Title: Health-related quality of life in Iranian patients with type 2 diabetes: An updated meta-analysis study

Running Title: Health-related quality of life in Iranian patients with type 2 diabetes.

Authors:

Zahra Mokhtari

PhD Candidate, Deptment of Nursing, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran **Email:** Zahramokhtari2011@gmail.com

Reza Ghanei Gheshlagh

Assistant professor, Department of Nursing, Faculty of Nursing and Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran**. Email: Ghanei@muk.ac.ir**

Amanj Kurdi

Lecturer in Pharmacoepidemiology and Pharmacy Practice, Strathclyde Institute of Pharmacy and Biomedical Science, University of Strathclyde, Glasgow, UK**. Email:** amanj.baker@strath.ac.uk

Corresponding Author: Reza Ghanei Gheshlagh

Assistant professor, Department of Nursing, Faculty of Nursing and Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran**. Tel:** +98 9244050284 **Email:** Rezaghanei30@yahoo.com

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Abstract

Diabetes is the most common metabolic causes of increased mortality rate due to multiple complications of this disease. Diabetes, thus, influences patients' quality of life due to its resultant physical disabilities and mental health problems. This study aimed to investigate health-related quality of life among Iranian patients with type 2 diabetes. In this meta-analysis study, a search was conducted with the keywords Quality of Life, Health-Related Quality of Life, QoL, HRQoL, Shortform questionnaire 36, SF-36, Diabetes and Iran in the national and international databases such as SID, MagIran, ISI/Web of Science, PubMed [including Medline], and Scopus between 2011 and 2018. Based on the heterogeneity of data, the random effects model was used. Data was analyzed using the Stata software version 14. Overall, 17 studies were eligible, with a total sample size of 5472 patients, showed that the mean score of the physical dimension in patients with type 2 diabetes (53.5, 95% CI: 43.1-63.9) was less than the mean of mental dimension score (54.5, 95% CI: 47-61.9). By increasing the age of samples, the mean of the HRQoL score of the Iranian patients with type 2 diabetes was significantly decreased ($p = 0.015$). The highest and lowest scores for the quality of life subscales were social function and general health, respectively. Patients with type 2 diabetes have a moderate quality of life. Providing solutions to improve the quality of life of this group of patients especially in the physical aspect is required.

Keywords: Diabetes, Health-related quality of life, Iran, Meta-analysis

1. Introduction

Diabetes is the most common metabolic and epidemic disease of the third millennium, which has been shown to reduce the life expectancy of patients (1, 2). Due to its similarity to the plague epidemic in the 14th century in terms of morbidity and mortality, diabetes is also known as the plague of the 21st century (3). Due to its microvascular complications including retinopathy, nephropathy, neuropathy and macrovascular diseases such as cardiovascular, cerebrovascular and stroke, the mortality rate for diabetic patients is twice than that for non-diabetic patients (4). According to reports in 2005, the prevalence of diabetes in Iran was 7.7% (equivalent to 2 million people), and is projected to increase to 5 million people by 2025 (5). Every patient with diabetes has a unique life career. While many patients cannot effectively control their illness, it is believed that diabetes has a huge impact on patients' health condition (6). Diabetes can lead to a reduction in patients' health-related quality of life (7).

The quality of life refers to the individual's point of view about the difference between what is and what should be (8). Food constraints and inconsistencies in social roles, psychosocial problems, and continuous maintenance of self-management behaviors have significant effects on the quality of life of these patients (9, 10). In the study of Wandell et al. (2005), macrovascular complications (especially cardiovascular disease) were the strongest predictors of the quality of life of patients with diabetes (11).

Quality of life (QoL) is often measured by self-reported instruments, including SF-36 which has two main physical and mental dimensions, and each of these dimensions has been consisted of 4 sub-scales. Physical dimension of quality of life includes four

subscales of physical function, physical activity limitation, physical and general health. The psychological dimension includes subscales of vitality, social function, mental role retardation and mental health (12). Contrary to some quality of life instruments that are limited to a specific group and are always criticized for such a limitation, the SF-36 instrument is a general tool and can measure all important aspects of patient health. This instrument can compare similar patients or patients with various conditions and diseases (13). This questionnaire was translated and revised by Montazeri et al. (2005) (14). Accordingly, the purpose of this study was to estimate HRQoL among Iranian patients with type 2 diabetes using the SE-36 instrument. The study findings could be useful for policy-makers and decision-makers to improve their knowledge of quality of life and provide a background for evidence-based decision making.

2. Methodology

2.1. Search strategy

In this systematic review and meta-analysis, the PRISMA guideline was used to review health -related quality of life (HRQoL) of Iranian patients with type 2 diabetes (15). Two independent researchers reviewed the national and international scientific information databases including Scientific Information Database (SID), MagIran, Google Scholar, ISI / Web of Science, PubMed [including Medline], and Scopus between 2011 and 2018. In the study of Kiadaliri et al. (2013), the quality of life of patients with diabetes was assessed and reported until year 2011 (4). The references' list of the reviewed articles were also assessed to improve coverage. The QoL, HRQoL, Shortform questionnaire 36, SF-36, Diabetes, Iran, the Quality of Life, Health-Related

Quality of Life, and the combination of these terms were used to search strategy in the PubMed database as follows: ("Quality of Life"[All Fields] OR "Health-Related Quality of Life"[All Fields] OR "QOL"[All Fields] OR "HRQoL"[All Fields]) AND ((Shortform[All Fields] AND ("surveys and questionnaires"[MeSH Terms] OR ("surveys"[All Fields] AND "questionnaires"[All Fields]) OR "surveys and questionnaires"[All Fields] OR "questionnaire"[All Fields]) AND 36[All Fields]) OR "SF-36"[All Fields]) AND "Diabetes"[All Fields] AND "Iran"[All Fields].

2.2. Selection of studies and data extraction

First, all the articles referred to the quality of life of patients with type 2 diabetes were collected. Inclusion criteria were: observational (non-interventional) studies, published in Farsi or English languages, studying exclusively on patients with type 2 diabetes, assessing the health related quality of life using the SF-36 questionnaire, and providing adequate information related to the research objectives. Exclusion criteria included non-relevance to the study topic, inadequate data, repeated studies, research on the combination of both types of patients with diabetic type 1 and type 2, and lack of access to the full text of articles. Accordingly, the abstracts of the articles were examined by the researchers and the relevant ones were selected. A checklist was used to extract data on the author of the first article, the year of publication, place of the study, sample size, place of the research, scores of the eight subscales and two main dimensions of quality of life and the overall score of the quality of life. Each article was studied independently by two researchers, and, in case of controversy, the article was judged by another author who was expert in the field of meta-analysis.

2.3. Review of the methodological quality of the articles

The methodological quality of the articles was evaluated using a tool applied in various Iranian and foreign studies. This tool included 5 items of the study plan, comparison group, description of the characteristics of samples, sample size, and tool used, each item was scored from 0 to 3, with a higher score indicating a higher methodological quality. Accordingly, the articles were categorized into three categories of weak (score 0-5), moderate (6-10), and strong (scores above 10) in terms of methodological quality (16-18). Some of these studies did not report the mean score of the main physical and mental dimensions of the quality of life, and some did not report the mean score of eight subscales, so only articles with sufficient and adequate data was included in data analysis.

2.4. Statistical analysis

Since the quality of life score had a normal distribution, the variance of each research was calculated using the variance of normal distribution as follow: $\mathrm{Var}(x) = \sigma^2/n$. The weight assigned to each study was proportional to the variance. The mean score of the quality of life related to health and its dimensions was estimated at a 95% confidence interval. To analyze the heterogeneity of the data, I^2 and Q-Cochran test were used. If the I^2 index was more than 50% or the probability of the Q-Cochran test was less than 0.05 ($p<0.05$), the random effect model was used and otherwise the fixed-effect model was used for estimating the scores of the quality of life. To study the association between physical and mental dimensions of the quality of life with mean age, year of the study, sample size and mean scores of methodological quality of studies, a meta-regression model was used. The probability of bias in the publication of study was

investigated using the Begg's funnel plot. Data analysis was performed via the Stata software version 14 and the significance level was set as $p<0.05$.

3. Results

The initial search retrived 534 articles, of which 446 were excluded due to a lack of relevance to the subject. Of the remaining 88 articles, 17 articles were selected for data analysis (Figure 1).

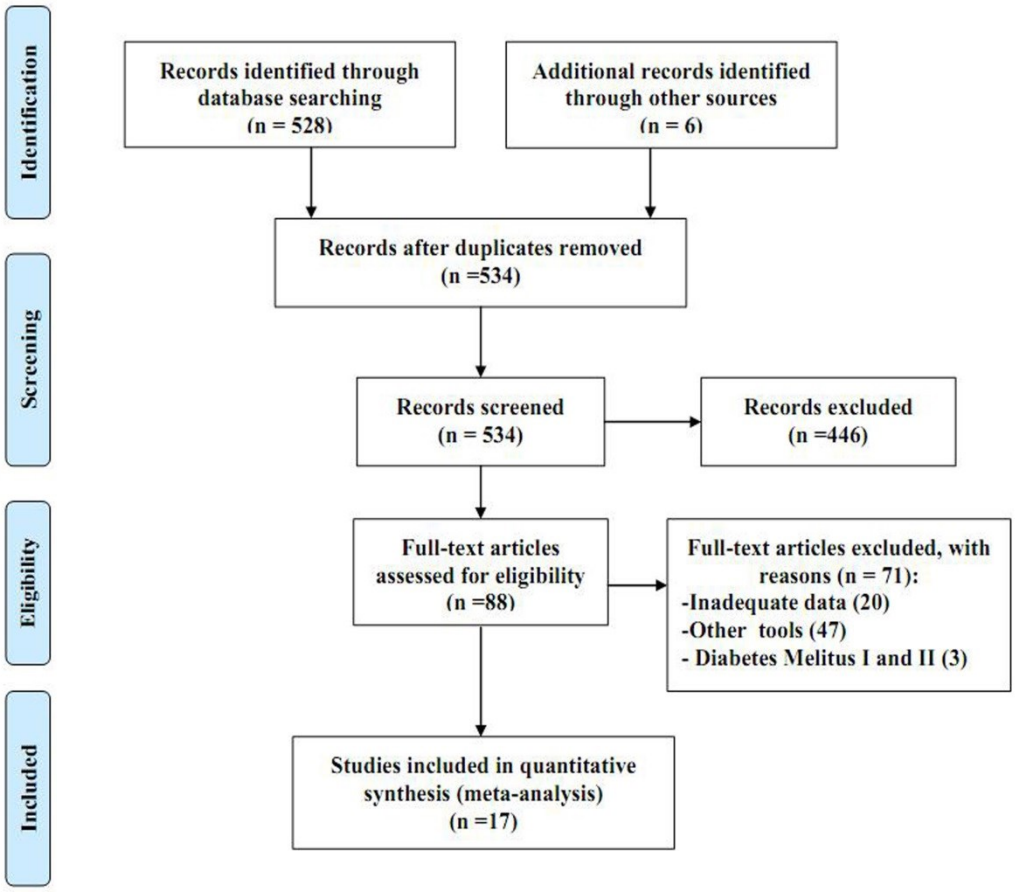

Figure 1. Flowchart of screening and selection of qualified articles according to the PRISMA guideline

The largest and lowest sample sizes were in the studies by Gholami (n=1847) and Aghakoochak (n=50), respectively. Furthermore, nine articles were published in English and eight in Farsi (Table 1).

Table 1: Table 1. Characteristics of the eligible articles

N	First Author	Year	Sample size	Age	Women (n)	Place	Quality
1	Zareipour (19)	2017	250	-	182	Urmia	6
2	Karimi moghadam (10)	2017	197	56.7±1.02	152	Sabzevar	8
3	Gholami (20)	2017	1847	59.6±12.3	1289	Neyshabur	6
4	Ebrahimi (21)	2017	80	-	-	Zanjan	10
5	Borhaninezhad (22)	2016	120	71.3±5.1	69	Kerman	8
6	Hajian (23)	2016	747	-	375	Babol	9
7	Kashfi (24)	2015	124	51.5±11.4	89	Larestan	11
8	Mohammadshahi (25)	2015	110	53.4±8.1	51	Ahvaz	8
9	Aghakoochak(26)	2014	50	55.3±14.2	25	Yazd	7
10	Ghorbani (27)	2014	114	47±9.3	66	Qazvin	6
11	Ghorbani (28)	2013	1103	-	576	Qazvin	7
12	Hatamloo (29)	2013	60	-	30	Tabriz	9
13	Kazemi-Galougahi (30)	2012	120	49.1±12.5	38	Tehran	4
14	Arian (31)	2012	125	52.8±7.4	81	Tehran	9
15	Saadatjoo (32)	2012	100	42.8±16.5	54	Mash-had	10
16	Borzou (33)	2011	165	-	111	Hamadan	7
17	Yekta (34)	2011	160	50.3 ± 7.1	121	Urmia	8

The 17 eligible articles had a sample size of 5472 patients, with a mean of 322 patients. The mean of physical score for patients with type 2 diabetes (53.5%, 95% CI: 43.1-63.9) was lower than the mental score (54.5%, 95% CI: 47-61.9).

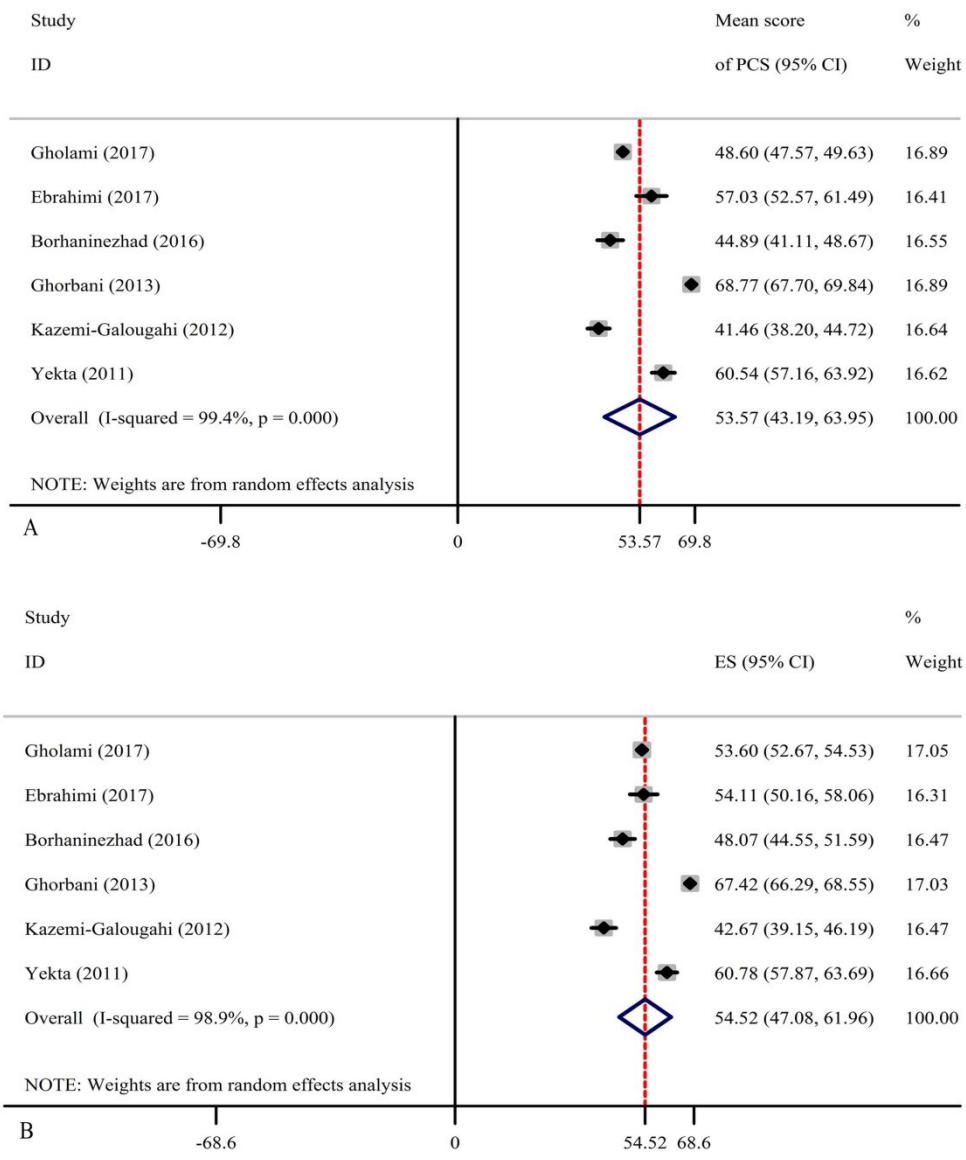

Figure 2: Mean scores on the physical (A) and Mental (B) dimension of HRQoL for patients with Diabetes type II. CI of 95% for each article is represented as horizontal lines near the main mean line;

dashed line at the mid represents an estimate of the total mean score; and the rhomboid represents CI of the mean HRQOL score

The highest and lowest mean scores for the quality of life subscales were for social functioning (64.3%) and general health (47.6%), respectively. The mean scores of all subscales of the quality of life were reported in Table 2 and Figure 3.

Table 2: The mean score of individuals with Type II diabetes on the physical and mental subscales of QOL

Subscales	Variables	Mean scores	95% Confidence interval		Heterogeneity		
			Down	Up	I^2	Q	P
Physical Domain	PF	62.2	55.5	68.9	98.9	1358.8	0.001
	RP	52.9	46.8	59	97.6	620.8	0.001
	BP	55.3	52.2	58.4	97.1	484.7	0.001
	GH	47.6	42.8	52.3	98.9	1341	0.001
Mental Domain	VI	49.3	45.4	53.2	98.3	884.7	0.001
	SF	64.3	58.7	70	98.9	1405.6	0.001
	RE	54.7	49.8	59.7	96.5	434.4	0.001
	MH	53.4	49.7	57.1	98.4	919.6	0.001

Abbreviations: RP, role limitations; PF, physical functioning; BP, bodily pain; GH, general health; VI, Vitality; SF, social functioning; RE, role limitations; MH, mental health.

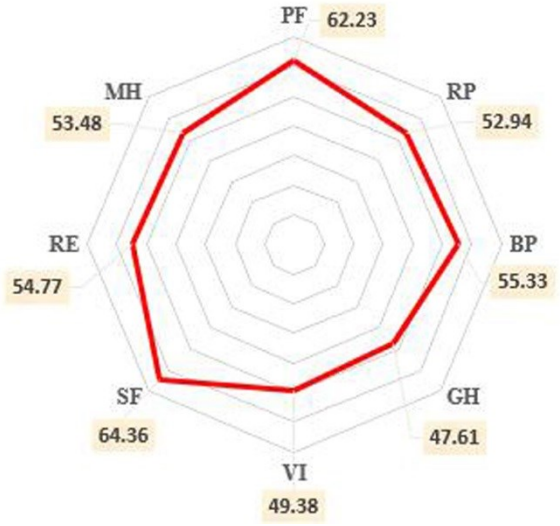

Figure 3: Combined mean for the eight HRQoL subscales extracted using the SF-36 in patients with Diabetes Type II.

The results of metaregression showed no relationship between the year of publication of the articles ($p = 0.404$), sample size ($p = 0.671$) and the methodological quality of articles ($p = 0.835$) with mean of the HRQoL score for patients with type 2 diabetes. However, by increasing the age of samples, the mean of the HRQoL score of the Iranian patients with type 2 diabetes was significantly decreased ($p = 0.015$).

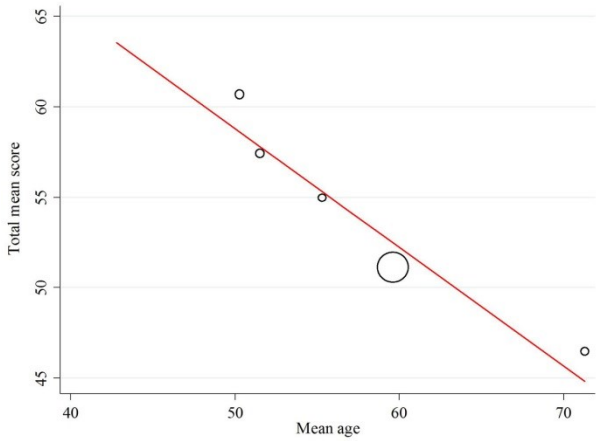

Figure 4. The meta-regression of the relationship between the mean age of patients with the overall quality of life in patients with type 2 diabetes

The results also showed that the selection bias was not statistically significant (p=0.251).

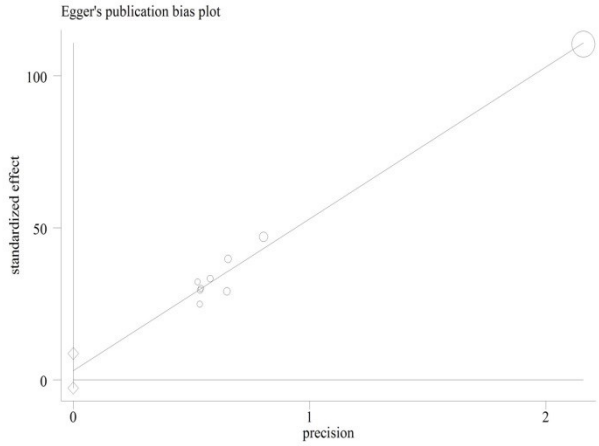

Figure 5: Publication bias

4. Discussion

Health-related quality of life is a multidimensional concept that focuses on the impact of illness and treatment on patients, and it can measure patients' perceptions of illness and treatment, their perceived needs for healthcare providers and their preferences for treatment and outcomes of the disease (35). This study aimed to estimate the mean scores of quality of life in Iranian patients with type 2 diabetes and its dimensions and showed that the mean scores of physical dimension and mental dimension were 53.5 and 54.5, respectively. Since the standard of quality of life of this group of patients in our society has not been determined, the mean of 50 with a standard deviation of 10 could be considered acceptable indices. Accordingly, the quality of life of Iranian patients with type 2 diabetes was reported as moderate (8). The results of this study showed that the mean score of the physical dimension of the quality of life of these patients was lower than the mean score of their mental health. In other words, diabetes impacted patients' physical aspect of the quality of life more than the mental dimension. This finding was consistent with the results of studies conducted in Canada and the Netherlands (36, 37). The results of study by Kuznetsov et al. on patients with type 2 diabetes in the three countries of the Netherlands, Denmark and the United Kingdom, showed that the mean score of physical dimension of the patients was less than the mean score of their mental dimension (38). Other studies also suggested that physical problems, such as diabetic foot ulcers, led to a reduction of the quality of life especially in the physical aspect due to decreased mobility and independence of the patients (39-41).

The highest and lowest mean scores for the quality of life subscales were social function (64.3%) and general health (47.6%), respectively, which were consistent with the

results of the study by Hermann et al. (1996) (42). The results of a study in Greece showed that the highest and lowest HRQoL scores for diabetic patients were related to physical function and general health subscales (43). Physical and mental health problems caused by diabetes have less effect on the social function of patients. The results of this study showed that with increasing patients' age, their quality of life significantly decreased. Various studies have supported this finding. For instance, in the study by Lindsay et al. (2011), the quality of life score declined with age (44). In Glasgow et al.'s study, younger patients had a better quality of life (45). The results of Trief et al.'s study showed that older people had more problems and lower quality of life than younger people (46). As the age increases, the risk of developing other diseases and the complications of diabetes will also increase. Therefore, the quality of life of patients with type 2 diabetes is expected to decrease as their age increases. The strength of this study was that it provided up-to-date and comprehensive outcome on health-related quality of life in Iranian patients with type II diabetes.

5. Conclusion

The results of this study can be used by policy makers and healthcare managers in order to provide strategies to improve the quality of life in patients with type 2 diabetes especially in the physical aspect.

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