

Effects of antihypertensive agents on the quality of life in diabetic hypertensive patients: A prospective study

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Abstract

Background: Diabetes mellitus is a chronic noncommunicable disease, and hypertension (HT) is the most common comorbidity which affects their quality of life (QoL).

Aim: The aim of the study was to assess the effects of antihypertensive agents (viz., amlodipine, ramipril, telmisartan, and ramipril with telmisartan) on the blood pressure (BP) and QoL.

Methodology: It was an open-labeled prospective intention-to-treat study done in diabetic hypertensive patients (CTRI/2016/10/007340). Patients were randomly assigned antihypertensive agents, namely, amlodipine, ramipril, telmisartan, and a combination of ramipril with telmisartan (RT) in four groups. They were evaluated for BP, blood sugar level, and QoL at baseline and 24th week.

Results: After 24 weeks of therapy, systolic BP (SBP) and diastolic BP (DBP) were significantly reduced in all groups. In amlodipine, there was a mean percentage fall of SBP by 15.85% (confidence interval [CI]: 21.38–28.13) and DBP by 11.22% (CI: 8.41–12.70); in ramipril – 14.4% (CI: 18.61–25.15) and 12.4% (CI 8.88–13.99); telmisartan – 18.4% (CI: 24.89–10.79) and 14.6% (CI 10.79–16.24); and in RT group, SBP 17.7% (CI: 23.38–29.18) and DBP 12.4% (CI: 9.05–13.02). QoL score increased by 30.56% (CI: 14.30–10.90), 30.94% (CI: 14.21–10.68), 28.07% (CI: 14.89–11.20), and 28.84% (CI: 15.49–11.77), in respective groups ($P < 0.0001$, each). However, they were nonsignificant between the study groups ($P > 0.05$).

Conclusion: Amlodipine, ramipril, telmisartan, and a combination of RT are equally effective to improve BP and QoL among diabetic hypertensive patients. However, amlodipine and telmisartan lacked in dry cough and more tolerable than the ramipril and RT therapy. Henceforth, amlodipine and telmisartan are better choice to control HT among DM patients.

Keywords: Amlodipine, blood pressure, Quality of Life Instrument in Diabetes Patients, ramipril, telmisartan

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INTRODUCTION

Diabetes mellitus (DM) is a chronic noncommunicable disease requiring long-term management.^[1] Hypertension (HT) is a common comorbid condition associated with it adversely affecting the general health of these patients.^[1] The quality

of health in an individual can be assessed by using the quality of life (QoL) scale at regular intervals. According to the WHO QoL is defined as *individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards*

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and concerns.^[2] Studies have shown that QoL in diabetic patients is not adequate as per the standard guidelines of the WHO.^[3,4] The study of Daivashiromani *et al.* found that diabetes showed a significant negative impact on all aspects of health-related QoL.^[4] Till date, few studies have reported follow-up assessment of QoL in diabetic patients. Most of these studies are cross-sectional and do not reveal the impact of treatment on the diabetic patients. Therefore, in the present study, we assessed QoL of the diabetic hypertensive patients.

Aim

The aim of the study was to assess the effects of antihypertensive agents, namely, amlodipine (calcium channel blocker [CCB]), ramipril (ACEI), telmisartan (angiotensin II receptor blockers [ARB]) and ramipril with telmisartan (RT) on the BP and QoL.

Objectives

The QoL in diabetic hypertensive patients was assessed by using QoL Instrument in Diabetes patients (QOLID) questionnaire at baseline and at the 24th week.

METHODOLOGY

An open-labeled, randomized, comparative, intention-to-treat, prospective study was conducted in diabetic hypertensive patients who were enrolled from the department of medicine at tertiary care teaching hospital. The institutional ethical committee approved the protocol (CTRI/2016/10/007340, retrospectively) and all the participants were enrolled after taking their written informed consent. Patients were evaluated on parameters such as blood pressure (BP), pulse rate, blood sugar level, glycated hemoglobin (HbA1c), and QOLID-Punjabi version (PV) questionnaire at baseline and then at the 24th week of therapy. QoL of the patients was assessed by using the QOLID questionnaire of Nagpal *et al.*^[5] We used the translated version of this questionnaires.

The validity of Quality of Life Instrument in Diabetes-Punjabi version

Permission has been obtained from the author (s) prior to using this QOLID questionnaire and the scale was validated by them. However, we translated it into the local language (Punjabi) for our study. The Punjabi version of QOLID Questionnaire was translated into the Punjabi language by a team of experts involving diabetes physician, nursing staff/field worker, and Punjabi and English language experts who translated this questionnaire in such a way that each question shall have the same meaning/content of health-related QoL, the same as that of original questionnaire. After translating the questionnaire into the

local Punjabi language, this was distributed among the diabetic individuals ($n = 20$) who read, write, and well understand the Punjabi language for their feedback. This feedback regarding questionnaire from the diabetic individuals was taken care and appropriate edition or modification was done after discussing with the expert committee who validated the final touch of this questionnaires. Interrater agreement among the expert for this questionnaire tested by kappa and its value was 0.72. Each question was rated on Likert scales from 1 to 5, where “1” predicted the poorest QoL, while the “5” denoted the best QoL of diabetic patients. These questionnaires have eight domains and 32 questions.

The reliability analysis of all questions was tested by the alpha model and Guttman Lambda. All the domains showed a good or very good value of Cronbach’s alpha and Guttman Lambda, for role limitation due to physical health, 0.926 and 0.738, physical endurance 0.892 and 0.751, general health 0.812 and 0.784, treatment satisfaction 0.712 and 0.810, symptom botherness 0.839 and 0.69, financial worries 0.868 and 0.880, emotional/mental health 0.746 and 0.861, and diet satisfaction domains 0.456 and 0.810, respectively. These values were concordant with those of Nagpal *et al.*^[5] and for the discriminant validity, QoL score of questionnaires (the Punjabi version) was compared across patients and healthy controls ($n = 30$, each) using independent samples by applying Mann–Whitney *U*-test and the difference was found to be statistically significant ($U = 108.5$, $P < 0.005$). This value also accords with that of Nagpal *et al.*^[5]

Inclusion criteria

Newly diagnosed cases of diabetes with HT and old diagnosed cases of HT with diabetes having mild-to-moderate HT as per the standard treatment guidelines were included.^[6] These diabetic patients were between the age group of 30 and 80 years of either sex and diagnosed according to the International Diabetes Federation guidelines.^[1]

Exclusion criteria

Patients of diabetes without HT, pregnant or lactating women with DM, those with thyroid disease, those with diabetic nephropathy, those with chronic obstructive pulmonary disease, and those with congestive heart failure (CHF) were excluded from this study. Patients who did not give written consent and fail to come for regular follow-up were also excluded from this study.

Sample size

This study was conducted to observe the effect of BP and QoL with respect to the use of antihypertensive agents.

A sample size of 50 (included dropout) for each arm was calculated to have 80% power and $\alpha = 0.05$ to detect a 30% difference in BP after therapy with the study drugs.

Study design

The patients were randomly enrolled into four groups and were assigned antihypertensive medicines, namely, amlodipine (2.5–10 mg/day) in Group A, ramipril (2.5–10 mg/day) in Group B, telmisartan (40–80 mg/day) in Group C, and a combination of ramipril (1.25–5 mg/day) and telmisartan (20–40 mg/day) (RT) in Group D. Assigning of antihypertensive therapy was done according to computer-generated sequences. The patients were assessed at day 1 and at 24 weeks. Doses were adjusted according to the BP of the patient. The QOLID-PV questionnaire was also used, and the results were recorded at baseline and at 24 weeks. Patients(s) who showed serious adverse event (s) and/or intolerable adverse drug reactions before 12 weeks were withdrawn from the study, although patients who had completed 12 weeks of study and developed aforementioned condition were withdrawn from the study, they were assessed for BP and QoL, and their data were counted in the final analysis.

Quality of Life Instrument in Diabetes-Punjabi Version

We categorized the scoring of QOLID-PV as per WHO-QoL BREF guidelines^[2] as (a) score <50 as poor, (b) 50–70 as good, and (c) >70 as better.

Statistical analysis

Statistical analysis of the generated data was done on the basis of mean, standard deviation, median, and mean percentage changes. The significance of results was evaluated by Student's *t*-test, analysis of variance, Kruskal–Wallis test, and Pearson's correlation test for association, reliability analysis, Mann-Whitney *U*-test, etc., $P < 0.05$ was considered statistically significant. Normality of the data was checked by Q-plot and histogram. GraphPad InStat version 3.06 (GraphPad Software, LLC, 2365 Northside Drive, Suite 560, San Diego, CA 92108, USA) was used for statistical analysis.

RESULTS

- Baseline characteristics of the study groups are described in Table 1. These values were comparable at the baseline ($P > 0.05$)
- Study parameters, namely, systolic BP (SBP), diastolic BP (DBP), pulse rate, fasting blood sugar (FBS), and HbA1c are described in Table 2. These values were comparable at the baseline ($P > 0.05$)
- BP (SBP and DBP) had significantly changed in all

the groups at 24 weeks [Table 3]. However, change in pulse rate was nonsignificant (>0.05) in all the groups

- QOLID-PV was assessed at the baseline and after 24 weeks. It showed the impact of diabetes disorder on patients' life and their day-to-day activities. It was observed that means of all the domains of QoL at baseline were comparable in all the groups but nonsignificant at $P > 0.05$ [Table 4]. Females had more QOLID score than males in all the groups
- Adverse events: Mild side effects were observed within all the groups. In amlodipine, it was 6%, in ramipril 12%, and telmisartan and combination RT Group, it was 10% each. Adverse events frequently observed were edema feet ($n = 1$), dizziness ($n = 1$), and headache ($n = 1$) in amlodipine; in ramipril – dry cough ($n = 4$), headache ($n = 1$), and gastrointestinal tract (GIT)-upset ($n = 1$); in telmisartan – dizziness ($n = 1$), headache ($n = 1$), weakness ($n = 2$), and GIT upset ($n = 1$); and in the RT group – dry cough ($n = 1$), dizziness ($n = 1$), headache ($n = 1$), weakness ($n = 1$), and GIT upset ($n = 1$). All the therapies were well tolerated, and none of them showed any serious adverse event. Five patients (four in ramipril group and one in RT group) developed dry cough at the 18th week to 22nd week and thus, discontinued from respective therapies
- QOLID-PV: At 24 weeks, the total mean score of the QOLID-PV increased in all the study groups [Table 4], while there was nonsignificant difference between them [Table 5]. The score of all domains of QOLID-PV increased significantly except in the financial worry domain in all the groups. However, there was a statistically insignificant ($P > 0.05$, each) difference between the score of various domains of QOLID-PV [Table 5] in the study groups.

Association of quality of life domains with other parameters

QoL domains did not show association with the other parameters of the patients in all the groups. However, when the patients of all the study groups were clubbed together, then a weak association was observed between the parameters. Physical health and physical endurance domains of QOLID were negatively (weakly) but insignificantly associated with the duration of diabetes disease ($r = -0.127$ and $r = -0.12$, respectively) and FBS ($r = -0.143$ and $r = -0.145$, respectively) [Table 6].

DISCUSSION

DM is a chronic metabolic disorder and commonly associated with HT.^[1] Therefore, both conditions requires

Table 1: Baseline characteristics of the population

	Group A (n=50)	Group B (n=50)	Group C (n=50)	Group D (n=50)	P**
Age (years)					
q1	48	49	44.25	44.25	0.115
Median	50.5	55	54	49	
q3	56.75	63.75	57.75	60	
IQR	8.75	14.75	13.5	15.75	
Duration of DM (months)					
q1	18	31.5	15.6	24	0.314
Median	48	69	36	51	
q3	96	120	84	84	
IQR	78	88.5	68.4	60	
Duration of HT (months)					
q1	1.02	1.2	6	2.4	0.668
Median	6.6	9.6	24	18	
q3	36	46.5	66	48	
IQR	34.98	45.3	60	45.6	
Sex					
Men	31	28	30	28	0.99
Women	19	22	20	22	
Alcoholic (n)	20	21	16	17	0.99
Smoker (n)	02	02	02	4	0.39
Vegetarian (n)	32	28	36	37	0.99

**ANOVA or Kruskal-Wallis Test. HT=Hypertension, DM=Diabetes mellitus, IQR=Interquartile range

Table 2: Baseline parameters values in the study groups

Parameters	Group A (amlodipine) (n=50) Value±SD, CI	Group B (ramipril) (n=50) Value±SD, CI	Group C (telmisartan) (n=50) Value±SD, CI	Group D (ramipril + telmisartan) (n=50) Value±SD, CI	P**
SBP (mmHg)	146.08±20.12, 140.41-151.74	142.88±12.75, 139.33-146.44	145.26±14.21, 141.59-148.94	147.64±12.82, 144.04-151.26	0.703
DBP (mmHg)	89.17±12.02, 85.79-92.56	87.88±9.501, 85.23-90.532	88.83±9.303, 86.43-91.237	88.62±8.261, 86.30-90.95	0.732
PR (pulse/min)	84.63±10.38, 81.70-87.55	87.04±8.887, 84.562-89.515	86.17±11.97, 83.074-89.26	86.90±10.33, 83.99-89.811	0.662
HbA1c (%age)	7.45±1.287, 7.08-7.809	7.58±1.013, 7.30-7.867	7.403±1.192, 7.09-7.711	7.76±1.37, 7.07-7.847	0.844
FBS (mg/dL)	168.05±50.13, 153.95-182.2	165.25±50.41, 151.20-179.30	159.38±56.02, 144.91-173.85	156.29±49.06, 142.48-170.11	0.679

**ANOVA or Kruskal-Wallis Test. SBP=Systolic blood pressure, DBP=Diastolic blood pressure, HbA1c=Glycated hemoglobin, FBS=Fasting blood sugar, PR=Pulse rate, SD=Standard deviation, CI=Confidence interval

simultaneous treatment by antidiabetic (oral hypoglycemic agents, insulin, etc.) and antihypertensive agents.^[1,6] There are various groups of anti-HT agents available, namely, CCBs, ACEI, ARB, diuretics, and alpha-blockers.^[6] All these antihypertensive agents have more or less side effects in the diabetic patients. It requires an evaluation of appropriate drugs (antidiabetic and antihypertensive), their doses, and impact on QoL.^[6]

In our study, amlodipine resulted in a significant decrease in the SBP and DBP at 24 weeks [Table 3]. The study was comparable to that of Zaman *et al.* (−8.43% and −8.16%, respectively)^[7] and Agodoa *et al.* (−14.94% and −11.4%, respectively).^[8]

In ramipril group, the decrease of SBP and DBP was comparable to that of Agodoa *et al.* (−10.93% and −14.37%, respectively) at 24 weeks. While the reduction of SBP was reported more in our study as compared to that of the ONTARGET (2008) (−4.51%)^[9] and ONTARGET-2012 (−3.05%) studies.^[10]

Telmisartan group resulted in decrease of SBP and DBP [Table 3] that was more as compared to Gadge *et al.* (−13.66% and −12.14%, respectively),^[11] Delles *et al.* (−9.06% and −9.05%, respectively),^[12] and ONTARGET-2012 (−3.01% and −5.23%, respectively)^[10] studies but similar to Morimoto *et al.* (−16.05% and −14.7%, respectively).^[13]

Therapy of RT also reduced both SBP and DBP [Table 3] that was more as compared to Nakao *et al.* (4.07% and 4%, respectively),^[14] the ONTARGET-2008 (−6.91% and −8.28%, respectively, at 12 weeks),^[9] and the ONTARGET-2012 (−6.46% and −5.84%, respectively)^[10] studies.

Hence, the results of our study were in concordance with the findings of other studies.^[7-14]

Quality of life

DM also adversely affect the health of an individual; we can assess the QoL by using QoL scale (s) at a regular interval. In this study, we had used QOLID-PV.^[5] The

Table 3: Mean percentage change in the parameters in the study at 24 weeks

Parameters	Amlodipine	Ramipril	Telmisartan	Combination RT	P**
SBP					
0 week	146.08±20.12, 140.41-151.74	142.88±12.75, 139.33-146.44	145.26±14.21, 141.59-148.94	147.64±12.82, 144.04-151.26	0.703
24 week	122.9±9.68, 120.28-126.8	122.56±12.32, 119.05-126.07	120.48±9.786, 117.70-123.26	121.59±9.228, 118.89-124.15	0.357
Percentage age change	-15.85	-14.4	-18.4	-17.7	
CI	21.38-28.13	18.61-25.15	24.89-32.06	23.38-29.18	
P*	0.0001	0.0001	0.0001	0.0001	
DBP					
0 week	89.176±12.02, 85.79-92.56	87.88±9.501, 85.237-90.532	88.833±9.303, 86.43-91.237	88.627±8.261, 86.302-90.95	0.732
24 weeks	78.8±6.797, 76.86-80.73	76.4±6.145, 74.67-78.13	76.48±6.128, 74.74-78.22	77.76±4.529, 76.47-79.048	0.139
Percentage change	-11.22	-12.4	-14.6	-12.4	
CI	8.415-12.705	8.88-13.992	10.79-16.24	9.057-13.023	
P*	0.0001	0.0001	0.001	0.0001	
PR (pulse/min)					
0 week	84.63±10.38, 81.70-87.55	87.04±8.887, 84.562-89.515	86.17±11.97, 83.074-89.26	86.90±10.33, 83.99-89.811	0.662
24 weeks	82.64±7.994, 80.38-84.89	85.2±9.116, 82.60-87.793	82.4±9.355, 79.73-85.061	81.88±9.059, 79.273-84.48	0.239
Percentage change	-2.52	-2.61	-4.64	-5.91	
CI	0.359-3.96	0.019-3.9	1.739-5.78	2.68-7.554	
P*	0.0001	0.0478	0.0005	0.0001	
HbA1c (%age)					
0 week	7.45±1.287, 7.085-7.809	7.58±1.013, 7.302-7.867	7.403±1.192, 7.095-7.711	7.76±1.37, 7.075-7.847	0.679
24 weeks	6.354±1.098, 6.045-6.663	6.796±1.32, 6.42-7.172	6.29±0.944, 6.023-6.561	6.606±1.43, 6.194-7.013	0.105
Percentage change	-15.33	-10.3	-13.2	-14.8	
CI	0.723-1.49	0.454-1.09	0.737-1.50	0.403-1.253	
P*	0.0001	0.0001	0.0001	0.0003	
FBS (mg/dL)					
0 week	168.05±50.13, 153.95-182.2	165.25±50.41, 151.20-179.30	159.38±56.02, 144.91-173.85	156.29±49.06, 142.48-170.11	0.844
24 weeks	132.20±24.017, 124.92±138.44	133.68±33.00, 125.29±144.07	127.82±39.56, 116.57-139.07	133.38±42.917, 121.17-145.59	0.79
Percentage change	-21.33	-19	-21.4	-14.9	
CI	22.98-46.45	15.79-48.05	19.52-47.36	18.61-35.82	
P*	0.0001	0.0002	0.0001	0.0019	

*Student's t-test, **ANOVA. RT=Ramipril with telmisartan, SBP=Systolic blood pressure, DBP=Diastolic blood pressure, HbA1c=Glycated hemoglobin, FBS=Fasting blood sugar, PR=Pulse rate, SD=Standard deviation, CI=Confidence interval

Table 4: Domains of Quality of Life Instrument in Diabetic Patients and their scores in study groups at baseline (0 week) and 24 weeks

Domains of QOLID-PV	Amlodipine		Ramipril		Telmisartan		Combination- RT	
	0	24 weeks	0	24 weeks	0	24 weeks	0	24 weeks
A Physical health	49.83	68.33	52.67	68.83	51.08	66.83	51.25	68.75
B Physical endurance	50.33	69.33	51.5	67.67	57.17	70.58	53.83	71.75
C General physical	43.33	68.33	43.33	71.83	43.16	69.5	44.33	72.33
D Treatment satisfaction	43	75.63	42.13	76.25	42.38	73.13	42.38	75.63
E Symptom botherness	51.33	78.67	47.5	74.17	49.83	74.5	52.83	75.5
F Financial worries	73.63	74.25	68.25	69.63	68.75	70.25	74.75	75.25
G Emotional/mental health	71.3	79.7	71.6	80.6	71.5	79.2	74	82
H Diet satisfaction	56.83	59.67	56.67	58.83	54.83	57.87	57.5	59.67
Total mean score of all domains (SD)	54.95±8.79	71.74±9.15	54.21±9.59	70.94±9.06	54.84±8.56	70.23±9.78	56.36±7.77	72.61±9.48
Male (mean±SD CI)	62.72±9.39, 59.44-66.00	75.47±9.7, 72.09-78.86	61.43±9.99, 57.55-65.30	73.81±10.25, 69.84-77.79	62.91±9.65, 59.31-66.59	74.19±10.42, 70.29-78.08	64.24±6.38, 60.56-67.927	80.57±7.8, 76.06-85.08
Female (mean±SD CI)	68.71±5.67, 65.68-71.73	81.0±6.65, 77.45-84.54	67.27±8.14, 63.66-70.88	79.79±5.95, 77.15-82.43	65.08±6.63, 61.98-68.19	80.79±7.32, 77.37-84.22	65.25±8.26, 62.46-88.05	77.84±10.05, 74.47-81.25

SD=Standard deviation, CI=Confidence interval, QOLID=Quality of Life Instrument in Diabetic Patients, PV=Punjabi version

mean of all domains of QOLID at baseline in all the groups [Table 4] was less as observed by that of Prajapati *et al.* (65.47%).^[3] Higher QOLID score was reported by Parajapati *et al.* because they used a different QoL

scale (MDQoL-17 questionnaire), which lacked certain domains, that is, treatment satisfaction, financial worries, and diet satisfaction that are present in QOLID. Second, because of comorbid conditions, for example, CAD, HT,

and nephropathy, 65% of cases comprised of diabetes without comorbid conditions.^[3] However, the average QOLID-PV score in our study improved from good to better ($P < 0.05$) from baseline and at the 24th-week interval [Table 4].

Domains of Quality of Life Instrument in Diabetes-Punjabi Version

It has been observed that physical health, physical endurance, general health, symptoms botherness, emotional/mental health, and diet satisfaction scores were good in all the groups at baseline. Emotional/mental health score in all the groups [Table 4] was more as also observed by Kavi *et al.* (40.27),^[15] but there was a statistically insignificant difference between the study groups.

At 24 weeks, the scores of QOLID-PV domains in all the study groups significantly (<0.0001) improved in all the domains except the financial worries. The total mean score of QOLID-PV increased from 28% to 31% (<0.0001 , each) in all the groups [Table 5]. Both ramipril and amlodipine have shown maximum change in the QOLID-PV score (30.94% and 30.56%, respectively) as compared to other groups. Males showed more percentage change in QOLID-PV score in RT group. Telmisartan group had more female sex preponderance. The average QoL score was changed from good to better [Table 4] in

all the study groups. Matchar *et al.* reported that ACEI and ARB were comparable with respect to their effects on the QoL score.^[16] Similar results were observed in our study compared to other studies.^[15,16] All these antihypertensive agents such as CCBs, ACEI, and ARB improved the QoL by lowering the raised BP.^[16,17] On comparing between class difference among antihypertensive agents, it was insignificant.

Glycemic parameters

FBS and HbA1c level had significantly reduced [Table 3] in all the study groups with the antidiabetic agent(s). In this study, various antidiabetic drugs were prescribed as oral antidiabetic agents such as glimepiride, gliclazide, metformin, and combinations of metformin with either glimepiride or gliclazide in diabetic hypertensive patients. Improvement of glycemic parameters was found without interclass difference. However, there was an insignificant difference ($P > 0.05$) between the study groups at 24 weeks.

Association of Quality of Life Instrument in Diabetes-Punjabi Version with other parameters

Physical health and physical endurance domains of QOLID-PV were weakly associated (negatively) with the duration of DM ($r = -0.127$, confidence interval [CI] -0.178 to -0.075 and $r = -0.120$, CI -0.1731 to -0.0629) and levels of FBS ($r = -0.145$, CI -0.287 to -0.007 and r

Table 5: Mean percentage change in the domain scores of Quality of Life Instrument in Diabetic Patients in all groups at 24 weeks

QOLID Domains of QOLID	Amlodipine (%)	Ramipril (%)	Telmisartan (%)	Combination RT (%)	P**
A Physical health P*	37.13 <0.0001	30.68 <0.0001	30.83 <0.0001	34.15 <0.0001	0.413
B Physical endurance P*	37.75 <0.0001	31.4 <0.0001	23.46 <0.0001	33.29 <0.0001	0.136
C General physical P*	57.7 <0.0001	65.77 <0.0001	61.03 <0.0001	63.16 <0.0001	0.480
D Treatment satisfaction P*	75.88 <0.0001	80.99 <0.0001	72.56 <0.0001	78.46 <0.0001	0.09
E Symptom botherness P*	53.26 <0.0001	56.15 <0.0001	49.51 <0.0001	42.91 <0.0001	0.80
F Financial worries P*	0.84 >0.05	2.022 >0.05	2.18 >0.05	0.67 >0.05	0.503
G Emotional/mental health P*	11.78 <0.0001	12.57 <0.0001	10.77 <0.0001	10.81 <0.0001	0.915
H Diet satisfaction P*	5 <0.01	3.82 <0.02	5.54 <0.01	3.77 <0.02	0.747
Mean percentage change (total score of all domains) CI P*	30.56 -14.30--10.90 <0.0001	30.94 -14.21--10.68 <0.0001	28.07 -14.89--11.20 <0.0001	28.84 -15.49--11.77 <0.0001	0.87
Male (mean percentage) CI P*	20.34 -14.95--10.56 <0.0001	20.17 -14.575--10.20 <0.0001	20.28 -13.61--8.94 <0.0001	25.42 -20.546--12.107 <0.0001	0.176
Female (mean percentage) CI P*	17.88 -15.21--9.37 <0.0001	18.22 -15.62--9.41 <0.0001	24.15 -18.55--12.88 <0.0001	19.29 -14.623--10.55 <0.0001	0.466

* P students' t-test at 0-24 weeks within the group and ** P ANOVA/Kruskal-Wallis Test at 24 weeks between the groups. RT=Ramipril with telmisartan, CI=Confidence interval, QOLID=Quality of Life Instrument in Diabetic Patients

Table 6: Association between the domains of Quality of Life Instrument in Diabetic Patients with other parameters

	FBS (n=200)	HbA1c (n=200)	Duration of diabetes (n=200)
Physical health			
<i>r</i>	-0.143	-0.0236	-0.1272
CI	-0.280-0.008	-0.079-0.337	-0.1783-0.7549
Physical endurance			
<i>r</i>	-0.145	-0.0314	-0.1184
CI	-0.281-0.006	-0.1006-0.098	-0.173-0.063
General health			
<i>r</i>	-0.1207	-0.082	-0.09531
CI	-0.255-0.0184	-0.154-0.0419	-0.155 to-0.035
Treatment satisfaction			
<i>r</i>	0.0938	0.0459	-0.089
CI	-0.045-0.229	-0.098-0.0612	-0.155-0.023
Symptom botherness			
<i>r</i>	0.0512	-0.0452	-0.0816
CI	-0.089-0.187	-0.183-0.094	-0.155-0.008
Financial			
<i>r</i>	-0.0939	-0.053	-0.0849
CI	-0.229-0.045	-0.087-0.1904	-0.169-0.001
Emotional			
<i>r</i>	-0.0685	-0.0593	-0.0773
CI	-0.265-0.071	-0.197-0.08	-0.180-0.027
Diet satisfaction			
<i>r</i>	-0.0465	-0.0157	-0.1219
CI	-0.184-0.093	-0.154-0.127	0.265-0.026

Pearson's correlation (*r*). CI=Confidence interval, HbA1c=Glycated hemoglobin, FBS=Fasting blood sugar

= -0.150, CI -0.278 to -0.006) [Table 6], but insignificant at $P > 0.05$. Similarly, reported in other studies^[4,16,17].

Implications of the study

The study recommends mandatory periodic follow-up of diabetic patients with/without HT to improve QOL.

Limitations

In our study, diabetic patients had serious comorbid conditions (CHF, AMI, stroke, and CKD); DM patients who underwent recent surgery and had Type 1 DM were not included. The follow-up was of short duration and the number of patients was less. Therefore, a double-blind randomized controlled trial with a large sample size and of longer duration is required for generalization.

CONCLUSION

It was concluded that amlodipine, ramipril, telmisartan, and a combination of RT are equally effective in improving BP and QoL among diabetic hypertensive patients. However, amlodipine and telmisartan have lesser side effects (no dry cough) and more tolerable than ramipril and RT therapy. Therefore, amlodipine and telmisartan are a better choice to control HT among DM patients.

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Ethical approval

The study was approved by the Institutional Ethics Committee and registered under CTRI/2016/10/007340 dated 05/10/2016, retrospectively.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. International Diabetes Federation. IDF DIABETES ATLAS Sixth edition (2013). Available via DIALOG. Available from: https://www.idf.org/sites/default/files/EN_6E_Atlas_Full_0.pdf. [Last accessed on 2015 Oct 19].
2. World Health Organization, WHOQOL: Measuring Quality of Life. Available via DIALOG. Available from: <https://www.who.int/healthinfo/survey/whoqol-qualityoflife/en/index1.html>. [Last accessed on 2020 Jan 10].
3. Prajapati VB, Blake R, Acharya LD, Seshadri S. Assessment of quality of life in type II diabetic patients using the modified diabetes quality of life (MDQoL)-17 questionnaire. *Braz J Pharm Sci* 2017;53: e17144-8.
4. Daivashiromani V, Kuna A, Devi SS, Kumari PA, Sowmya M. Effect of selected demographic characters on health related quality of life (HRQOL) in Type 2 diabetic subjects of Hyderabad and Rangareddy districts of Telangana State. *The J Res PJTSAU* 2017;45:104-12.
5. Nagpal J, Kumar A, Kakar S, Bhartia A. The development of "quality of life instrument for Indian diabetes patients (QOLID): A validation and reliability study in middle and higher income groups. *J Assoc Physicians India* 2010;58:295-304.
6. Standard Treatment Guidelines-Hypertension Screening, Diagnosis, Assessment and Management of Primary Hypertension in Adults in

- India-Quick Reference Guide (2016). Ministry of Health and Family Welfare, Government of India 2016. Available via DIALOG. Available from: <http://clinicaestablishments.gov.in/WriteReadData/6591.pdf>. 18. [Last accessed on 2018 Dec 11].
7. Zaman ZA, Kumari V. Comparison of the effects of amlodipine and cilnidipine on blood pressure, heart rate, proteinuria and lipid profile in hypertensive patients. *Int J Basic Clin Pharmacol* 2013;2:160-4.
 8. Agodoa LY, Appel L, Bakris GL, Beck G, Bourgoignie J, Briggs JP, *et al.* Effect of ramipril vs. amlodipine on renal outcomes in hypertensive nephrosclerosis: A randomized controlled trial. *JAMA* 2001;285:2719-28.
 9. ONTARGET Investigators, Yusuf S, Teo KK, Pogue J, Dyal L, Copland I, *et al.* Telmisartan, ramipril, or both in patients at high risk for vascular events. *N Engl J Med* 2008;358:1547-59.
 10. Redon J, Mancia G, Sleight P, Schumacher H, Gao P, Pogue J, *et al.* Safety and efficacy of low blood pressures among patients with diabetes: Subgroup analyses from the ONTARGET (ONGOing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial). *J Am Coll Cardiol* 2012;59:74-83.
 11. Gadge P, Gadge R, Paralkar N, Jain P, Tanna V. Effect of telmisartan on blood pressure in patients of type 2 diabetes with or without complications. *Perspect Clin Res* 2018;9:155-60.
 12. Delles C, Raff U, Mimran A, Fauvel JP, Ruilope LM, Schmieder RE. Effects of telmisartan and ramipril on adiponectin and blood pressure in patients with type 2 diabetes. *Am J Hypertens* 2008;21:1330-6.
 13. Morimoto S, Yano Y, Maki K, Sawada K. Renal and vascular protective effects of telmisartan in patients with essential hypertension. *Hypertens Res* 2006;29:567-72.
 14. Nakao N, Yoshimura A, Morita H, Takada M, Kayano T, Ideura T. Combination treatment of angiotensin-II receptor blocker and angiotensin-converting-enzyme inhibitor in non-diabetic renal disease (COOPERATE): A randomised controlled trial. *Lancet* 2003;361:117-24.
 15. Kavi A, Walvekar P, Mallapur M. Assessment of health related quality of life of elderly diabetic patients attending urban primary health care facility-a cross sectional study. *Int J Community Med Public Health* 2017;3:2258-63.
 16. Matchar DB, McCrory DC, Orlando LA, Patel MR, Patel UD, Patwardhan MB, *et al.* Systematic review: Comparative effectiveness of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers for treating essential hypertension. *Ann Intern Med* 2008;148:16-29.
 17. Chaturvedi R, Desai C, Patel P, Shah A, Dikshit RK. An evaluation of the impact of antidiabetic medication on treatment satisfaction and quality of life in patients of diabetes mellitus. *Perspect Clin Res* 2018;9:15-22.