edit based on a checklist and the collection in our archive (https://www.balimedicaljournal.org/index.php/bmj/issue/archive).

According to the new International regulation, please fulfill the requirements below:

- 1. Ethical clearance number/statement and/or informed consent at the end of the manuscript (**Confirmed**).
- 2. Please state your conflict of interest in the paper. (**Confirmed**)
- 3. Please state the funding (if any) in your paper. (Confirmed)
- 4. Please state each author's contribution. (Confirmed)
- 5. Based on our proofreading application, we detected 34 critical grammatical errors.
- 6. Please mention who the author were asses the article's quality and extract the data
- 7. In Discussion, please add more discussion about each article included in this study

According to our reviewers, your article need Minor Revision. Attached is the commentary file from our reviewers. Please read it carefully and revised your manuscript accordingly.

Please revise your article and send it back to us in 7 days (March 13th 2022)

In addition, I do need to remind you that Bali Medical Journal is free to submit and Open Access for our readers. However, if your manuscript is accepted for publication, as the author, you will be charged **1,000 USD for APC.** Your article will also be subjected for proofreading and editing (Formatting, Lay outing, and Galey) which costs 100 USD.

For revising your article, we offer you editing and revising assistance which is provided by our official editing partner REVISE and according to your revision status, it will cost **150 USD.** Please confirm if you agree with this information.

Thank you for trusting us with your hard work and we are looking forward for your response.

Warm regards,

Executive Editor BaliMedJ

Bali Medical Journal (BaliMedJ) P-ISSN: 2089-1180



zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> Kepada: SONY WIBISONO <sony.wibisono@fk.unair.ac.id> 10 Maret 2022 20.09

-----Forwarded message ------Dari: Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> Date: Sen, 7 Mar 2022 pukul 22.23 Subject: Re: Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review To: zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>

Dear Author

Attached is the commentary file from our reviewers. Please read it carefully and revised your manuscript accordingly. Please revise your article and send it back to us in <u>7 days (March 14th 2022)</u> Please send the revision by replying to this email

Also, please fulfill the ICJME Form and Author Contribution Form attached below

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Thank you for trusting us with your hard work and we are looking forward for your response.

Warm regards,

Executive Editor BaliMedJ

On Mon, Mar 7, 2022 at 7:46 PM zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> wrote:

First of all, thank you for reviewing our article and giving some feedback, we really appreciate it and we will revise it according to your comments. Based on this email, there was a statement about "attached is the commentary file from our reviewers". We want to ask and confirm about this, Is there any commentary file from reviewers that was attached? Because in this email and I checked my account in the journal web, there is no attached file about this. The second question, where can we send our revised article? Is it sent back to this email or uploaded again on the web? Thank you for your answer

[Kutipan teks disembunyikan]

3 lampiran

🔁 2986-BMJ-Commentary.pdf

8/6/22, 11:31 AM

Email Airlangga University - Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type ...

589K

Contribution Details (3).docx
15K

ICJME author ship criteria.pdf 658K

sony mudjanarko <sony.wibisono@fk.unair.ac.id> Kepada: Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> 11 Maret 2022 09.39

Dear BaliMedJ Editor Team

Thank you for receiving our manuscript will be reviewed. We will immediately correct it according to the corrections of the editor team and we will immediately send back the corrected manuscript.

regards

Sony Wibisono

Sent from Mail for Windows

[Kutipan teks disembunyikan]

zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> Kepada: SONY WIBISONO <sony.wibisono@fk.unair.ac.id> 22 Maret 2022 14.56

----- Forwarded message ------

From: zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>

Date: Mon, Mar 14, 2022, 18:26

Subject: Re: Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review

To: Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com>

Dear Editor Bali Medical Journal,

First, we would like to say thank you for reviewing our article and answering our questions. We have read the reviewer comments and suggestions. Hereby, our confirmation about some questions:

1. For method question number 1, we add in this revised version that if there were any articles with incomplete data, all authors examined the reason and explanation for the missing data from those articles. The articles with precise descriptions and supporting analysis were still included in this systematic review. DD score and HbA1c were required data for analyzing; the authors agreed minimally that the articles statistically explained the correlation, the articles still included, although they do not describe the data.

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Thank you for your consideration reviewing this article, we are looking forward to hearing from you soon.

Pada tanggal Sen, 7 Mar 2022 pukul 22.23 Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> menulis: Dear Author

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[Kutipan teks disembunyikan]

3 lampiran

Contribution Details_2986_The Relationship between Diabetes distress and hba1c.docx 17K

2986-10606-1-RV_The Relationship between Diabetes Distress and hba1c Level.docx 273K

ICJME author ship criteria_2986_The Relationship between Diabetes distress and hba1c.pdf 662K

zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> Kepada: SONY WIBISONO <sony.wibisono@fk.unair.ac.id> 22 Maret 2022 15.20

------ Forwarded message -------From: **Editor Bali Medical Journal** <editorbalimedicaljournal@gmail.com> Date: Mon, Mar 7, 2022, 22:23 Subject: Re: Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review To: zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>

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[Kutipan teks disembunyikan]

| 3 lampiran | | | | | |
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| 2986-BMJ-Commentary.pdf 589K | | | | | |
| Contribution Details (3).docx | | | | | |
| ICJME author ship criteria.pdf 658K | | | | | |

zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> Kepada: SONY WIBISONO <sony.wibisono@fk.unair.ac.id> 22 Maret 2022 15.44

------ Forwarded message ------Dari: **Editor Bali Medical Journal** <editorbalimedicaljournal@gmail.com> Date: Jum, 18 Mar 2022 pukul 23.27 Subject: Re: Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review To: zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>

Dear Authors,

Thank you for your revised manuscript and confirmation.

After considering the suggestion from reviewers and also the quality of your revision (assisted by REVISE), we decided to accept your manuscript for publication. We are sorry for the lengthy process but the editing team has to meet the review points provided by your reviewers.

Before we proceed the article, we do need to remind you that Bali Medical Journal is free to submit and Open Access for our readers. However, if your manuscript is accepted for publication, as the author, you will be charged **1,000 USD for APC**. Your article will also be subjected for proofreading and editing (Formatting, Lay outing, and Galey) which costs **100 USD**.

Please confirm if you agree with this information.

Congratulations on the acceptance of your article. We are looking for your future publication.

Warm regards,

Executive Editor BaliMedJ

8/6/22, 11:31 AM

Email Airlangga University - Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type ...

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Bali Medical Journal (BaliMedJ) P-ISSN: 2089-1180 E-ISSN 2302-2914 Indexed at: Web of Science (WOS) Clarivate Analytics **SCOPUS Elsevier** All Indexing Organisation



Email Airlangga University - Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type ... 8/6/22, 11:31 AM

[Kutipan teks disembunyikan]

sony mudjanarko <sony.wibisono@fk.unair.ac.id>

22 Maret 2022 15.54 Kepada: Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com>, zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>, "khairina@fk.unair.ac.id" <khairina@fk.unair.ac.id>

Dear BaliMedJ Editor Team

We had received email on 18 March 2022 23: 27. Our manuscript with title The relationship between diabetes distress and Hba1c level in type 2 diabetes mellitus therapy : A systemic review already your accept in the journal. We want the next to payment APC and editing. Can we get the LOA is possible.

Looking forward you massage

Sincerely

Sony, Khairina and Zefo

Sent from Mail for Windows

From: sony mudjanarko Sent: Friday, March 11, 2022 9:39 AM To: Editor Bali Medical Journal

[Kutipan teks disembunyikan]

[Kutipan teks disembunyikan]

Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> Kepada: sony mudjanarko <sony.wibisono@fk.unair.ac.id>

22 Maret 2022 20.58

Dear Authors,

Thank you for your confirmation.

Attached below is the invoice for your article and please use the rate from your bank when you want to pay in IDR.

Also please send us the proof of your payment through this email, so we can process your article for publication. Your LoA will send 1 or 2 days after we confirm your payment

Congratulations on the acceptance of your article. We are looking for your future publication. [Kutipan teks disembunyikan]

invoice-BMJ-2986.pdf 122K

Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> 23 Maret 2022 23.41 Kepada: zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id>, sony mudjanarko <sony.wibisono@fk.unair.ac.id>, khairina@fk.unair.ac.id

Dear Authors,

Thank you for your confirmation.

Attached below is the invoice for your article and please use the rate from your bank when you want to pay in IDR.

Also please send us the proof of your payment through this email, so we can process your article for publication. Your LoA will send 1 or 2 days after we confirm your payment

Congratulations on the acceptance of your article. We are looking for your future publication.

On Wed, Mar 23, 2022 at 5:52 PM zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> wrote: Dear Editor BalimedJ, We would like to say thank you for accepting our manuscript in Bali Medical Journal. Our corresponding author (sony.wibisono@fk.unair.ac.id) sent an email yesterday that agrees with the APC and proofreading and editing costs. For the next email about mechanism of payment and LoA, could the email be sent to all authors email, is it possible? Thank you for your answer, we are looking forward your massage Sincerely Sony, Khairina and Zefo Pada tanggal Jum, 18 Mar 2022 pukul 23.27 Editor Bali Medical Journal <editorbalimedicaljournal@gmail.com> menulis: Dear Authors, Thank you for your revised manuscript and confirmation. After considering the suggestion from reviewers and also the quality of your revision (assisted by REVISE), we decided to accept your manuscript for publication. We are sorry for the lengthy process but the editing team has to meet the review points provided by your reviewers. Before we proceed the article, we do need to remind you that Bali Medical Journal is free to submit and Open Access for our readers. However, if your manuscript is accepted for publication, as the author, you will be charged 1,000 **USD for APC.** Your article will also be subjected for proofreading and editing (Formatting, Lay outing, and Galey) which costs 100 USD. Please confirm if you agree with this information. Congratulations on the acceptance of your article. We are looking for your future publication. Warm regards, Executive Editor BaliMedJ On Mon, Mar 14, 2022 at 7:26 PM zefo kiyosi <zefo.kiyosi.wibowo-2018@fk.unair.ac.id> wrote: Dear Editor Bali Medical Journal, First, we would like to say thank you for reviewing our article and answering our questions. We have read the reviewer comments and suggestions. Hereby, our confirmation about some questions: 1. For method guestion number 1, we add in this revised version that if there were any articles with incomplete data, all authors examined the reason and explanation for the missing data from those articles. The articles with precise descriptions and supporting analysis were still included in this systematic review. DD score and HbA1c were required data for analyzing; the authors agreed minimally that the articles statistically explained the correlation, the articles still included, although they do not describe the data. 2. For result question number 1, yes, the articles only published about percentage samples who got that score. The percentage was not 100% because the other 33% samples were the samples with depression which exclusion criteria in this systematic review. The explanation and categorization of DD, we have added in this revised version.

| 8/6/22, 11:3 | 1 AM Email Airlangga University - Revision Required (BaliMedJ) The Relationship between Diabetes Distress and HbA1c Level in Type |
|-------------------|---|
| | 3. The other suggestions and revisions, we have added in this revised version Thank you for your consideration reviewing this article, we are looking forward to hearing from you soon. |
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| | Attached is the commentary file from our reviewers. Please read it carefully and revised your manuscript accordingly. |
| | replying to this email Also, please fulfill the ICJME Form and Author Contribution Form attached below |
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| | For revising your article, we offer you editing and revising assistance which is provided by our official editing partner REVISE and according to your revision status, it will cost 150 USD . |
| | Please confirm if you agree with this information. |
| | Thank you for trusting us with your hard work and we are looking forward for your response. |
| | Warm regards, |
| | Executive Editor BaliMedJ |
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The relationship between diabetes distress and HbA1C level in type 2 diabetes mellitus therapy patients: a systematic review

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ABSTRACT

Introduction: The success of therapy did not follow the increasing number of type 2 diabetes mellitus patients. This systematic review aimed to evaluate the relationship between diabetes distress and HbA1c in type 2 diabetes mellitus patients during therapy.

Methods: The authors systematically searched databases (PubMed, Cochrane library, and ScienceDirect) up to January 2021. Articles were screened according to PRISMA 2020 statements. The selection criteria of this study were patients' characteristics, type of therapy, and outcomes.

Results: The search started from 1.303 articles to 17 eligible articles. Furthermore, seventeen studies included 11,976 patients. The mean HbA1c level was around 6.4% to 9.9%. The result of diabetes distress scores were five studies with low scores, eight moderate scores, and two high scores. Emotional burden and regimen-related distress were the highest domain score. Age, health facilities, and type of therapy affected diabetes distress. The correlation between diabetes distress and HbA1c was dominant in the range of 0.15 to 0.26.

Conclusion: Diabetes distress had a low-moderate correlation with HbA1c. The dominant domains were an emotional burden and regiment-related distress. There were two mechanisms of effect, direct by hormones and indirect through medication adherence, self-management, and 12 months of quality of life.

Keywords: Diabetes Distress, HbA1c, Type 2 Diabetes Mellitus, Therapy

INTRODUCTION

Diabetes is a chronic disease that caused 1.5 million deaths in 2012, and about 90% of people with diabetes had type 2 diabetes mellitus (T2DM).¹ The improvement of therapy was still low; however, the number of T2DM patients was increasing.²⁻⁴ Physicians, patients, and the healthcare systems were a factor that influenced therapy.⁵ Psychological conditions affected 30% of therapy because they had a role in the patient's condition.⁵ The most common

problem is stress. Patients have reached target therapy still less than 50% of the population, mainly in Asia.²⁻⁴ In one hospital in Taiwan, 83.5% of patients did not reach the therapeutic target (HbA1c > 7%).² In South Korea, 55.5% of patients had poor glycemic control (mean HbA1c = 8.08%).³ This finding was the same in 2013; there was no improvement in reaching therapeutic targets in five years.³ However, Indonesia has the same condition that only 30.8% of patients achieve the targeted therapy.⁴

The DAWN (Diabetes, Attitudes, Wishes, Needs) study conducted a large crosscountry research on patients and healthcare professionals in the management of diabetes.⁶ Diabetes distress (DD) was the most common and interfered with patient self-management.⁶ It was the negative feelings like worries, anxiety, and threats because of diabetes.⁷ The DAWN 1 study, with 5,104 samples from 13 countries, 41% of patients had DD.⁷ The DAWN 2 study was conducted in 18 countries with 8,596 samples, and there were 44.6% DD patients.⁷ Farm et al. found that there was moderate DD in 620 patients in primary clinics and tertiary hospitals in two provinces of Indonesia.⁸

Diabetes distress was a major issue in T2DM patients, and it was a widespread problem.^{9,10} Perrin et al. supported that diabetes distress was under-recognized and inadequately treated in Type 2 diabetes.¹⁰ The growth of diabetes distress without DD reached around 17% and became high DD in 18 months.⁹ The effect of diabetes distress was poor glycemic control, low treatment compliance, poor self-management behavior, and high risky lifestyle behavior.^{9,11} Gonzales et al. found that diabetes distress affects medication adherence and A1C directly or through perceived control.¹²

Diabetes distress and fasting blood sugar have a significant relationship.⁸ In Taiwan, Chen et al. analyzed that diabetes distress with increasing empowerment significantly correlated with blood glucose.² Diabetes distress has a positive correlation that contrasts with empowerment.² Diabetes distress is a psychosocial condition that has a more significant impact than decisional balance for insulin injection, health knowledge, and self-efficacy.

To evaluate the relationship between diabetes distress and HbA1c level in type 2 diabetes mellitus patients during therapy, the authors performed a systematic review to summarize the correlation between the two variables. The analysis is according to the scoring instrument, mechanism of correlation in each study, and the factor that affects diabetes distress. The first systematic review analyzes those variables to find effective target intervention.

METHODS

Data sources and searches

Published articles were selected from three databases [PubMed, Cochrane library, and ScienceDirect]. We searched the articles up to January 2021. We used the following keyword ((Type 2 Diabetes Mellitus) OR (T2DM)) AND ((diabetes-related distress) OR (Diabetes distress)) AND (HbA1c) AND (therapy). We exported the studies to Mendeley to manage the references and remove duplicates.

Selection of studies

This systematic review is based on standard preferred reporting items for systematic reviews and meta-analyses (PRISMA) 2020 statements. The flow of articles was selected according to this guideline. The articles used English languages and had samples over 19 years old. Microsoft Excel and Mendeley recorded the results, managed references, and eliminated duplicated studies.

The first and second authors independently screened articles. If there were any different opinions between the two authors, we discussed them and asked the third author's opinion until we got a consensus. The selection is according to inclusion and exclusion criteria. The articles chosen were cross-sectional and cohort; the sample age was over 19

years old, HbA1c became an indicator of blood sugar assessment, diabetes distress examining, and an analysis of the relationship between diabetes distress and HbA1c. The exclusion criteria were patient had received psychological therapy and was in a psychotic condition.

Quality Assessment

All authors discussed and assessed the quality of the articles. Quality assessment in cross-sectional and cohort studies using the Newcastle Ottawa Scale. Assessment according to screening, comparability, and outcome in each study. Assessment indicators for each aspect of cross-sectional and cohort studies are based on validated assessment standards. Ratings each object gets one star and will be a total at the end. Total scores over 7-8 include good category, 3-6 were fair categories, and <3 were poor categories.

Data extraction and Data analysis

The authors extract data by sorting between study characteristics and outcomes. The indicators taken for study characteristics are study design, place, sample amount, mean age, duration of type 2 diabetes mellitus, therapy method (oral medication, insulin injection, combination, and no medication), and diabetes distress instrument. The outcome table explained the HbA1c level, diabetes distress score, significance level (p-value), and Pearson correlation value (r). The domain of diabetes distress was defined in different tables.

The first author extracted all data. The second and third authors cross-checked the data. The second author was concerned about the type of therapy, HbA1c level, demography, and outcomes. The third author specifically checked data about the DD instrument, the score of DD, demography, and outcomes. If there were any articles with incomplete data, all authors examined the reason and explanation for the missing data from the article. The articles with precise descriptions and supporting the analysis were still included in this systematic review. DD score and HbA1c were required data for analysis; the authors agreed minimally that the articles statistically explained the correlation, although the articles do not describe the data

Firstly, we separated the tables to analyze the characteristics and outcomes. Furthermore, we analyzed the demography with diabetes distress levels to identify factors that affect diabetes distress—statistic values interpretation like significance level and Pearson correlation between diabetes distress and HbA1c. Next, we determined the flow of the impact of diabetes distress on HbA1c, either direct or indirect. The last result was the aspects that affect diabetes distress and the correlation between diabetes distress and HbA1c. All authors analyzed the correlation of each data and summarized it.

RESULT

Begin with 1,303 studies from 254 in PubMed, 72 in Cochrane library, and 977 in ScienceDirect (Figure 1). A total of 981 studies were removed with automation tools and 47 duplicate studies. Three hundred twenty-two studies were initially screened, and 256 were excluded (Figure 1). There were 66 studies selected according to inclusion and exclusion criteria—three with samples aged under 19 years and duration of diagnosis less than three months. Twenty studies were not cohort or cross-sectional studies. Two studies had not identified the correlation between diabetes distress and HbA1c. HbA1c was not a marker in the two studies. Six studies with samples received a psychological intervention, six studies on depressed patients, and nine studies used diabetes distress as an outcome (Figure 1). The total number of excluded studies is 49 studies. The number of included studies was 17 studies, with 15 cross-sectional studies and two cohort studies. Fourteen studies were a good category, and three other studies had fair from the Newcastle Ottawa Scale assessment (Table 1).

Seventeen studies were selected, and they had 11,976 patients. Sixteen studies with samples from one region and eight studies from Asia (Table 2). One study with samples from

18 countries.¹³ The study sample in this systematic review was 11,976 patients (96.06%) from the initial samples—the dominant study from Asia, eight studies in 7 countries, followed by America. According to data from the diabetes center, one study with varied samples from many nations. This study described data from various health facilities (Table 2). Of fifteen studies, five were at primary care, one at a healthcare institution, two at hospitals, one at a university hospital, one at an endocrinology clinic, one at major medical care, one at a diabetes outpatient clinic, and three at diabetes centers. Two other studies in more than one health facility area. There are urban and suburban areas.¹⁴ In addition, there are additions in rural areas.¹⁵

Of seventeen studies, six studies had a mean sample age of over 60 years, and one of them reached up to 70 years (Table 2). The other ten studies had ages 50 to 60 years. One further study described the average age with the percentage in each age range, with the dominant age being 50 to 64 years. Fifteen studies reported the duration of the sample undergoing T2DM therapy. A total of nine studies had a duration of more than ten years, and six studies with 7 to 10 years.



Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020

| Quality Assessment Criteria | Aghili R et al.,2016 | Asuzu CC et al.,2017 | Chen SY et al., 2019 | Chew BH et al., 2018 | Choi WH et al.,2017 | Darawad MW et al.,2017 | Hsu <i>et al.</i> ,2018 | Kuniss et al.,2017 | Lin <i>et al.</i> ,2017 | Linetzky B et al., 2016 | Lum ZK et al., 2018 | Mirghani <i>et al.</i> ,2016 | Nanayakkara N <i>et al.</i> , 2016 | Sukkarieh-Haraty O et al.,2019 | Walker RJ et.al, 2019 | Wardian <i>et al.</i> ,2017 | Winchester RJ et al., 2016 |
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| Selection | | | | | | | | | | | | | | | | | |
| ss of the exposed | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Selection of the non-exposed | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| cases Ascertainment of | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Selection of outcome parameters clearly specified in methods Comparability | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Study controls for age and sex? | - | - | - | - | - | - | - | - | - | - | - | * | - | - | - | - | - |
| Study controls for the history of HbA1c? Outcome | - | - | - | - | * | - | - | - | - | - | - | - | - | - | - | - | - |
| Assessment of outcome? | * | * | * | * | * | - | * | * | * | * | * | * | * | * | * | * | - |
| long enough for outcomes to | - | - | - | * | - | - | * | - | - | - | - | - | - | - | - | - | - |
| Non-response rate | * | * | * | * | * | * | * | * | * | * | * | * | * | - | * | * | * |
| Total score | 7 | 7 | 7 | 8 | 8 | 6 | 8 | 7 | 7 | 7 | 7 | 8 | 8 | 6 | 7 | 7 | 6 |

Table 1. Newcastle Ottawa Scale

| No | Author, year | Study Design | Place (Country; Healthcare) | Sample | Mean age (years) | Duration T2DM (years) |
|----|---|---------------------|---|--------|--|--------------------------|
| 1 | Aghili et al.,2016 ¹⁶ | Cross- Sectional | Iran; Major medical clinic | 380 | 54.73 ± 8.00 | 8.94 ± 6.5 |
| 2 | Asuzu et al 2017^{17} | Cross- sectional | Southeastern United States; Primary care | 615 | 61.3 ± 10.9 | 12.3 ± 9.1 |
| 3 | Chen et 2019^2 | Cross- sectional | Taiwan; Endocrinology | 255 | 56.58 ± 10.92 | 13.37 ± 8.87 |
| 4 | Chew et al. 2018^{15} | Cross- Sectional | Malaysia; Urban, suburban, and rural health clinics | 338 | 60.6 ± 10.1 | 9.8 ± 5.9 |
| 5 | Choi et al.,2018 ³ | Cross- sectional | South Korea, University | 171 | 59.55 ± 9.75 | 12.36 ± 8.53 |
| 6 | Darawad et al 2017 ¹⁸ | Cross- sectional | Jordania; Hospital | 325 | 55.3 ± 13.2 | NR |
| 7 | Hsu et al.,2018 ¹⁹ | Cross- Sectional | Southern Taiwan; Diabetes | 382 | 58.78 ± 11.48 | 10.03 ± 7.29 |
| 8 | Kuniss et al 2017 ²⁰ | Cohort | Germany; Primary care | 336 | 72.3 ± 9.7 | 12.4 ± 10.2 |
| 9 | Lin et al.,2017 ¹⁴ | Cross- Sectional | China; Suburban and urban outpatient departement | 254 | 55.26 ± 0.63 | 8.15 ± 0.42 |
| 10 | Linetzky et al.,2017 ¹³ | Cross- sectional | Argentina, Brazil, Canada, China, Germany, India, Israel, Italy, Japan, Mexico, Russia, Saudi Arabia, South Korea, Spain, Turkey, United Arab Emirates, UK, and United States, including Puerto Rico: Primary care | 4341 | 61.77 ± 11.02 | 12.65 ± 7.98 |
| 11 | Lum et al., 2018^{21} | Cross- sectional | Singapore; Healthcare Institution | 246 | 59.9 ± 7.6 | 9.4 ± 8.8 |
| 12 | Mirghani, 2016 ²² | Cross sectional | Sudan; Diabetes center | 89 | 59.64 ± 9.60 | 9.14 ± 8.1 |
| 13 | Nanayakkara et al2016 ²³ | Cross sectional | Australia; Diabetes center | 2552 | 63 ± 13 | 12 ±10 |
| 14 | Sukkarieh- Haraty et al2019 ²⁴ | Cross sectional | Lebanon; Hospital | 280 | 58.24 ± 13.48 | 7.83 |
| 15 | Walker et.al, 2019 ²⁵ | Cross sectional | United States; Primary care | 615 | 61.3 ± 10.9 | 12.3 ± 9.1 |
| 16 | Wardian et al2017 ²⁶ | Cohort | United States; Diabetes center | 436 | 59.9 | 16.9 |
| 17 | Winchester et al.,2016 ²⁷ | Cross- sectional | United States; Primary clinic | 361 | 18–49 years (10.6%) 50–64 years (43.0%) 65–74 years (29.1%) 75–89 years (17.3%) | NR |

 Table 2. Summary of Studies Characteristics

Abbreviation: NR: Not Reported

Not all studies report the type of therapy patients. Eleven studies described the percentage of patients who did therapy into four categories (Table 3). Two studies had total samples that were all insulin or oral medication.^{13,24} There were three studies with samples in four categories; 2 studies were dominant with oral antihyperglycemic therapy samples, and 1 study was diet alone. The other five studies were in only two types; 3 were predominant with oral antihyperglycemic, 1 study in combination, and one on insulin therapy. One study reported a disproportionate sample percentage of 90% in oral antihyperglycemic therapy but about 57% in another category.¹⁵

 Table 3. Summary of Type Therapies Studies

| | | | Thera | ру (%) | |
|--------|--|------------------------|---------------------------|---------|-----------------------------|
| N o | Author, year | Oral medicatio n | Insulin ± oral medication | Insulin | No Medication/ Diet only |
| 1 | Aghili et al.,2016 ¹⁶ | 54,80% | 38,40% | 5% | 1,80% |
| 2 | Asuzu et al.,2017 ¹⁷ | NR | NR | NR | NR |
| 3 | Chen et al.,2019 ² | NR | 72,90% | 27,10% | NR |
| 4 | Chew et al.,2018 ¹⁵ | 90% | NR | 47,50% | 10,94% |
| 5 | Choi et al.,2018 ³ | 64,30% | 35,70% | - | - |
| 6 | Darawad et al.,2017 ¹⁸ | NR | NR | NR | NR |
| 7 | Hsu et al.,2018 ¹⁹ | NR | NR | NR | NR |
| 8 | Kuniss et al.,2017 ²⁰ | 26,20% | 14% | 17,80% | 42,00% |
| 9 | Lin et al.,2017 ¹⁴ | 59,50% | 40,50% | - | - |
| 10 | Linetzky et al.,2017 ¹³ | NR | NR | 100% | NR |
| 11 | Lum et al., 2018 ²¹ | 60,60% | 29,30% | 1,60% | 8,50% |
| 12 | Mirghani, 2016 ²² | 91,10% | NR | 8,90% | NR |
| 13 | Nanayakkara et al.,2016 ²³ | NR | NR | 74% | 26% |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁴ | 100% | NR | NR | NR |
| 15 | Walker et.al, 2019 ²⁵ | NR | NR | NR | NR |
| 16 | Wardian et al.,2017 ²⁶ | NR | NR | 56,90% | 17,60% |
| 17 | Winchester et al.,2016 ²⁷ | NR | NR | NR | NR |

Abbreviation:

NR: Not Reported

Twelve studies used the 17-DDS instrument (Table 4). Three of them use other countries' versions, such as Korean, Arabic, and Chinese. Four other studies used the PAID Scale, and two of them were Chinese versions. One recent study used 12 DFS-Ars to assess a patient's level of distress.

The outcomes of the studies were diabetes distress score, HbA1c level, significance (p-value), and Pearson correlation (r). The diabetes distress score is related to the instrument so that the mean and indicator are different. Two studies did not report mean DD scores. However, Aghili et al. still wrote the result of diabetes distress statistics.¹⁶ Sukkarieh-Haraty et al. published the analysis of distress in a statistic.²⁴ One study reported the percentage of samples that scored 0-3 (65%) and >3 (2%) because there were two sample categories and

there is no data as a mean score. Seven of the 14 studies included low DD levels, the other five studies were moderate, and two studies had high DD levels.

The target of therapy is HbA1c below 7%. Only one study reported reaching the target.²⁰ Another 14 studies had a mean HbA1c above 7% (Table 4). There is one study that reported the percentage of HbA1c >7% (64%) and HbA1c <7% (36%). One study did not record HbA1c levels. Sixteen studies were significant, and one other study was not significant in total diabetes distress score.²² Ten studies described the correlation between HbA1c and DD with the Pearson correlation. Two other studies are not directly related.^{14,19} The other five studies did not report any correlation values. One high correlation study (0.69), 3 moderate correlation studies (0.2-0.5), and 6 low correlation studies (< 0.2).

| No. Author yoor | | DD Instrument | DD Score | HbA1c | Outcomes | |
|-----------------|--|------------------------------------|--|------------------------|----------|-------|
| INO | Author, year | DD Instrument | (/max score) | (% (mmol)) | p-value | r |
| 1 | Aghili et al.,2016 ¹⁶ | DDS17 | NR | 7.78 ± 1.7 (62) | < 0.001 | 0.173 |
| 2 | Asuzu et al.,2017 ¹⁷ | DDS17 | $1.6 \pm 0.7/6$ (low) | 7.9 ± 1.8 (63) | < 0.001 | 0.69 |
| 3 | Chen et al.,2019 ² | Short-Form PAID Scale (Chinese) | 10.98/32 (low) | 8.33 ± 1.49 (68) | < 0.05 | 0.144 |
| 4 | Chew et al.,2018 ¹⁵ | DDS17 | $2.3 \pm 1.4/6$ (moderate) | 8.3 (67) | < 0.05 | NR |
| 5 | Choi et al.,2018 ³ | DDS17 (Korean) | $2.25 \pm 0.56/6$ (moderate) | 7.37 ± 1.27 (57) | < 0.05 | NR |
| 6 | Darawad et al.,2017 ¹⁸ | DDS17 (Arab) | $47.2 \pm 14.5/85$ (high) | 7.88 ± 1.78 (63) | < 0.05 | 0.153 |
| 7 | Hsu et al.,2018 ¹⁹ | PAID Scale (Chinese) | 7.61 ± 7.02 / 32 (low) | 7.39 ± 1.11 (57) | < 0.01 | NR* |
| 8 | Kuniss et al.,2017 ²⁰ | PAID scale | $3.9 \pm 7.0/43.75$ (low) | 6.4 ± 1.0 (46) | < 0.001 | 0.253 |
| 9 | Lin et al.,2017 ¹⁴ | DDS17 (Chinese) | $38.94 \pm 0.81/90$ (low) | >7% = 64% <7% = 36% | < 0.01 | NR* |
| 10 | Linetzky et al.,2017 ¹³ | DDS17 | $2.27 \pm 1.13/6$ (moderate) | 8.13 ± 1.75 (65) | < 0.01 | 0.171 |
| 11 | Lum et al., 2018 ²¹ | PAID Scale | 26.2/80 (moderate) | 8.6 ± 1.5 (70) | < 0.01 | 0.235 |
| 12 | Mirghani, 2016 ²² | DDS17 | 3.67 ± 0.64 (high) | 9.9 ± 2.60 (85) | >0.05 | 0.176 |
| 13 | Nanayakkara et al.,2016 ²³ | DDS17 | 0-3 (65%) >3 (2%) (dominant low) | 8±2 (64) | <0.001 | NR |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁴ | 12-item DFS-Ar | NR | 7.73 ± 2.2 (61) | < 0.05 | NR |
| 15 | Walker et.al, 2019 ²⁵ | DDS17 | $1.6 \pm 0.7/6$ (low) | 7.9 ± 1.8 (63) | < 0.001 | 0.25 |
| 16 | Wardian et al.,2017 ²⁶ | DDS17 | 2.8/6 (moderate) | 8.38 (68) | < 0.05 | NR |
| 17 | Winchester et al.,2016 ²⁷ | DDS17 | 1.4/6 (low) | NR | < 0.05 | 0.179 |

Table 4. Summary of variables result and outcome studies

Abbreviation: (*): No direct correlation NR: Not Reported DDS17: 17-item Diabetes Distress Scale PAID Scale: Problem Areas in Diabetes scale 12-item DFS-Ar: The **12**- item Diabetes Fatalism Scale- Arabic The graphic presents two variables with a horizontal line of diabetes distress score and a vertical line of HbA1c level (%) (Figure 2). The red vertical line is the mark for the diabetes distress category—the horizontal line is an HbA1c target mark. Nine of 12 studies support that a high diabetes distress score has a high HbA1c (Figure 2). One study with high diabetes distress and HbA1c level.²² Seven studies have moderate diabetes distress with HbA1c level >7%.^{23,13,15,18,21,26} In one study, the result was low diabetes distress, but the HbA1c level >7%.^{17,19,25}



Figure 2. Graphic Diabetes distress score and HbA1c level

Diabetes distress has four domains; emotional burden, physician-related distress, regimen-related distress, and interpersonal distress (Table 5). Four studies listed the mean score, and two of them also recorded the correlation between HbA1c and DD. The four studies show the mean value of DD is medium and high. Both studies had low correlations for HbA1c in the EB and RD domains and low values in the other two domains. The value of all studies is significant.

| | | | | 2 | | | | | | |
|--------|-----------------------------------|--------------------|-------|--------------------|----------------------------|------------|------------------------------|------|------------------------|--------|
| | | | | Doma | ain Diabete | s Distress | | | | |
| N o | Author, year | ' Emotional Burden | | Physician distr | Physician-related distress | | Regimen- related distress | | Interpersonal distress | |
| | - | Mean | r | Mean | r | Mean | r | Mean | r | |
| 1 | Choi et al.,2018 ³ | 2.46 | NR | 1.86 | NR | 2.41 | NR | 2.14 | NR | < 0.05 |
| 2 | Darawad et al.,2017 ¹⁸ | 15.2 | 0.193 | 10 | -0.017 | 14 | 0.151 | 7.1 | -0.04 | < 0.05 |

 Table 5. Summary of diabetes distress domain

| 3 | Mirghani, 2016 ²² | $\begin{array}{c} 4.08 \pm \\ 0.88 \end{array}$ | 0.221 | 3.75 ± 1.13 | -0.009 | 3.35 ± 1.43 | 0.331 | 3.445 ± 0.92 | - 0.129 | < 0.05 |
|---|-----------------------------------|---|-------|------------------|--------|-----------------|-------|------------------|------------|--------|
| 4 | Wardian et al.,2017 ²⁶ | 2.108 ± 1.15 | NR | 1.261 ± 0.76 | NR | 2.137 ± 1.06 | NR | 1.50 ± 0.89 | NR | < 0.05 |
| | | | | | | | | | | |

Abbreviation: NR: Not Reported

DISCUSSION

This systematic review presents a significant relationship between diabetes distress and HbA1c levels. Only Mirghani et al. had result significant correlation with the domain score but not the total score.²² Emotional burden and regimen-related distress are strong predictors of glycemic control.²² The dominant low correlation is because HbA1c level is affected by diabetes distress and other factors. However, diabetes distress is a strong determinant compared with other psychosocial such as depression. Lee et al. supported diabetes distress as an effective target intervention to improve glycemic control.²⁸ Ten of 17 studies found that DD was directly positively correlated with HbA1c level. Diabetes distress can increase the cortisol hormone, which suppresses insulin production.² The impact of low insulin is increasing HbA1c. Nevertheless, Chew et al. did not find a correlation between diabetes distress and HbA1c level.¹⁵ Differences in population culture such as family, social network, and health mindset influenced stress and glycemic control.¹⁶

Five of 17 studies found that medication adherence is a mediator between diabetes distress and HbA1c level. Medication adherence is the most specific and easy adherence practice in therapy.¹⁶ High diabetes distress enhances poor medication adherence. Then, it will increase HbA1c levels.^{13,15,16} Medication adherence is a critical role in treatment, so failing this step will disturb T2DM therapy. Mirghani et al.'s finding supported that T2DM patients feel desperate and overwhelmed with this condition.²² It induced poor adherence and concerned poor glycemic control. Diabetes distress affects self-efficacy, then the impact is 0.26 points of self-management.¹⁴ Self-management influenced the HbA1c level.¹⁴ It was consistent with studies in China and Thailand that self-management was the key to diabetes management and a predictor of blood glucose.²⁹ Interventions in self-management can be effective because improving it one point reduces the risk of suboptimal T2DM therapy.¹⁴ Twelve months of quality of life (QoL) months also mediates the two variables in two of 17 studies. Diabetes distress affects QoL through life satisfaction and motivation, so it takes time before the HbA1c level.¹⁹ Diabetes distress disturbs self-care in the long term. The impact of low selfcare on HbA1c is disturbing diet, exercise, and blood glucose management. If it is less than six months, the effect of diabetes distress is not apparent, especially when the level of diabetes distress is still low.

Emotional burden and regimen-related distress are two dominant domains in diabetes distress. They can be strong predictors of glycemic control. Emotional burdens are present in patients who feel hard to do routines as type 2 diabetes mellitus patients, and the lack of social support will reinforce this.^{24,26} The regimen-related distress is identical to being irregular in monitoring blood glucose and therapy so that it is related to the type of therapy.^{3,26} Physician-related distress through hurried communication disturbs glycemic control because the patients do not understand what to do.¹³ High emotional burden and regimen-related distress will suppress glycemic control, and the HbA1c will increase.^{17,18}

Age significantly affects the level of diabetes distress. The higher risk of diabetes distress, the younger the patient is first diagnosed with type 2 diabetes.¹⁶ Seven of 17 studies have the same finding.^{3,14,18,20-22,26} T2DM patients during working age will inhibit activities and disturb need compliance. The longer the duration of experiencing type 2 DM, the higher the DD score.²⁰ However, Wardian et al. supported this statement.²⁶ Previous studies did not show

the same result because those conclusions were from some sample groups.²⁰ This finding aligns with other studies that duration does not affect DD but can affect self-care.^{18,19}

The finding of the present systematic review is different from the previous study about the effect of the level of health facilities on diabetes distress. In primary care, the level of diabetes distress is low. The glycemic control is better than at the secondary or tertiary level because, at the tertiary level, the patient has blood sugar levels that are more uncontrolled.^{14,20} Nevertheless, primary care has a higher level of distress because it is associated with physician capability in the previous study.⁸ The difference in findings is because each country has different standards of health care facilities.

The type of patient therapy can affect the level of diabetes distress. The type of therapy is the group of regimen-related distress. In patients who use therapy, there is a tendency for high levels of distress because it is related to strictness in the use of insulin, namely in terms of time, dose, and fear of hypoglycemia.^{2,26} Patients with combination therapy need accuracy in insulin therapy and consume oral antihyperglycemic drugs.³ Therefore, the type of therapy does not explicitly affect diabetes distress because each treatment has some concerns. The patients will feel anxiety and stress if they do therapy for a long time, whatever the type of therapy.

This systematic review implies that diabetes distress is significantly related to HbA1c with a low correlation. Nevertheless, it can be the target of intervention and improve the success of therapy. The first limitation of this study is that it does not proceed to a meta-analysis due to the various types of studies and instruments. By analyzing the meta-analysis, it will be more quantitative to see the correlation of two variables and the effect of diabetes distress on HbA1c. Second, the correlation between the two dominant variables is weak, so further research is needed. The other cause because HbA1c is not only affected by psychological conditions but many factors.

CONCLUSIONS

In this study, diabetes distress and HbA1c have a low-moderate relationship, but it can be an effective target intervention for improving type 2 diabetes mellitus therapy. Diabetes distress has one direct mechanism hormones. The indirect effect of diabetes distress is through medication adherence, self-management, and 12 months of quality of life. Age, health facilities, and type of therapy can affect diabetes distress. Furthermore, emotional burden and regimen-related distress are the most dominant domain in diabetes distress, and they can be the specific target for intervention.

FUNDING

This study did not receive any funds from funding agencies, commercial or another sector.

CONFLICT OF INTEREST

The authors declared there is no conflict of interest regarding this study between authors and other organizations or people that influence the objectivity of research.

AUTHOR CONTRIBUTOR

The first and third authors created and discussed the concept. The first and second authors created the studies design and searched literature with selected articles. All authors analyzed the result and wrote some notes. After we concluded the last analysis, the first author wrote and prepared the manuscript. The second and third authors reviewed and evaluated it.

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Letter of Acceptance 25 April 2022

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I am very excited to accept your paper entitled: **"The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review."** Your paper will be published in the issue of of Vol. 11 Number 1, 2022. http://dx.doi.org/10.15562/bmj.v11i1.2986 (Online Link: http://balimedicaljournal.org/index.php/bmj/article/view/2986).

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Please do not hesitate to contact us if you need anything. It has been a pleasure for us to proofread and edit your work, and we are looking forward to your colleagues and your other papers in the near future.





Commentary

Dear Sir/Madam,

Here are some commentaries to the manuscript entitled "**The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review**"

| No | Section | Commentary |
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| А | Title and | 1. Please write the title using "sentence case" format \rightarrow has |
| | Affiliation | edited by BMJ editor |
| В | Abstract | 1. |
| С | Introduction | 1. Please add more description and urgency about diabetes |
| | | distress and its effect to response therapy of type 2 DM |
| | | patients \rightarrow has edited by author |
| D | Method | 1. If there were any articles with incomplete or insufficient |
| | | data to be extract, was also included in this study? If a |
| | | study does not show the results of the DD Score, can it still |
| | | be included in this systematic review? \rightarrow has edited by |
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| | | 2. Please name the author who carried out the quality |
| | | assessment, as well as data extraction and data analysis \rightarrow |
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| Е | Result | 1. On Table 3, DD score of Nanayakkara et al., 2016, was |
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| | | DD score like any other in that table \rightarrow has edited by |
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| | | each study included in this article \rightarrow has edited by author |
| F | Discussion | 1. Please add more explanation about possible mechanism |
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| G | Conclusions | 1 |
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| | | Ponten et al., showed that fasciocutaneus flap could be |
| | | utilized to cover lower leg soft tissue defects. ¹ |
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| | | 1. Pontén B. The fasciocutaneous flap: its use in soft tissue |
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The Relationship between Diabetes Distress and hba1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review

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> Word count: 5595 Number of Tables: 5 Number of Figures: 2

ABSTRACT

Introduction: The success of therapy did not follow the increasing number of type 2 diabetes mellitus patients. This systematic review aimed to evaluate the relationship between diabetes distress and HbA1c in type 2 diabetes mellitus patients during therapy.

Methods: The authors systematically searched databases (PubMed, Cochrane library, and ScienceDirect) up to January 2021. Articles were screened according to PRISMA 2020 statements. The selection criteria of this study were patients' characteristics, type of therapy, and outcomes.

Results: The search started from 1.303 articles to 17 eligible articles. Furthermore, seventeen studies included 11,976 patients. The mean HbA1c level was around 6.4% to 9.9%. The result of diabetes distress scores were five studies with low scores, eight moderate scores, and two high scores. Emotional burden and regimen-related distress were the highest domain score. Age, health facilities, and type of therapy affected diabetes distress. The correlation between diabetes distress and HbA1c was dominant in the range of 0.15 to 0.26.

Conclusion: Diabetes distress had a low-moderate correlation with HbA1c. The dominant domains were an emotional burden and regiment-related distress. There was two mechanisms effect, direct by hormone and indirect through medication adherence, self-management, and 12 months quality of life.

Keyword: Diabetes Distress, HbA1c, Type 2 Diabetes Mellitus, Therapy

INTRODUCTION

Diabetes is a chronic disease that had caused 1.5 million deaths in 2012, and about 90% of people with diabetes had type 2 diabetes mellitus (T2DM).¹ The improvement of therapy was still low; however, the number of T2DM patients was increasing.²⁻⁴ Physicians, patients, and the healthcare systems were a factor that influenced therapy.⁵ Psychological conditions affected 30% of therapy because they had the role of the patient's condition.⁵ The most common problem is stress. Patients have reached target therapy still less than 50% of the population, mainly in Asia.²⁻⁴ In one hospital in Taiwan, 83.5% of patients did not reach the therapeutic target (HbA1c > 7%).² In South Korea, 55.5% of patients had poor glycemic control (mean HbA1c = 8.08%).³ This finding same within 2013; there was no improvement in reaching therapeutic targets in five years ³. However, Indonesia has the same condition that only 30.8% of patients achieve the targeted therapy.⁴

The DAWN (Diabetes, Attitudes, Wishes, Needs) study conducted a large crosscountry research of patients and healthcare professionals in the management of diabetes.⁶ Diabetes distress (DD) was the most common and interfered with patient self-management.⁶ It was the negative feelings like worries, anxiety, and threats because of diabetes.⁷ The DAWN 1 study, with 5,104 samples from 13 countries, 41% of patients had DD.⁷ The DAWN 2 study was conducted in 18 countries with 8,596 samples, and there were 44.6% DD patients.⁷ Farm et al. found that there was moderate DD in 620 patients in primary clinics and tertiary hospitals in two provinces of Indonesia.⁸

Diabetes distress was a major issue in T2DM patients, and it was a widespread problem.^{9,10} Perrin et al. supported that diabetes distress was under-recognized and inadequately treated in Type 2 diabetes.¹⁰ The growth of diabetes distress from without DD reached around 17% became high DD in 18 months.⁹ The effect of diabetes distress was poor glycemic control, low treatment compliance, poor self-management behavior, and high risky lifestyle behavior.^{9,11} Gonzales et al. found that diabetes distress affects medication adherence and A1C directly or through perceived control.¹²

Diabetes distress and fasting blood sugar have a significant relationship.⁸ In Taiwan, Chen et al. analyzed that diabetes distress with increasing empowerment significantly correlated with blood glucose.² Diabetes distress has a positive correlation that contrasts with empowerment.² Diabetes distress is a psychosocial condition that has a more significant impact than decisional balance for insulin injection, health knowledge, and self-efficacy.

To evaluate the relationship between diabetes distress and HbA1c level in type 2 diabetes mellitus patients during therapy, the authors performed a systematic review to summarize the correlation of two variables. The analysis is according to score instrument, mechanism of correlation in each study, and the factor that affects diabetes distress. The first systematic review analyzes those variables to find effective target intervention.

METHODS

Data sources and searches

Published articles were selected from three databases [PubMed, Cochrane library, and ScienceDirect]. We searched the articles up to January 2021. We used the following keyword ((Type 2 Diabetes Mellitus) OR (T2DM)) AND ((diabetes-related distress) OR (Diabetes distress)) AND (HbA1c) AND (therapy). We exported the studies into Mendeley for managing the references and removing duplicates.

Selection of studies

This systematic review is based on standard preferred reporting items for systematic reviews and meta-analyses (PRISMA) 2020 statements. The flow of articles selection according to this guideline. The articles used English languages and had samples over 19 years old. Microsoft Excel and Mendeley recorded the results, managed references, and eliminated duplicated studies.

The first and second authors independently screened articles. If there were any different opinions between the two authors, we discussed it and asked the third author's opinion until we got a consensus. The selection is according to inclusion and exclusion criteria. The articles chosen were cross-sectional and cohort; the sample age was over 19 years old, HbA1c became an indicator of blood sugar assessment, diabetes distress examining, and an analysis of the relationship between diabetes distress and HbA1c. The exclusion criteria were patient had received psychological therapy and was in a psychotic condition.

Quality Assessment

All authors discussed and assessed the quality of the articles. Quality assessment in cross-sectional and cohort studies using the Newcastle Ottawa Scale. Assessment according to screening, comparability, and outcome in each study. Assessment indicators each aspect for cross-sectional and cohort studies based on validated assessment standards. Ratings each object gets one star and at the end will be total. Total score over 7-8 include good category, 3-6 were fair categories, and <3 were poor categories.

Data extraction and Data analysis

The authors extract data by sorting between study characteristics and outcomes. The indicators taken for study characteristics are study design, place, samples amount, mean age, duration of type 2 diabetes mellitus, therapy method (oral medication, insulin injection, combination, and no medication), and diabetes distress instrument. The outcome table explained the HbA1c level, diabetes distress score, significance level (p-value), and Pearson correlation value (r). The domain of diabetes distress was defined in different tables.

The first author extracted all data. The second and third authors cross-checked data. The second author was concerned about the type of therapy, HbA1c level, demography, and outcomes. The third author specifically checked data about the DD instrument, the score of DD, demography, and outcomes. If there were any articles with incomplete data, all authors

examined the reason and explanation for the missing data from the article. The articles with precise descriptions and supporting the analysis were still included in this systematic review. DD score and HbA1c were required data for analyzing; the authors agreed minimally that the articles statistically explained the correlation, although the articles do not describe the data

Firstly, we separated the tables to analyze the characteristics and outcomes. Furthermore, we analyzed the demography with diabetes distress levels to identify factors that affect diabetes distress—statistic values interpretation like significance level and Pearson correlation between diabetes distress and HbA1c. Next, we determined the flow of the impact of diabetes distress to HbA1c, either direct or indirect. The last result was the aspects that affect diabetes distress and the correlation between diabetes distress and HbA1c. All authors analyzed the correlation of each data and summarized it.

RESULT

Begin with 1,303 studies from 254 in PubMed, 72 in Cochrane library, and 977 in ScienceDirect (Figure 1). A total of 981 studies were removed with automation tools and 47 duplicate studies. Three hundred twenty-two studies were initially screened, and 256 were excluded (Figure 1). There were 66 studies selected according to inclusion and exclusion criteria—three with samples aged under 19 years and duration of diagnosis less than three months. Twenty studies were not cohort or cross-sectional studies. Two studies had not identified the correlation between diabetes distress and HbA1c. HbA1c was not a marker in the two studies. Six studies with samples received a psychological intervention, six studies on depressed patients, and nine studies using diabetes distress as an outcome (Figure 1). The total excluded studies are 49 studies. The number of included studies was 17 studies with 15 cross-sectional studies and two cohort studies. Fourteen studies were a good category, and three other studies had fair from the Newcastle Ottawa Scale assessment (Table 1).

Seventeen studies were selected, and they had 11,976 patients. Sixteen studies with samples from one region and eight studies from Asia (Table 2). One study with samples from 18 countries.¹³ The study sample in this systematic review was 11,976 patients (96.06%) from the initial samples—the dominant study from Asia, eight studies in 7 countries, followed by America. According to data from the diabetes center, one study with varied samples from many nations. This study described data from various health facilities (Table 2). From fifteen studies, five at primary care, one at a healthcare institution, two at hospitals, one at a university hospital, one at endocrinology clinic, one at major medical care, one at diabetes outpatient clinic, and three at diabetes centers. Two other studies in more than one health facility area. There are urban and suburban areas.¹⁴ In addition, there are additions in rural areas.¹⁵

From seventeen studies, six studies had a mean sample age of over 60 years, and one of them reached up to 70 years (Table 2). The other ten studies had ages 50 to 60 years. One further study described the average age with the percentage in each age range, with the dominant age being 50 to 64 years. Fifteen studies reported the duration of the sample undergoing T2DM therapy. A total of nine studies had a duration of more than ten years and six studies with 7 to 10 years.



| Quality Assessment Criteria | Aghili R <i>et al.</i> ,2016 | Asuzu CC <i>et al.</i> ,2017 | Chen SY <i>et al.</i> ,2019 | Chew BH et al.,2018 | Choi WH <i>et al.</i> ,2017 | Darawad MW <i>et al.</i> ,2017 | Hsu <i>et al.</i> ,2018 | Kuniss <i>et al.</i> ,2017 | Lin <i>et al.</i> ,2017 | Linetzky B <i>et al.</i> ,2016 | Lum ZK <i>et al.</i> , 2018 | Mirghani <i>et al.</i> ,2016 | Nanayakkara N <i>et al.</i> , 2016 | Sukkarieh-Haraty O <i>et al.</i> ,2019 | Walker RJ et.al, 2019 | Wardian <i>et al.</i> ,2017 | Winchester RJ et al.,2016 |
|--|------------------------------|------------------------------|-----------------------------|---------------------|-----------------------------|--------------------------------|-------------------------|----------------------------|-------------------------|--------------------------------|-----------------------------|------------------------------|------------------------------------|--|-----------------------|-----------------------------|---------------------------|
| Selection | | - 1 | • | | • | | | | | | | | | | | | |
| Representativene ss of the exposed cases | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Selection of the non-exposed cases | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Ascertainment of exposure | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Selection of outcome parameters clearly specified in methods | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| Comparability | | | | | | | | | | | | | | | | | |
| Study controls for age and sex? | - | - | - | - | - | - | - | - | - | - | - | * | - | - | - | - | - |
| Study controls for the history of HbA1c? | - | - | - | - | * | - | - | - | - | - | - | - | - | - | - | - | - |
| Outcome | | | | | | | | | | | | | | | | | |
| Assessment of outcome? | * | * | * | * | * | - | * | * | * | * | * | * | * | * | * | * | - |
| Was follow-up long enough for outcomes to occur? | - | - | - | * | - | - | * | - | - | - | - | - | - | - | - | - | - |
| Non-response rate | * | * | * | * | * | * | * | * | * | * | * | * | * | - | * | * | * |
| Total score | 7 | 7 | 7 | 8 | 8 | 6 | 8 | 7 | 7 | 7 | 7 | 8 | 8 | 6 | 7 | 7 | 6 |

Table 1: Newcastle Ottawa Scale

| | Table 2. Sui | illiar y Ur | Studies Characteristic | | | |
|----|---------------------------|-----------------|--|------------|------------------------|--------------------------|
| No | Author, year | Study Design | Place (Country; Healthcare) | Sampl e | Mean age (years) | Duration T2DM (vears) |
| 1 | Aghili et | Cross- | Iran [.] Major medical clinic | 380 | 54.73 ± 8.00 | 8.94 ± 6.5 |
| - | al2016 ¹⁶ | Sectional | | 200 | 0.000 | 0.5 1 0.0 |
| 2 | Asuzu et | Cross- | Southeastern United States: | 615 | 61.3 ± 10.9 | 12.3 ± 9.1 |
| _ | al2017 ¹⁷ | sectional | Primary care | | | |
| 3 | Chen et | Cross- | Taiwan: Endocrinology | 255 | 56.58 ± 10.92 | 13.37 ± 8.87 |
| - | al2019 ² | sectional | clinic | | | |
| 4 | Chew et | Cross- | Malavsia: Urban, suburban. | 338 | 60.6 ± 10.1 | 9.8 ± 5.9 |
| | al.,201815 | Sectional | and rural health clinics | | | |
| 5 | Cl : (1 00103 | Cross- | South Korea, University | 171 | 59.55 ± 9.75 | 12.36 ± 8.53 |
| | Choi et al., 2018^3 | sectional | hospital | | | |
| 6 | Darawad et | Cross- | Jordania; Hospital | 325 | 55.3 ± 13.2 | NR |
| | al.,201718 | sectional | · • | | | |
| 7 | Hay at al 201919 | Cross- | Southern Taiwan; Diabetes | 382 | 58.78 ± 11.48 | 10.03 ± 7.29 |
| | HSu et al.,2018 | Sectional | Outpatient clinic | | | |
| 8 | Kuniss et | Cohort | Germany; Primary care | 336 | 72.3 ± 9.7 | 12.4 ± 10.2 |
| | al.,201720 | | | | | |
| 9 | Lin et al. 2017^{14} | Cross- | China; Suburban and urban | 254 | 55.26 ± 0.63 | 8.15 ± 0.42 |
| | Lin et al.,2017 | Sectional | outpatient departement | | | |
| 10 | Linetzky et | Cross- | Argentina, Brazil, Canada, | 4341 | 61.77 ± 11.02 | 12.65 ± 7.98 |
| | al.,2017 ¹³ | sectional | China, Germany, India, | | | |
| | | | Israel, Italy, Japan, Mexico, | | | |
| | | | Russia, Saudi Arabia, South | | | |
| | | | Korea, Spain, Turkey, | | | |
| | | | United Arab Emirates, UK, | | | |
| | | | and United States, including | | | |
| | | ~ | Puerto Rico; Primary care | | | |
| 11 | Lum et al., | Cross- | Singapore; Healthcare | 246 | 59.9 ± 7.6 | 9.4 ± 8.8 |
| | 201821 | sectional | Institution | 0.0 | 50 (1) 0 (0 | 0.14 - 0.1 |
| 12 | Mirghani, | Cross | Sudan; Diabetes center | 89 | 59.64 ± 9.60 | 9.14 ± 8.1 |
| 10 | 2016 ²² | sectional | | 2552 | (2 + 12) | 10 + 10 |
| 13 | Nanayakkara et | Cross | Australia; Diabetes center | 2552 | 63 ± 13 | 12 ± 10 |
| 14 | $a_{1,2016^{23}}$ | sectional | Tahawaya II awital | 200 | 50 04 + 12 40 | 7.02 |
| 14 | Sukkarien- | Cross | Lebanon, Hospital | 280 | 38.24 ± 13.48 | 1.85 |
| | Haraty et | sectional | | | | |
| 15 | Wallser et al | Cross | United States: Drimony care | 615 | 61.2 ± 10.0 | 12.2 ± 0.1 |
| 15 | 2010^{25} | closs | United States, Finnary care | 015 | 01.5 ± 10.9 | 12.5 ± 9.1 |
| 16 | 2019 Wardian et | Cohort | United States: Diabetes | 126 | 50.0 | 16.0 |
| 10 | v and all et | Conort | center | 430 | 59.9 | 10.9 |
| 17 | ui.,2017 Winchester et | Cross | United States: Primary clinic | 361 | 18_49 years (10.6%) | NP |
| 1/ | 2016^{27} | sectional | Onice States, I finary clinic | 501 | 50-64 years (10.070) | INIX |
| | u1.,2010 | sectional | | | 65-74 years (29.1%) | |
| | | | | | 75_{89} vers (17 3%) | |
| | | | | | (17.370) | |

Table 2. Summary of Studies Characteristic

Abbreviation: NR: Not Reported

Not all studies report the type of therapy patients. Eleven studies described the percentage of patients who did therapy into four categories (Table 3). Two studies had total samples that were all insulin or oral medication.^{13,24} There were three studies with samples in four categories; 2 studies were dominant with oral antihyperglycemic therapy samples, and 1 study was diet alone. The other five studies were in only two types; 3 were predominant with oral antihyperglycemic, 1 study in combination, and one on insulin therapy. One study reported a disproportionate sample percentage of 90% in oral antihyperglycemic therapy but about 57% in another category.¹⁵

Table 3. Summary of Type Therapies Studies

| | | Therapy (%) | | | | | | | | |
|--------|--|------------------------|---------------------------|---------|-----------------------------|--|--|--|--|--|
| N 0 | Author,year | Oral medicatio n | Insulin ± oral medication | Insulin | No Medication/ Diet only | | | | | |
| 1 | Aghili et al.,2016 ¹⁶ | 54,80% | 38,40% | 5% | 1,80% | | | | | |
| 2 | Asuzu et al.,2017 ¹⁷ | NR | NR NR | | NR | | | | | |
| 3 | Chen et al.,2019 ² | NR | 72,90% | 27,10% | NR | | | | | |
| 4 | Chew et al.,2018 ¹⁵ | 90% | NR | 47,50% | 10,94% | | | | | |
| 5 | Choi et al.,2018 ³ | 64,30% | 35,70% | - | - | | | | | |
| 6 | Darawad et al.,2017 ¹⁸ | NR | NR | NR | NR | | | | | |
| 7 | Hsu et al.,2018 ¹⁹ | NR | NR | NR | NR | | | | | |
| 8 | Kuniss et al.,2017 ²⁰ | 26,20% | 14% | 17,80% | 42,00% | | | | | |
| 9 | Lin et al.,2017 ¹⁴ | 59,50% | 40,50% | - | - | | | | | |
| 10 | Linetzky et al.,2017 ¹³ | NR | NR | 100% | NR | | | | | |
| 11 | Lum et al., 2018 ²¹ | 60,60% | 29,30% | 1,60% | 8,50% | | | | | |
| 12 | Mirghani, 2016 ²² | 91,10% | NR | 8,90% | NR | | | | | |
| 13 | Nanayakkara et al.,2016 ²³ | NR | NR | 74% | 26% | | | | | |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁴ | 100% | NR | NR | NR | | | | | |
| 15 | Walker et.al, 2019 ²⁵ | NR | NR | NR | NR | | | | | |
| 16 | Wardian et al.,2017 ²⁶ | NR | NR | 56,90% | 17,60% | | | | | |
| 17 | Winchester et al.,2016 ²⁷ | NR | NR | NR | NR | | | | | |

Abbreviation:

NR: Not Reported

Twelve studies used the 17-DDS instrument (Table 4). Three of them use other countries' versions, such as Korean, Arabic, and Chinese. Four other studies used the PAID Scale, and two of them were Chinese versions. One recent study used 12 DFS-Ars to assess a patient's level of distress.

The outcomes of studies were diabetes distress score, HbA1c level, significant (p-value), and Pearson correlation (r). The diabetes distress score is related to the instrument so that the mean and indicator are different. Two studies did not report mean DD scores. However, Aghili et al. still wrote the result of diabetes distress statistics.¹⁶ Sukkarieh-Haraty et al. published the analysis of distress in a statistic.²⁴ One study reported the percentage of samples that scored 0-3 (65%) and >3 (2%) because there were two sample categories and

there is no data as a mean score. Seven of the 14 studies included low DD levels, the other five studies were moderate, and two studies had high DD levels.

The target of therapy is HbA1c below 7%. Only one study reported reaching the target.²⁰ Another 14 studies had a mean HbA1c above 7% (Table 4). There is one study that reported the percentage of HbA1c >7% (64%) and HbA1c <7% (36%). One study did not record HbA1c levels. Sixteen studies were significant, and one other study was not significant in total diabetes distress score.²² Ten studies described the correlation between HbA1c and DD with the Pearson correlation. Two other studies are not directly related.^{14,19} The other five studies did not report any correlation values. One high correlation study (0.69), 3 moderate correlation studies (0.2-0.5), and 6 low correlation studies (< 0.2).

| Ne | Authorwood | DD Instrument | DD Score | HbA1c | Outcomes | | |
|-----|--|------------------------------------|--|------------------------|----------|-------|--|
| INU | Author,year | DD Instrument | (/max score) | (% (mmol)) | p-value | r | |
| 1 | Aghili et al.,2016 ¹⁶ | DDS17 | NR | 7.78 ± 1.7 (62) | < 0.001 | 0.173 | |
| 2 | Asuzu et al.,2017 ¹⁷ | DDS17 | $1.6 \pm 0.7/6$ (low) | 7.9 ± 1.8 (63) | < 0.001 | 0.69 | |
| 3 | Chen et al.,2019 ² | Short-Form PAID Scale (Chinese) | 10.98/32 (low) | 8.33 ± 1.49 (68) | < 0.05 | 0.144 | |
| 4 | Chew et al.,2018 ¹⁵ | DDS17 | $2.3 \pm 1.4/6$ (moderate) | 8.3 (67) | < 0.05 | NR | |
| 5 | Choi et al.,2018 ³ | DDS17 (Korean) | $2.25 \pm 0.56/6$ (moderate) | 7.37 ± 1.27 (57) | < 0.05 | NR | |
| 6 | Darawad et al.,2017 ¹⁸ | DDS17 (Arab) | $47.2 \pm 14.5/85$ (high) | 7.88 ± 1.78 (63) | < 0.05 | 0.153 | |
| 7 | Hsu et al.,2018 ¹⁹ | PAID Scale (Chinese) | 7.61 ± 7.02 / 32 (low) | 7.39 ± 1.11 (57) | < 0.01 | NR* | |
| 8 | Kuniss et al.,2017 ²⁰ | PAID scale | $3.9 \pm 7.0/43.75$ (low) | 6.4 ± 1.0 (46) | < 0.001 | 0.253 | |
| 9 | Lin et al.,2017 ¹⁴ | DDS17 (Chinese) | $38.94 \pm 0.81/90$ (low) | >7% = 64% <7% = 36% | < 0.01 | NR* | |
| 10 | Linetzky et al.,2017 ¹³ | DDS17 | $2.27 \pm 1.13/6$ (moderate) | 8.13 ± 1.75 (65) | < 0.01 | 0.171 | |
| 11 | Lum et al., 2018 ²¹ | PAID Scale | 26.2/80 (moderate) | 8.6 ± 1.5 (70) | < 0.01 | 0.235 | |
| 12 | Mirghani, 2016 ²² | DDS17 | 3.67 ± 0.64 (high) | 9.9 ± 2.60 (85) | >0.05 | 0.176 | |
| 13 | Nanayakkara et al.,2016 ²³ | DDS17 | 0-3 (65%) >3 (2%) (dominant low) | 8±2 (64) | < 0.001 | NR | |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁴ | 12-item DFS-Ar | NR | 7.73 ± 2.2 (61) | < 0.05 | NR | |
| 15 | Walker et.al, 2019 ²⁵ | DDS17 | $1.6 \pm 0.7/6$ (low) | 7.9 ± 1.8 (63) | < 0.001 | 0.25 | |
| 16 | Wardian et al.,2017 ²⁶ | DDS17 | 2.8/6 (moderate) | 8.38 (68) | < 0.05 | NR | |
| 17 | Winchester et al.,2016 ²⁷ | DDS17 | 1.4/6 (low) | NR | < 0.05 | 0.179 | |

Table 4. Summary of variables result and outcome studies

Abbreviation: (*): No direct correlation NR: Not Reported DDS17: 17-item Diabetes Distress Scale PAID Scale: Problem Areas in Diabetes scale 12-item DFS-Ar: The **12**- item Diabetes Fatalism Scale- Arabic The graphic presents two variables with a horizontal line of diabetes distress score and a vertical line of HbA1c level (%) (Figure 2). The red vertical line is the mark for the diabetes distress category—the horizontal line is an HbA1c target mark. Nine of 12 studies support that the high diabetes distress score has a high HbA1c (Figure 2). One study with high diabetes distress and HbA1c level.²² Seven studies have moderate diabetes distress with HbA1c level >7%.^{2,3,13,15,18,21,26} In one study, the result was low diabetes distress with HbA1c level <7%.²⁰ The other 3 studies have opposite results, low diabetes distress, but the HbA1c level >7%.^{17,19,25}



Figure 2. Graphic Diabetes distress score and HbA1c level

Diabetes distress has four domains; emotional burden, physician-related distress, regimen-related distress, and interpersonal distress (Table 5). Four studies listed the mean score, and two of them also recorded the correlation between HbA1c and DD. The four studies show the mean value of DD, which is medium and high. Both studies had low correlations for HbA1c in the EB and RD domains and low values in the other two domains. The value of all studies is significant.

| | | | Domain Diabetes Distress | | | | | | | |
|--------|-----------------------------------|---|---------------------------------|-------------------------------|--------|------------------------------|-------|------------------------|------------|--------|
| N 0 | Author, year | Emotional Burden | | Physician-related distress | | Regimen- related distress | | Interpersonal distress | | р |
| | | Mean | r | Mean | r | Mean | r | Mean | r | |
| 1 | Choi et al.,2018 ³ | 2.46 | NR | 1.86 | NR | 2.41 | NR | 2.14 | NR | < 0.05 |
| 2 | Darawad et al.,2017 ¹⁸ | 15.2 | 0.193 | 10 | -0.017 | 14 | 0.151 | 7.1 | -0.04 | < 0.05 |
| 3 | Mirghani, 2016 ²² | $\begin{array}{c} 4.08 \pm \\ 0.88 \end{array}$ | 0.221 | 3.75 ± 1.13 | -0.009 | 3.35 ± 1.43 | 0.331 | 3.445 ± 0.92 | - 0.129 | < 0.05 |
| 4 | Wardian et al.,2017 ²⁶ | 2.108 ± 1.15 | NR | 1.261 ± 0.76 | NR | 2.137 ± 1.06 | NR | 1.50 ± 0.89 | NR | < 0.05 |

 Table 5. Summary of diabetes distress domain

Abbreviation:

NR: Not Reported

DISCUSSION

This systematic review presents a significant relationship between diabetes distress and HbA1c levels. Only Mirghani et al. had result significant correlation with the domain score but not the total score.²² Emotional burden and regimen-related distress are strong predictors of glycemic control.²² The dominant low correlation because HbA1c level is affected by diabetes distress and other factors. However, diabetes distress is a strong determinant compared with other psychosocial such as depression. Lee et al. supported diabetes distress as an effective target intervention to improve glycemic control.²⁸ Ten of 17 studies found that DD was directly positively correlated with HbA1c level. Diabetes distress can increase the cortisol hormone, which suppresses insulin production.² The impact of low insulin is increasing HbA1c. Nevertheless, Chew et al. did not find a correlation between diabetes distress and HbA1c level.¹⁵ Differences in population culture such as family, social network, and health mindset influenced stress and glycemic control.¹⁵

Five of 17 studies found that medication adherence is a mediator between diabetes distress and HbA1c level. Medication adherence is the most specific and easy adherence practice in therapy.¹⁶ High diabetes distress enhances poor medication adherence then, it will increase HbA1c levels.^{13,15,16} Medication adherence is the critical role of treatment, so failing this step will disturb T2DM therapy. Mirghani et al.'s finding supported that T2DM patients feel desperate and overwhelmed with this condition.²² It induced poor adherence and concerned poor glycemic control. Diabetes distress affects self-efficacy, then the impact is 0.26 points of self-management.¹⁴ Self-management influenced the HbA1c level.¹⁴ It was consistent with studies in China and Thailand that self-management was the key in diabetes management and a predictor of blood glucose.²⁹ Interventions in self-management can be effective because improving it one point, reducing the risk of suboptimal T2DM therapy.¹⁴ Twelve months of quality of life (QoL) months also mediates the two variables in two of 17 studies. Diabetes distress affects QoL through life satisfaction and motivation, so it takes time before the HbA1c level.¹⁹ Diabetes distress disturbs self-care in the long term. The impact of low self-care on HbA1c is disturbing diet, exercise, and blood glucose management. If it is less than six months, the effect of diabetes distress is not apparent, especially when the level of diabetes distress is still low.

Emotional burden and regimen-related distress are two dominant domains in diabetes distress. They can be strong predictors of glycemic control. Emotional burden present in patients who feel hard to do routines as type 2 diabetes mellitus patients and the lack of social support will reinforce this.^{24,26} The regimen-related distress is identical to being irregular in monitoring blood glucose and therapy so that it is related to the type of therapy.^{3,26} Physician-

related distress through hurried communication disturbs glycemic control because the patients do not understand what to do.¹³ High emotional burden and regimen-related distress will suppress glycemic control, and the HbA1c will increase.^{17,18}

Age significantly affects the level of diabetes distress. The higher risk of diabetes distress, the younger the patient is first diagnosed with type 2 diabetes.¹⁶ Seven of 17 studies have the same finding.^{3,14,18,20-22,26} T2DM patients during working age will inhibit activities and disturb need compliance. The longer the duration of experiencing type 2 DM, the higher the DD score.²⁰ However, Wardian et al. supported this statement.²⁶ Previous studies did not show the same result because those conclusions were from some sample groups.²⁰ This finding aligns with other studies that duration does not affect DD but can affect self-care.^{18,19}

The finding of the present systematic review is different from the previous study about the effect of the level of health facilities on diabetes distress. In primary care, the level of diabetes distress is low. The glycemic control is better than the secondary or tertiary level because, at the tertiary level, the patient has blood sugar levels that are more uncontrolled.^{14,20} Nevertheless, primary care has a higher level of distress because it is associated with physician capability in the previous study.⁸ The difference in findings is because each country has different standards of health care facilities.

The type of patient therapy can affect the level of diabetes distress. The type of therapy is the group of regimen-related distress. In patients who use therapy, there is a tendency for high levels of distress because it is related to strictness in the use of insulin, namely in terms of time, dose, and fear of hypoglycemia.^{2,26} Patients with combination therapy need accuracy in insulin therapy and consume oral antihyperglycemic drugs.³ Therefore, the type of therapy does not explicitly affect diabetes distress because each treatment has some concerns. The patients will feel anxiety and stress if they do therapy for a long time, whatever the type of therapy.

This systematic review implies that diabetes distress is significantly related to HbA1c with low correlation. Nevertheless, it can be the target of intervention and improve the success of therapy. The first limitation of this study is that it does not proceed to a metaanalysis due to the various types of studies and instruments. By analysis with the metaanalysis, it will be more quantitative to see the correlation of two variables and the effect of diabetes distress on HbA1c. Second, the correlation between the two dominant variables is weak, so further research is needed. The other causes because HbA1c is not only affected by psychological conditions but many factors.

CONCLUSIONS

In this study, diabetes distress and HbA1c have a low-moderate relationship, but it can be the effective target intervention for improving type 2 diabetes mellitus therapy. Diabetes distress has one direct mechanism through hormones. The indirect effect of diabetes distress is through medication adherence, self-management, and 12 months quality of life. Age, health facilities, and type of therapy can affect diabetes distress. Furthermore, emotional burden and regimen-related distress are the most dominant domain in diabetes distress, and they can be the specific target for intervention.

FUNDING

This study did not receive any funds from funding agencies, commercial or another sector.

CONFLICT OF INTEREST

The authors declared there is no conflict of interest regarding this study between authors and other organizations or people that influence the objectivity of research.

AUTHOR CONTRIBUTOR

The first and third authors created and discussed the concept. The first and second authors created the studies design and searched literature with selected articles. All authors analyzed the result and wrote some notes. After we concluded the last analysis, the first author wrote and prepared the manuscript. The second and third authors reviewed and evaluated it.

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Journal Website: https://www.balimedicaljournal.o rg/index.php/bmj Invoice no: **2986-22032022** Invoice date: **March 22^{nd,} 2022** Recent Status: **Unpaid** Submission due date: **Valid until March 29^{th,} 2022**

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|---|----------|------------|------------|
| Basic Administration and Article Processing Charge | 1 | USD 1000 | USD 1000 |
| "The Relationship between Diabetes Distress and hba1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review" | | | |
| Proofread, editing, and reviewing of Manuscript | 1 | USD 100 | USD 100 |
| | • | Subtotal | USD 1100 |
| | | Tax (0,5%) | USD 1105,5 |
| | | Total | USD 1105,5 |

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Notes: *Letter of Acceptance* (LoA) of publication include with Volume, Issues, year of publication, and DOI number of the manuscript will be processed soon after full payment.

The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review

by Wibowo Zefo Kiyosi

Submission date: 05-Mar-2022 10:55PM (UTC+0700) Submission ID: 1777143840 File name: 2986-10606-1-RV.docx (256.84K) Word count: 4916 Character count: 27432 The Relationship between Diabetes Distress and HbA1c Level in Type 2 Diabetes Mellitus Therapy Patients: A Systematic Review

Relationship Diabetes Distress and HbA1c

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22Vord count: 4970 Number of Tables: 4 Number of Figures: 2

ABSTRACT

Introduction: The number of diabetics was not followed by the success of therapy. This study aimed to evaluate the relationship between diabetes distress and HbA1c in type 2 diabetes mellitus patients during therapy.

Methods: The authors systematically searched databases (PubMed, Cochrane library, and ScienceDirect) up to January 2021. Articles were screened according to PRISMA 2020 statements. Characteristics of patients, type of therapy, and outcomes correlation were described as selection criteria.

Results: The search started from 1.303 articles to 17 eligible articles. Furthermore, seventeen articles were reviewed, and they included 11,976 patients. The mean HbA1c level was around 6.4% to 9.9%. The result of diabetes tress scores were five studies with low scores, eight moderate scores, and two high scores. Emotional burden and regimen-related distress were the highest domain score. Ag, health facilities, and type of therapy had a role in diabetes distress. The range of correlation between diabetes distress and HbA1c was dominant in the range 0.15 to 0.26.

Conclusion: Diabetes distress had a low-moderate correlation with HbA1c. The dominant domains were emotional burden and regiment-related distress. There was two mechanisms effect, direct by hormone and indirect through medication adherence, self-management, and 12 months quality of life.

Keyword: Diabetes Distress, HbA1c, Type 2 Diabetes Mellitus, Therapy

INTRODUCTION

Diabetes is a chronic disease that had caused 1.5 million deaths in 2012 and about 90% of people with diabetes had type 2 diabetes mellitus (T2DM).¹ The improvement of therapy was still low, whereas the number of T2DM patients was increasing.²⁻⁴ Physicians, patients, and the healthcare systems were a factor that influenced therapy.⁵ Psychological conditions affected 30% of therapy because it had the role of the patient's condition.⁵ The most common psychological problem is stress.

Patients have reached target therapy still less than 50% of the population, mainly in Asia.²⁻⁴ In one hospital in Taiwa1183.5% of patients did not reach the therapeutic target (HbA1c > 7%).² In South Korea, 55.5% of patients had poor glycemic control (mean HbA1c = 8.08%).³ It was the same with research in 2013; there was no improvement in reaching therapeutic targets in five years ³. However, Indonesia has the same condition that only 30.8% of patients achieve the targeted therapy.

The DAWN (Diab 142s, Attitudes, Wishes, Needs) study conducted a large cross-country research of patients and healthcare professionals in the management of diabetes.⁶ Diabetes distress was the most common happened and interfered with patient self-management.⁶ Diabetes distress was the negative feelings like worries, anxiety, and threats because of diabetes.⁷ In the DAWN 1 study with 5,104 samples from 13 countries, 41% of patients had diabetes distress.7 The DAWN 2 study was conducted in 18 countries with 8,596 samples, and there were 44.6% diabetes distress patients.⁷ In Indonesia, there was moderate diabetes distress in 620 patients in primary clinics and tertiary hospitals in East Java and Central Java.⁸

Diabetes distress and fasting blood sugar have a significant relationship in Indonesia.⁸ In another study in Taiwan, diabetes distress with increasing empowerment significantly correlated with blood glucose.² Diabetes distress has a positive correlation that contrasts with the effect of emports rment.² Diabetes distress is a psychosocial condition that has a more significant impact than decisional balance for insulin injection, health knowledge, and selfefficacy.

To evaluate the relationship between diabetes dissess and HbA1c level in type 2 diabetes mellitus patients during therapy, the researchers performed a systematic review to summarize the correlation of two variables. The analysis is according to score instrument, mechanism of correlation in each study, and the factor that affects diabetes distress. It is the first systematic review that analyzes those variables to find effective target intervention.

METHODS

Data sources and searches

Published articles were selected from three databases [PubMed, Cochrane library, and ScienceDirect]. We searched the articles up to January 2021. We used the following keyword ((Type 2 Diabetes Mellitus) OR (T2DM)) AND ((diabetes-related distress) OR (Diabetes distress)) AND (HbA1c) AND (therapy). We exported the studies into Mendeley for managing the references and removing duplicates.

Selection of studies

This systematic review was selected based on standard preferred reporting items for systematic reviews and meta-analyses (PRISMA) 2020 statements. The flow of articles selection was described in this guideline. The articles used English languages and had samples over 19 years old. The results were recorded using Microsoft Excel and Mendeley to manage references and eliminate duplicated studies.

The first and second authors independently screened articles. If there were any different opinions between the two authors are discussed it and asked the third author's opinion until we got a consensus. The selection is based on inclusion and exclusion criteria. The articles chosen were cross-sectional and cohort; the sample age was over 19 years old, HbA1c became an indicator of blood sugar assessment, diabetes distress was assessed, and there was an analysis of the relationship between diabetes distress and HbA1c. The exclusion criteria were patient had received psychological therapy and was in a psychotic condition.

Quality Assessment

Quality assessment in cross-sectional and cohort studies using the Newcastle Ottawa Scale. Assessment according to screening, comparability, and outcome in each study. Assessment indicators each aspect for cross-sectional and cohort studies based on validated assessment standards. Ratings each object gets one star and at the end will be total. Total score over 7-8 include good category, 3-6 were fair categories, and <3 were poor categories.

Data extraction and Data analysis

Data were extracted by sorting between study characteristics and outcomes. The indicators taken for study characteristics are study design, place, samples amount, mean age, duration of type 2 diabetes mellitus, therapy method (oral medication, insulin injection, combination, and no medication), and diabetes distress instrument. The outcome table explained the HbA1c level, diabetes distress score, significance level (p-value), and Pearson correlation value (r). The domain of diabetes distress was defined in different tables.

Firstly, we separated the tables to analyze the characteristics and outcomes. Furthermore, we analyzed the demography with diabetes distress levels to identify factors that affect diabetes distress—statistic values interpretation like significance level and Pearson correlation between diabetes distress and HbA1c. Next, we determined the flow of the impact 25 diabetes distress to HbA1c, either direct or indirect. The last result was the aspects that affect diabetes distress and the correlation between diabetes distress and HbA1c.

RESULT

Of 1,303 studies from 254 in PubMed, 72 in Cochrane library, and 977 in ScienceDirect (Figure 1). A total of 981 studies were removed with automation tools and 47 duplicate studies. A total of 322 were initially screened, and 256 studies were excluded (Figure 1). There were 66

studies selected according to inclusion and exclusion criteria. Three studies with samples aged under 19 years and duration of diagnosis less than three months. Twenty studies were naccohort or cross-sectional studies. HbA1c was not a marker in the two studies. Correlation between diabetes distress and HbA1c was not identified in the two studies. Six studies with sample studies receiving a psychological intervention, six studies on depressed patients, and nine studies. The number of included studies was 17 studies with 15 cross-sectional studies and two cohort studies. Fourteen studies were included in the good category and three were considered fair category from the Newcastle Ottawa Scale assessment.

Seventeen studies were selected, and they had 11,976 patients. Sixteen studies with samples from one region and eight studies were conducted in Asia (Table 1). One study with samples from 18 countries.⁹ The study sample in this systematic review was 11,976 patients (96.06%) from the initial samples—the dominant study from Asia, eight studies in 7 countries, followed by America. One study was according to data from the diabetes centre with varied samples from many nations. Data were collected from various health facilities (Table 1). From fifteen studies, five at primary care, one at a healthcare institution, two at hospitals, one at a university hospital, one at endocrinology clinic, one at major medical care, one at diabetes outpatient clinic, and three at diabetes centres. Two other studies were conducted in more than one area of the health facility. There are urban and suburban areas.¹⁰ In addition, there are additions in rural areas.¹¹

From seventeen studies, six studies had a mean sample age of over 60 years, and one of them reached up to 70 years (Table 1). The other ten studies had ages 50 to 60 years. One further study described the average age with the percentage in each age range, with the dominant age being 50 to 64 years. Fifteen studies reported the duration of the sample undergoing T2DM therapy. A total of nine studies had a period of more than ten years. The other six studies interval 7 to 10 years.



Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020

| | Table 1. Sum | nary of S | tudies Characteristic | | | |
|----|---|---------------------|--|--------|--|--------------------------|
| No | Author, year | Study Design | Place (Country; Healthcare) | Sample | Mean age (years) | Duration T2DM (years) |
| 1 | Aghili et al.,2016 ¹² | Cross- Sectional | Iran; Major medical clinic | 380 | 54.73 ± 8.00 | 8.94 ± 6.5 |
| 2 | Asuzu et al. 2017 ¹³ | Cross- sectional | Southeastern United States; Primary care | 615 | 61.3 ± 10.9 | 12.3 ± 9.1 |
| 3 | Chen et $a1.2019^2$ | Cross- sectional | Taiwan; Endocrinology | 255 | 56.58 ± 10.92 | 13.37 ± 8.87 |
| 4 | Chew et al. 2018 ¹¹ | Cross- Sectional | Malaysia; Urban, suburban and rural health clinics | 338 | 60.6 ± 10.1 | 9.8 ± 5.9 |
| 5 | Choi et al.,2018 ³ | Cross- sectional | South Korea, University | 171 | 59.55 ± 9.75 | 12.36 ± 8.53 |
| 6 | Darawad et al.,2017 ¹⁴ | Cross- sectional | Jordania; Hospital | 325 | 55.3 ± 13.2 | NR |
| 7 | Hsu et al.,2018 ¹⁵ | Cross- Sectional | Southern Taiwan; Diabetes Outpatient clinic | 382 | 58.78 ± 11.48 | 10.03 ± 7.29 |
| 8 | Kuniss et al.,2017 ¹⁶ | Cohort | Germany; Primary care | 336 | 72.3 ± 9.7 | 12.4 ± 10.2 |
| 9 | Lin et al.,201710 | Cross- Sectional | China; Suburban and urban outpatient departement | 254 | 55.26 ± 0.63 | 8.15 ± 0.42 |
| 10 | Linetzky et al.,2017 ⁹ | Cross- sectional | 7 gentina, Brazil, Canada, China, Germany, India, Israel, Italy, Japan, Mexico, Russia, Saudi Arabia, South Korea, Spain, Turkey, United Arab Emirates, UK, and US, including Puerto Rico; Primary care | 4341 | 61.77 ± 11.02 | 12.65 ± 7.98 |
| 11 | Lum et al., 2018 ¹⁷ | Cross- sectional | Singapore; Healthcare Institution | 246 | 59.9 ± 7.6 | 9.4 ± 8.8 |
| 12 | Mirghani, 2016 ¹⁸ | Cross sectional | Sudan; Diabetes center | 89 | 59.64 ± 9.60 | 9.14 ± 8.1 |
| 13 | Nanayakkara et al.,2016 ¹⁹ | Cross sectional | Australia; Diabetes center | 2552 | 63 ± 13 | 12 ±10 |
| 14 | Sukkarieh- Haraty et al.,2019 ²⁰ | Cross sectional | Lebanon; Hospital | 280 | 58.24 ± 13.48 | 7.83 |
| 15 | Walker et.al, 2019 ²¹ | Cross sectional | United States; Primary care | 615 | 61.3 ± 10.9 | 12.3 ± 9.1 |
| 16 | Wardian et al.,2017 ²² | Cohort | United States; Diabetes center | 436 | 59.9 9 | 16.9 |
| 17 | Winchester et al.,2016 ²³ | Cross- sectional | United States; Primary clinic | 361 | 18–49 years (10.6%) 50–64 years (43.0%) 65–74 years (29.1%) 75–89 years (17.3%) | NR |

Abbreviation:

NR: Not Reported

Not all studies report the type of therapy patients. Eleven studies described the percentage of patients who did therapy into four categories (Table 2). Two studies had total samples that were all insulin or oral medication.⁹²⁰ There were 3 studies with samples in four categories; 2 studies were dominant with oral antihyperglycemic therapy samples, and 1 study was diet alone. The other five studies were in only two types; 3 were predominant with oral antihyperglycemic, 1 study in combination, and 1 on insulin therapy. One study reported a disproportionate sample percentage of 90% in oral antihyperglycemic therapy but about 57% in another category.11



| | | Therapy (%) | | | | | | | |
|----|--|-----------------|---------------------------|---------|-----------------------------|--|--|--|--|
| No | Authoryear | Oral medication | Insulin ± oral medication | Insulin | No Medication/ Diet only | | | | |
| 1 | Aghili et al.,2016 ¹² | 54,80% | 54,80% 38,40% | | 1,80% | | | | |
| 2 | Asuzu et al.,2017 ¹³ | NR | NR | NR | NR | | | | |
| 3 | Chen et al.,2019 ² | NR | 72,90% | 27,10% | NR | | | | |
| 4 | Chew et al.,201811 | 90% | NR | 47,50% | 10,94% | | | | |
| 5 | Choi et al.,2018 ³ | 64,30% | 35,70% | - | - | | | | |
| 6 | Darawad et al.,2017 ¹⁴ | 8 NR | NR | NR | NR | | | | |
| 7 | Hsu et al.,2018 ¹⁵ | NR | NR | NR | NR | | | | |
| 8 | Kuniss et al.,2017 ¹⁶ | 26,20% | 14% | 17,80% | 42,00% | | | | |
| 9 | Lin et al.,2017 ¹⁰ | 59,50% | 40,50% | - | | | | | |
| 10 | Linetzky et al.,20179 | 8 NR | NR | 100% | NR | | | | |
| 11 | Lum et al., 2018 ¹⁷ | 60,60% | 29,30% | 1,60% | 8,50% | | | | |
| 12 | Mirghani, 2016 ¹⁸ | 91,10% | NR | 8,90% | NR | | | | |
| 13 | Nanayakkara et al.,2016 ¹⁹ | NR | NR | 74% | 26% | | | | |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁰ | 100% | NR | NR | NR | | | | |
| 15 | Walker et.al, 2019 ²¹ | NR | NR | NR | NR | | | | |
| 16 | Wardian et al.,2017 ²² | NR | NR | 56,90% | 17,60% | | | | |
| 17 | Winchester et al.,2016 ²³ | 8 NR | NR | NR | NR | | | | |

Table 2. Summary of Type Therapies Studies

Abbreviation:

NR: Not Reported

Twelve studies used the 17-DDS instrument (Table 3). Three of them use other countries' versions, such as Korean, Arabic, and Chinese. Four other studies used the PAID Scale, and two of them were Chinese versions. One recent study used 12 DFS-Ars to assess a patient's level of distress.

The outcomes of studies were diabetes distress score, HbA1c level, significant (p-value), and Pearson correlation (r). The diabetes distress score is related to the instrument so that the mean and indicator are different. Two studies did not report mean DD scores. One study wrote in specific the percentage of samples that scored 0-3 (65%) and >3 (2%). Seven of the 14

studies included low DD levels, the other five studies were moderate, and two studies had high DD levels.

The target of therapy is HbA1c below 7%. Only one study reported reaching the target.¹⁶ Another 14 studies had a mean HbA1c above 7% (Table 3). There is one study that reported the percentage of HbA1c >7% (64%) and HbA1c <7% (36%). One study did not record HbA1c levels. Sixteen studies were significant, and one other study was not significant in total diabetes distress score.¹⁸ The correlation between HbA1c and DD was described in 10 studies with the Pearson correlation. Two other studies are not directly related.^{10,15} The other five studies did not report any correlation values. One high correlation study (0.69), 3 moderate correlation studies (0.2-0.5), and 6 low correlation studies (< 0.2).

| No | Anthon yoon | DD Instrument | DD Score | HbA1c | Outcomes | |
|----|--|------------------------------------|---------------------------------|------------------------|----------|-------|
| NO | Author,year | DD Instrument | (/max score) | (% (mmol)) | p-value | r |
| 1 | Aghili et al.,201612 | DDS17 | NR | 7.78 ± 1.7 (62) | <0.001 | 0.173 |
| 2 | Asuzu et al.,2017 ¹³ | DDS17 | 1.6 ± 0.7/6 (low) | 7.9 ± 1.8 (63) | <0.001 | 0.69 |
| 3 | Chen et al.,2019 ² | Short-Form PAID Scale (Chinese) | 10.98/32 (low) | 8.33 ± 1.49 (68) | < 0.05 | 0.144 |
| 4 | Chew et al.,201811 | DDS17 | $2.3 \pm 1.4/6$ (moderate) | 8.3 (67) | <0.05 | NR |
| 5 | Choi et al.,2018 ³ | DDS17 (Korean) | $2.25 \pm 0.56/6$ (moderate) | 7.37 ± 1.27 (57) | <0.05 | NR |
| 6 | Darawad et al.,2017 ¹⁴ | DDS17 (Arab) | 47.2 ± 14.5/85 (high) | 7.88 ± 1.78 (63) | <0.05 | 0.153 |
| 7 | Hsu et al.,2018 ¹⁵ | PAID Scale (Chinese) | 7.61 ± 7.02 / 32 (low) | 7.39 ± 1.11 (57) | <0.01 | NR* |
| 8 | Kuniss et al.,2017 ¹⁶ | PAID scale | 3.9 ± 7.0/43.75 (low) | 6.4 ± 1.0 (46) | <0.001 | 0.253 |
| 9 | Lin et al.,2017 ¹⁰ | DDS17 (Chinese) | 38.94 ± 0.81/90 (low) | >7% = 64% <7% = 36% | <0.01 | NR* |
| 10 | Linetzky et al.,20179 | DDS17 | $2.27 \pm 1.13/6$ (moderate) | 8.13 ± 1.75 (65) | < 0.01 | 0.171 |
| 11 | Lum et al., 2018 ¹⁷ | PAID Scale | 26.2/80 (moderate) | 8.6 ± 1.5 (70) | <0.01 | 0.235 |
| 12 | Mirghani, 2016 ¹⁸ | DDS17 | 3.67 ± 0.64 (high) | 9.9 ± 2.60 (85) | >0.05 | 0.176 |
| 13 | Nanayakkara et al.,2016 ¹⁹ | DDS17 | 0-3 (65%) >3 (2%) | 8±2 (64) | <0.001 | NR |
| 14 | Sukkarieh-Haraty et al.,2019 ²⁰ | 12-item DFS-Ar | NR | 7.73 ± 2.2 (61) | <0.05 | NR |
| 15 | Walker et.al, 2019 ²¹ | DDS17 | 1.6 ± 0.7/6 (low) | 7.9 ± 1.8 (63) | <0.001 | 0.25 |
| 16 | Wardian et al.,2017 ²² | DDS17 | 2.8/6 (moderate) | 8.38 (68) | <0.05 | NR |
| 17 | Winchester et al.,2016 ²³ | DDS17 | 1.4/6 (low) | NR | <0.05 | 0.179 |

| | Table 3. | Summarv | of | variables | result | and | outcome | studies |
|--|----------|---------|----|-----------|--------|-----|---------|---------|
|--|----------|---------|----|-----------|--------|-----|---------|---------|

Abbreviation:

(*): No direct correlation

NR: Not Report

DDS17: 17-item Diabetes Distress Scale

B3ID Scale: Problem Areas in Diabetes scale

12-item DFS-Ar: The 12- item Diabetes Fatalism Scale- Arabic

The graphic presents two variables with a horizontal line of diabetes distress score and a vertical line of HbA1c level (%) (Figure 2). The red vertical line is the mark for the diabetes

distress category—the horizontal line is an HbA1c target mark. Nine of 12 studies support that the high diabetes distress score has a high HbA1c (Figure 2). One study with high diabetes distress and HbA1c level.¹⁸ Seven studies have moderate diabetes distress with HbA1c level >7%.^{2,3,9,11,14,17,22} In one study, the result was low diabetes distress with HbA1c level <7%.¹⁶ The other 3 studies have opposite results, low diabetes distress, but the HbA1c level >7%.^{13,15,21}



Figure 2. Graphic Diabetes distress score and HbA1c level

4

Diabetes distress has four domains; emotional burden, physician-related distress, regimen-related distress, and interpersonal distress (Table 4). Four studies listed the mean score, and two of them also recorded the correlation between HbA1c and DD. The four studies show the mean value of DD, which is medium and high. Both studies had low correlations for HbA1c in the EB and RD domains and low values in the other two domains. The value of all studies is significant.

| | | Domain Diabetes Distress | | | | | | | | |
|----|-----------------------------------|--------------------------|--------------|---------------------|----------|------------------|----------|-------------------|---------------|-------|
| No | Author, year | 18 Emotional | Burden 30 | Physician distre | -related | Regimen distr | -related | Interper distr | rsonal ess | р |
| | | Mean | r | Mean | r | Mean | r | Mean | r | |
| 1 | Choi et al.,2018 ³ | 2.46 | NR | 1.86 | NR | 2.41 | NR | 2.14 | NR | <0.05 |
| 2 | Darawad et al.,2017 ¹⁴ | 15.2 | 0.193 | 10 | -0.017 | 14 | 0.151 | 7.1 | -0.04 | <0.05 |
| 3 | Mirghani, 2016 ¹⁸ | 4.08 ± 0.88 | 0.221 | 3.75 ± 1.13 | -0.009 | 3.35 ± 1.43 | 0.331 | 3.445 ± 0.92 | - 0.129 | <0.05 |
| 4 | Wardian et al.,2017 ²² | 2.108 ± 1.15 | NR | 1.261 ± 0.76 | NR | 2.137 ± 1.06 | NR | 1.50 ± 0.89 | NR | <0.05 |

Table 4. Summary of diabetes distress domain

Abbreviation:

NR: Not Reported

DISCU₃₂ION

This systematic review presents a significant relationship between diabetes distress and HbA1c levels. One study only significantly correlated with the domain score but not for the total diabetes distress score. Emotional burden and regimen-related distress are domains which as a strong predictors of glycemic control.¹⁸ Ten of 17 studies found that diabetes distress was directly positively correlated with HbA1c level. It also becomes a mediator between HbA1c level and other factors. Most studies said that their correlation is moderate and low. HbA1c level is not only affected by diabetes distress but also other factors. However, diabetes distress is a strong determinant compared with other psychosocial. It can be a target intervention to improve glycemic control like other studies.²⁴ The increase in HbA1c can be caused by decreasing insulin secretion by increasing cortisol hormone during distress.² Nevertheless, one study did not find a correlation between diabetes distress and HbA1c level. The reason is that differences in population culture such as family, social network, and health mindset affect the level of stress.¹¹

Five of 17 studies found that medication adherence is a mediator between diabetes distress and HbA1c level. The negative correlation with DD has an impact on the positive correlation with HbA1c level. Medication adherence is the most specific and easy adherence practice in therapy.¹² Diabetes distress affects self-efficacy for 0.26 points of self-mar27 ement before impacting HbA1c level.¹⁰ It is consistent with studies in China and Thailand that self-management is the key in diabetes management and a predictor of blood glucose.²⁵ Interventions in self-management can be effective because improving one point will reduce the risk of suboptimal type 2 DM therapy.¹⁰ Twelve months of quality of life (QoL) months also mediates the two variables in two of 17 studies. Diabetes distress affects QoL through life satisfaction and motivation, so it takes time before impacting HbA1c level.¹⁵ Diabetes distress can affect self-care in the long term. The impact of low self-care on HbA1c is disturbing diet, exercise, and blood glucose management. If it is less than six months, the effect of diabetes distress is not apparent, especially when the level of diabetes distress is still low.

Emotional burden and regimen-related distress are two dominant domains in diabetes distress. They can be strong predictor 110 f glycemic control. Emotional burden present in patients who feel hard to do routines as type 2 diabetes mellitus patients and the lack of social support will reinforce this.^{20,22} The regimen-related distress is identical to being irregular in monitoring blood glucose and therapy so that it is related to the type of therapy.^{3,22} Physician-related distress through hurried communication disturbs glycemic control because the patients do not understand what to do.⁹

Age significantly affects the level of diabetes distress. The higher the risk of diabetes distress is the younger when the patient is first diagnosed with type 2 diabetes.¹² Seven of 17 studies have the same finding.^{3,10,14,16–18,22} If the patient got type 2 diabetes mellitus at working age, it will inhibit activities and disturb need compliance. The longer the duration of experiencing type 2 DM, the higher the DD score.¹⁶ However, there is only one study that supports this statement.²² Previous studies did not show the same result because those conclusions were from some sample groups.¹⁶ This finding aligns with other studies that duration does not affect DD but can affect self-care.^{14,15}

The finding of the present systematic review is different find in the previous study about the effect of the level of health facilities on diabetes distress. In primary care, the level of diabetes distress is low. The glycemic control is better than the secondary or tertiary level because, at the tertiary level, the patient has blood sugar levels that are more uncontrolled.^{10,16} Nevertheless, primary care has a higher level of distress because it is associated with physician capability for the previous study.⁸ The difference in finding is because each country has different standards of health care facilities.

The type of patient therapy can affect the level of diabetes distress. The type of therapy is included a regimen related to distress. In patients who use therapy, there is a tendency for high levels of distress because it is related to strictness in the use of insulin, namely in terms of time, dose, and fear of hypoglycemia.^{2,22} Patients with combination therapy need accuracy in insulin therapy and consume oral antihyperglycemic drugs.³ Therefore, the type of therapy does not explicitly affect diabetes distress because each treatment has some concerns. The patients will feel anxiety and stress if they do therapy for a long time, whatever the type of therapy.

This systematic review implies that diabetes distress is significantly related to HbA1c with low correlation. Nevertheless, it can be the target of intervention ar 29 mprove the success of therapy. The first limitation of this study is that it does not proceed to a meta-analysis due to the various types of studies and instruments. By analysis with the meta-analysis, it will be more quantitative to see the correlation of two variables and the effect of diabetes distress on HbA1c. Second, the correlation between the two dominant variables is weak, so further research is needed. The other causes because HbA1c is not only affected by psychological conditions but many factors.

CONCLUSIONS

In this study, diabetes distress and HbA1c have a low-moderate relationship, but it can be the effective target intervention for improving type 2 diabetes mellitus therapy. Diabetes distress has one direct mechanism through hormones. The indirect effect of diabetes distress is through medication adherence, self-management, and 12 months quality of life. Age, health facilities, and type of therapy can affect diabetes distress. Furthermore, emotional burden and regimen-related distress are the most dominant domain in diabetes distress, and they can be the specific target for intervention.

FUNDING

This study did not receive any fund from funding agencies, commercial or another sector.

CONFLICT OF INTERES¹⁰

The authors declared there is no conflict of interest regarding this study between authors and other organizations or person that influence objectivity of research.

AUTHOR CONTRIBUTOR

All authors created and discussed the concept. First and second author selected articles and third author reviewed. All authors analyzed the result and wrote some note for conclusion. After we got consensus for last analysis, first author wrote the manuscript. Second and third author reviewed and evaluated it.

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