IMPLEMENTATION OF DIABETIC PHARMACEUTICAL CARE PLAN (DPCP) AND EVALUATION ON PHARMACIST INTERVENTION &CLINICAL OUTCOME FOR IMPROVING PATIENT ADHERENCE

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Abstract

In 2011, India reported to have 62.4 million people with diabetes and 77.2 million people with prediabetes. Pharmacists represent the third largest health profession in the world [5] after doctors and nurses. Community pharmacies provide a range of products (in respect to diabetes prescription and non-prescription medication, blood glucose meters, and testing strips, needles, and swabs, dietary supplements) and services (such as medication review, vaccination, unit dose dispensing, needle exchange, point of care testing, disposal of unwanted medicines, etc.)

This was a cross-sectional, randomized control trial based on the community pharmacy settings. A total of 1189 patients were enrolled. The participants were divided into intervention group and non-intervention group. There was a total of 6 visits in the study: two hospital visits and four telephonic visits. Four questionnaires were used in the study: MARS, DKQ, DSMQ, HRQOL. A total of 4 community pharmacists were identified and trained regarding the administration of questionnaires and counselling. While comparing the mean difference values of indicators using independent-t test, the current study shows a significant improvement between interventional and non-interventional groups.Mean difference of HbA1C (0 visit- 6th visit) for interventional group is 0.648±0.713 and non-interventional group is 0.378±0.619, which is significant (P-value=0.0001).

Keywords: Diabetic Mellitus, Pharmacist intervention, patient medication-related beliefs, diabetes-related knowledge, patient empowerment.

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Introduction

In 2011, India reported to have 62.4 million people with diabetes and 77.2 million people with prediabetes. [1] India is known as diabetes capital, and it holds the maximum DM patients in the world. The average costs per diabetic patient with and without comorbidities were found to be United States dollars (USD) 314.15 and USD 29.91, respectively. The average cost for those with diabetic complications was USD 125.01 for macrovascular complications, USD 90.43 for microvascular complications.[2]Diet and physical activity are the mainstay of non-pharmacological diabetes treatment. For satisfactory blood glucose control about 40% of diabetes sufferers require oral agents, and about 40% need insulin injections. [3]It is essential that the patients themselves administer the therapies prescribed by the doctor to help the patients with diabetes function. These therapies may need to be taken repetitively and consistently, often multiple times per day to combat out of control surges or dips in blood sugar concentration. Blood sugar, ketones, and other relevant factors need to be self-monitored which is essential to this process. Patient counselling is a process that improves patients' ability to cope and make informed decisions regarding their disease and medication and motivates the patients to change their dietary habits and lifestyle, which are harmful to their current health status[4].Since diabetes is a chronic complication affecting the diabetic patient at various levels, the counselling should focus on the nature of the disease, lifestyle modifications, medications, and acute and chronic complications. The general goals of the treatment of diabetes are to avoid acute decompensation, prevent or delay the appearance of late disease complications, decrease mortality, and maintain a good quality of life. Counselling approach that incorporates motivational interviewing as part of structured lifestyle intervention has been found to have beneficial effects in diabetes management.

Role of Community Pharmacist in Managing Diabetes Mellitus

Pharmacists represent the third largest health profession in the world [5] after doctors and nurses. Most pharmacists work in the community with a smaller proportion in hospital pharmacy, academia, industry, and research. Community pharmacies provide a range of products (in respect to diabetes prescription and non-prescription medication, blood glucose meters, and testing strips, needles, and swabs, dietary supplements) and services (such as medication review, vaccination, unit dose dispensing, needle exchange, point of care testing, disposal of unwanted medicines, etc.).[6] Community pharmacists are considered to be the most accessible health care professionals, as no appointments are required to see them and to have the highest level of patient contact. Pharmacists can help identify patients with diabetes through screening and should target patients at high risk. They can provide counselling about monitoring glucose levels and how to manage out-of-range levels, including developing an action plan for what to do if sugar levels go too low. The pharmacist can help patients select the most appropriate hypoglycaemic management strategy on an individual basis and can counsel on an appropriate diet and exercise routine to complement medication management in treating diabetes Pharmacists can also help guide patients through the management of adverse effects. For patients requiring insulin, the pharmacist can help instruct the patient on how to administer the medication, as well as answer common questions and concerns. Pharmacists are in a unique position to play a vital role in patients' medication adherence and quality of life improvement as such; they are well placed to play a significant role in the care of patients with T2DM. [7]The aim of the study was to assess the role of community pharmacists in diabetes self-management including adherence to pharmacotherapy and self-care recommendations and monitoring practices. Secondary objectives of the study were to assess the prescribing pattern of OHAs, the medication adherence in T2DM patients and to evaluate the influence of community pharmacists on patient medication-related beliefs, diabetes-related knowledge, patient empowerment, and satisfaction with diabetes care.

Methodology

Study Design: This was a cross-sectional, randomized control trial based on the community pharmacy settings.

Study Site: Community pharmacy attached with 400 bedded Manipal super specialty tertiary care teaching hospital in Vijayawada.

Study period: 30 months, the first year of the study we collected baseline data and the following year post-baseline data was collected. And the last 6 months we assessed and analysed the data. A total of 1189 patients were enrolled. The participants were divided into intervention group and non-intervention group.

There was a total of 6 visits in the study: two hospital visits and four telephonic visits. Four questionnaires were used in the study: MARS,

DKQ, DSMQ, HRQOL. A total of 4 community pharmacists were identified and trained regarding the administration of questionnaires and counselling. The study measured the glycated haemoglobin, with the intermediate health outcomes of blood lipids, serum creatinine, blood pressure, and body mass index.

Inclusion criteria: Patients diagnosed as T2DM for at least 6 months, either male or female of age >21 was included in the study. Patients who were diagnosed with uncontrolled T2DM (HbA1C:7), patients who are on OHAs and still having uncontrolled T2DM, patients with no significant clinical abnormalities and who were willing to provide an informed consent were included in the study.

Exclusion criteria: T2DM patients with hypersensitivity to any type of OHAs or with any cardiac disorders/renal insufficiency, pregnant or lactating patients were excluded from the study. Patients who were already enrolled in any studies or who were already enrolled in any DPCP /had any plans to enrol in a diet, weight, or exercise program were also excluded from the study.

Statistical analysis

Chi-square test, Fisher's exact test and independent t- test were used to analyse data. P value<0.05 was considered significant.

Results:

Table 1: Socio-demographic factors

	Intervention group N=699, n (%)	Non-intervention group N=490, n (%)	P value
Age category			
<45 yrs	297 (42.5)	133 (27.1)	<0.001
46-60 yrs	202 (28.9)	143 (29.2)	
>60 yrs	200 (28.6)	214 (43.7)	
Sex			
Male	376 (53.8)	240 (49)	0.1
Female	323 (46.2)	250 (51)	
Social history			
Smoker	19 (2.7)	20 (4.1)	0.00001
Drinker	37 (5.3)	33 (6.7)	
Smoker and drinker	66 (9.4)	119 (24.3)	
Nil	577 (82.5)	318 (64.9)	
Hereditary history			
Yes	273 (39.1)	170 (34.7)	0.125
No	417 (60.9)	320 (65.3)	
Duration of diabetes (years)			
<1 year	28 (4)	16 (2.3)	0.45
1-5 years	120 (17.2)	95 (13.6)	
5-10 years	365 (52.2)	237 (33.9)	
>10 years	186 (26.6)	142 (20.3)	

*Chi-square test used. P value<0.05 is significant

The table 1 shows that the intervention group consist of 699 patients with 376 male and 323 female patients. The non-intervention group consist of 490 patients with 240 male and 250 female patients. In the intervention group, 297 patients were from the age group of <45years (42.5%), 202 patients (28.9%) between 46- 60 years of age and 200 (28.6%) patients were above 60 years. In the non-intervention group, 133 patients were from the age-group <45 years (27.1%), between 143 (29.2%) were between the age-group of 46- 60 years and 214 (43.7%) were more than 60 years of age (43.7%). 19 (2.7%) patients from the intervention groups were smokers, 37 (5.3%) had drinking habit and 66 (9.4%) had both. Among the non-intervention group, 20 (4.1%) were smokers and 33 (6.7%) were alcoholic and 119 (24.3%) were both alcoholic and smokers. 577 (82.5%) from the intervention group and 318 (64.9%) from the non-intervention group had no smoking or drinking habit. 273 (39.1%) of patients from intervention group and 170 (34.7%) from non- intervention group had a hereditary history of diabetes.

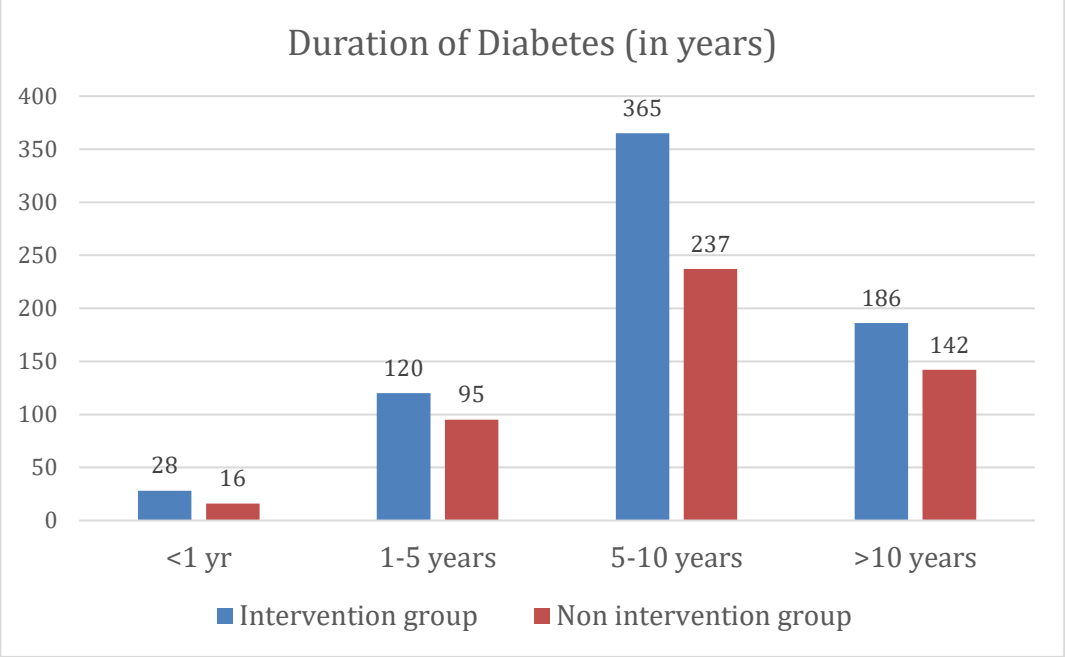


Fig. 1: Duration of diabetes among patients

The Fig 1 shows the duration of diabetes in 28 (4%) of patients from intervention group was <1 year, in 120 (17.2%) it was 1-5 years, in 365 (52.2%) it was 5-10 years and in 186 (26.6%) it was >10 years. Among non-intervention group, duration of diabetes in 16 (2.3%) of patients was <1 year, in 95 (13.6%) it was 1-5 years, in 237 (33.9%) it was 5-10 years and in 142 (20.3%) it was >10 years

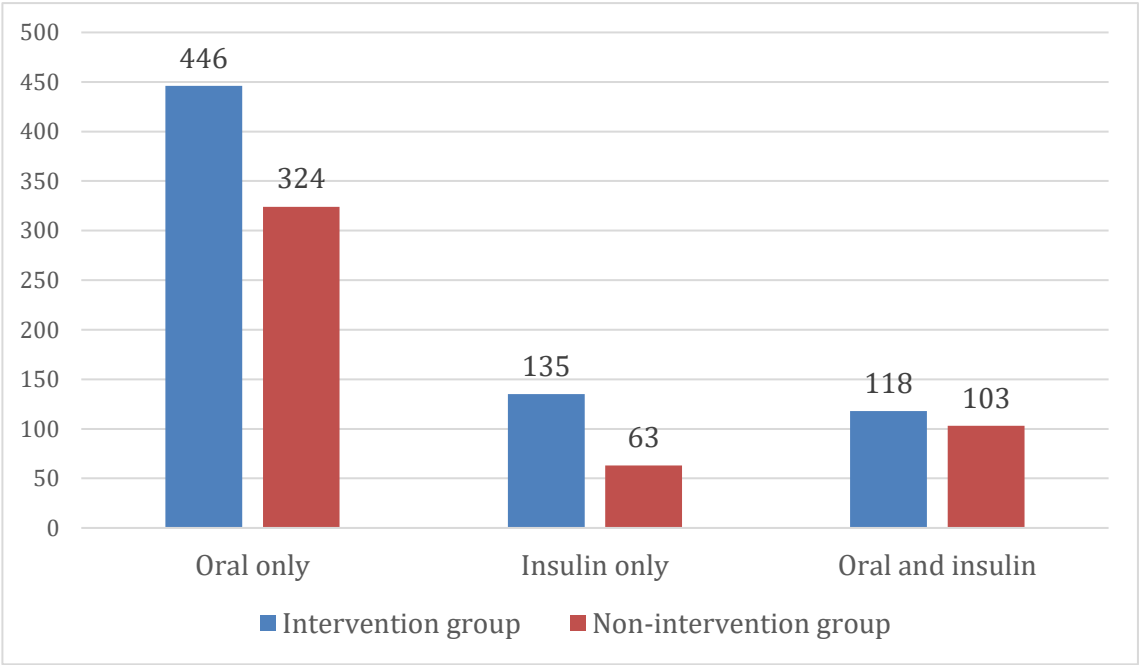


Fig. 2: Insulin prescription pattern among patients

The Fig 2 shows the Insulin prescription pattern among patients as 63.8% and 66.1% in intervention group and non-intervention group respectively were taking OHAs. Patients taking only insulin were 135 (19.3%) in intervention group and 63 (12.9%) in non-intervention group. 118 (16.9%) and 103 (21%) patients from both groups were taking both oral medications and insulin.

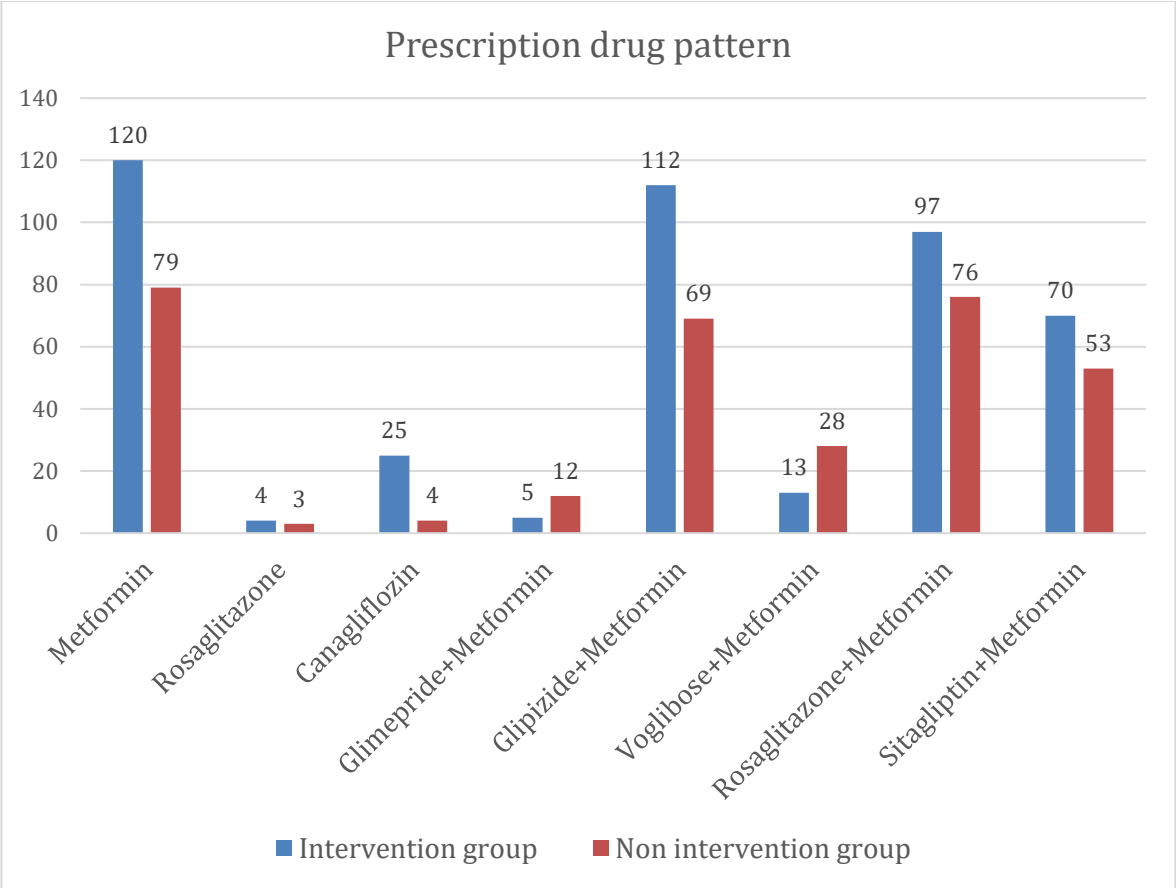


Fig. 3: Prescription pattern of oral hypo-glycaemic drugs among patients

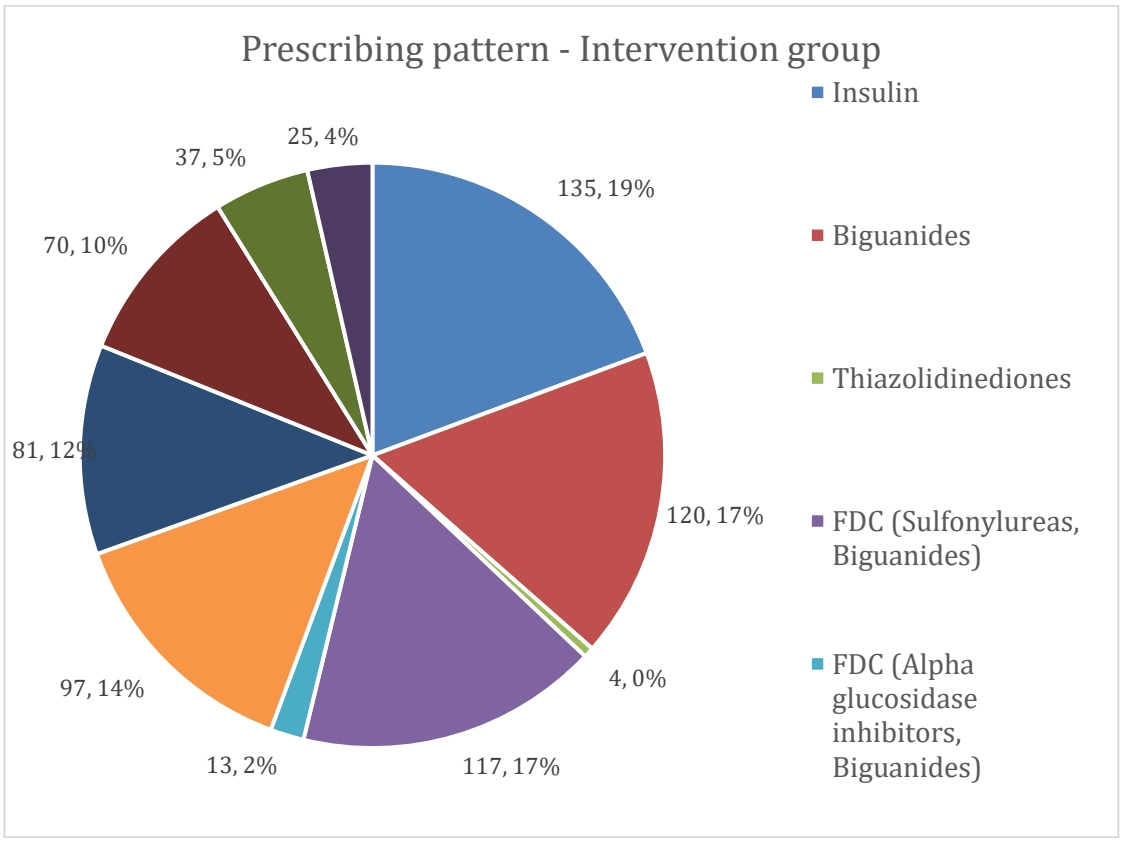


Fig. 4: Prescription pattern of oral hypo-glycaemic drugs in intervention group

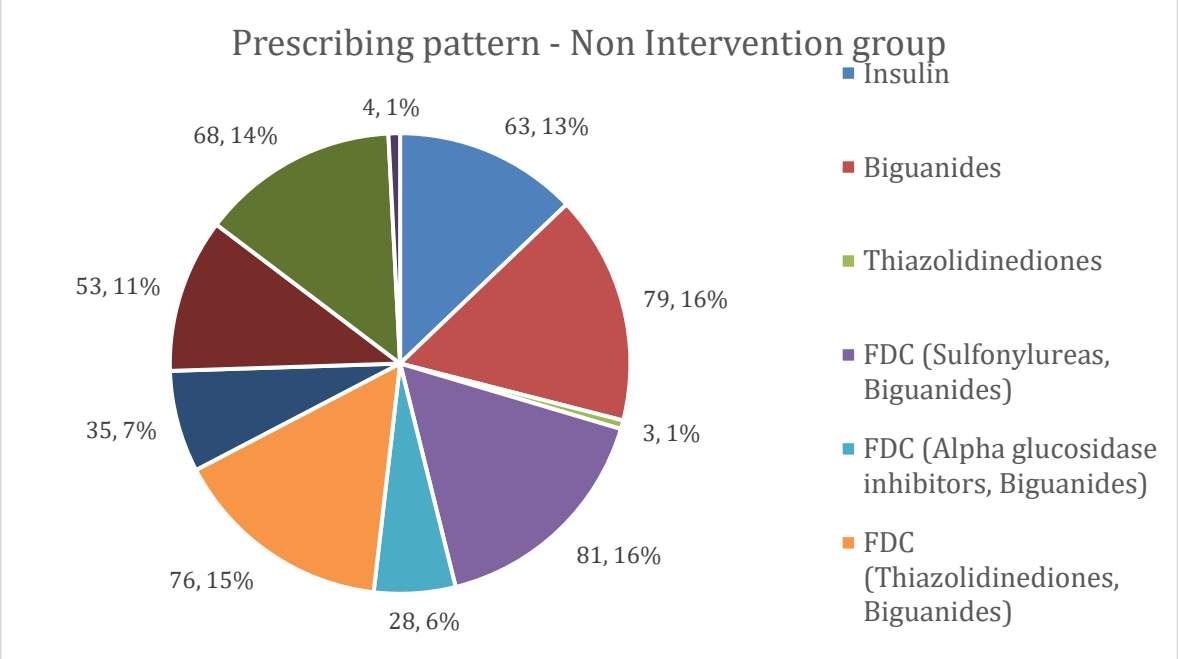
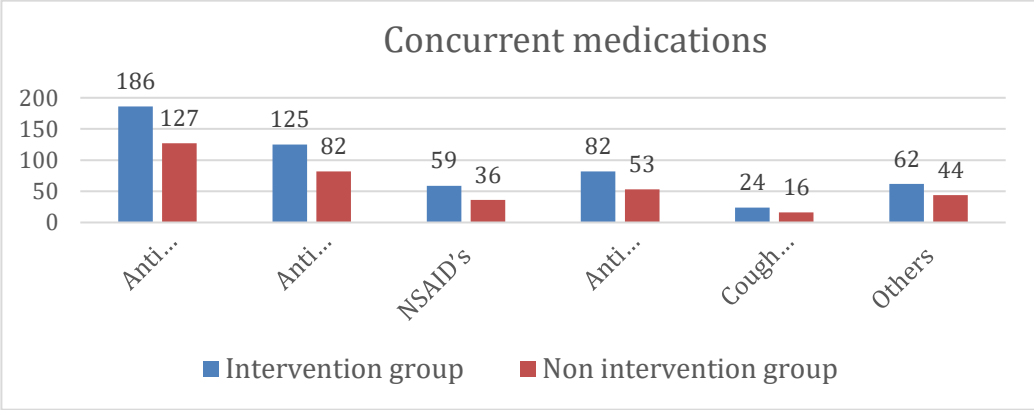


Fig. 5: Prescription pattern of oral hypo-glycaemic drugs in non-intervention group



***** Values are not mutually exclusive

Fig. 6: Concurrent medications prescribed

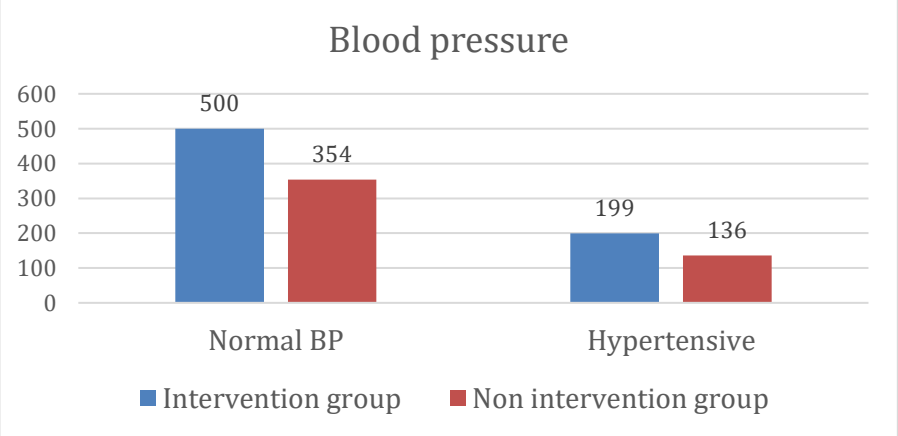
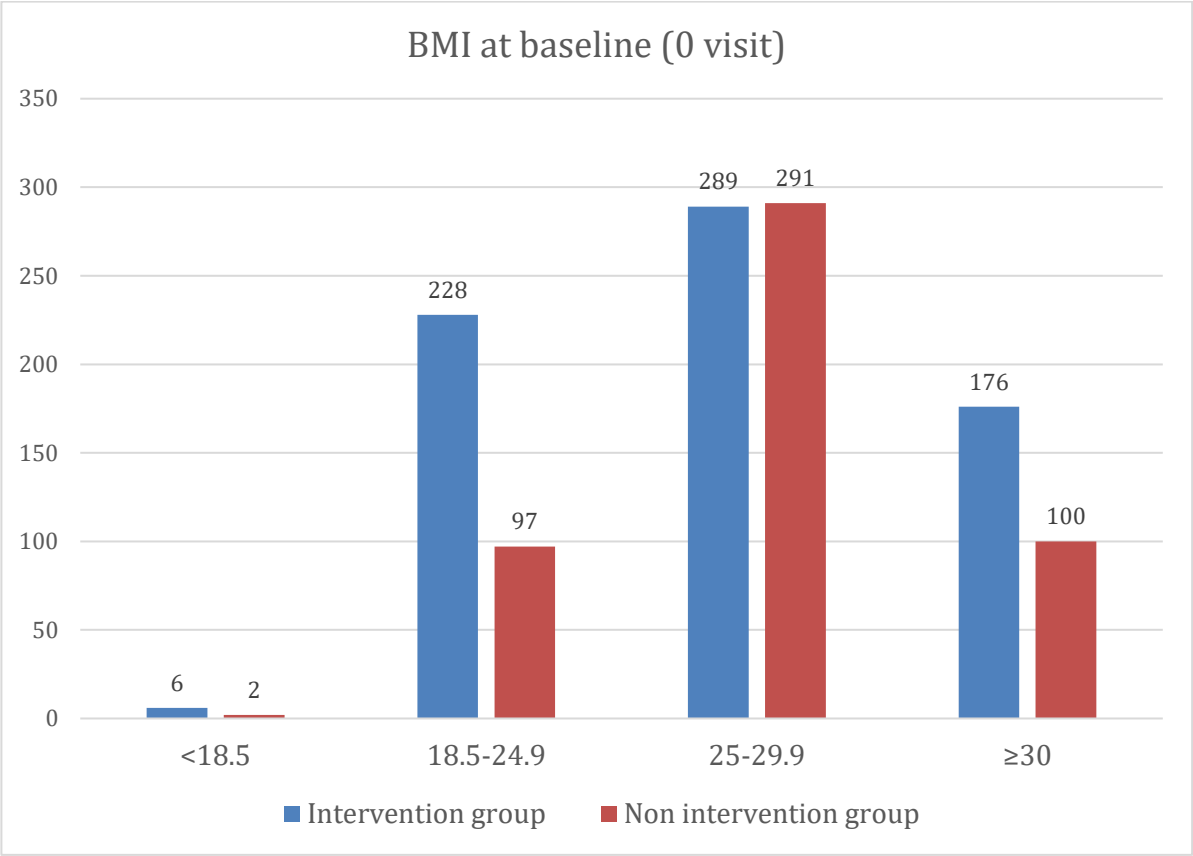


Fig. 7: Blood pressure levels of patients

The Fig 7 shows the blood pressure of 699 patients from intervention group among which 500 (71.5%) were normal and 199 (28.5%) hypertensives. Among 490 patients from non-intervention group, 354 (72.2%) were normal and 136 (27.8%) hypertensives.

Table 2: BMI levels of patients

	Intervention group N=699, n (%)	Non-intervention group N=490, n (%)	P value
BMI at Baseline (0 visit)			
<18.5	6 (0.9)	2 (0.4)	0.00001*
18.5-24.9	228 (32.6)	97 (19.8)	
25-29.9	289 (41.3)	291 (59.4)	
≥30	176 (25.2)	100 (20.4)	
BMI at 3rd visit			
<18.5	7 (1)	8 (1.6)	0.00001
18.5-24.9	228 (32.6)	279 (57)	
25-29.9	294 (42.1)	144 (29.4)	
≥30	170 (24.3_	59 (12)	
BMI at 6th visit			
<18.5	7 (1)	2 (0.4)	0.00001*
18.5-24.9	228 (32.6)	311 (63.5)	
25-29.9	386 (55.2)	128 (26.1)	
≥30	78 (11.2)	49 (10)	



*Chi-square test used. P value<0.05 is significant, *Fisher's exact test used

Fig. 8: BMI levels of patients at baseline

The figure 8 shows the body mass index of patients from interventional and non-interventional group at 3rd visit. Among interventional group, 7 (1%) group, 8 (1.6%) were under-weight, 279 (57%) were normal, 144 (29.4%) overweight and 59 (12%) were obese. The fig 10.shows the body mass index of patients from interventional and non-interventional group at 6th visit. Among interventional group, 7 (1%) were under-weight, 228 (32.6%) were normal, 294 (42.1%) overweight and 170 (24.3%) were obese. Among non-interventional
228 (32.6%) were normal, 386 (55.2%) over weight and 78 (11.2%) were obese. Among non-interventional group, 2 (0.4%) were under-weight, 311 (63.5%) were normal, 128 (26.1%) over weight and 49 (10%) were obese.

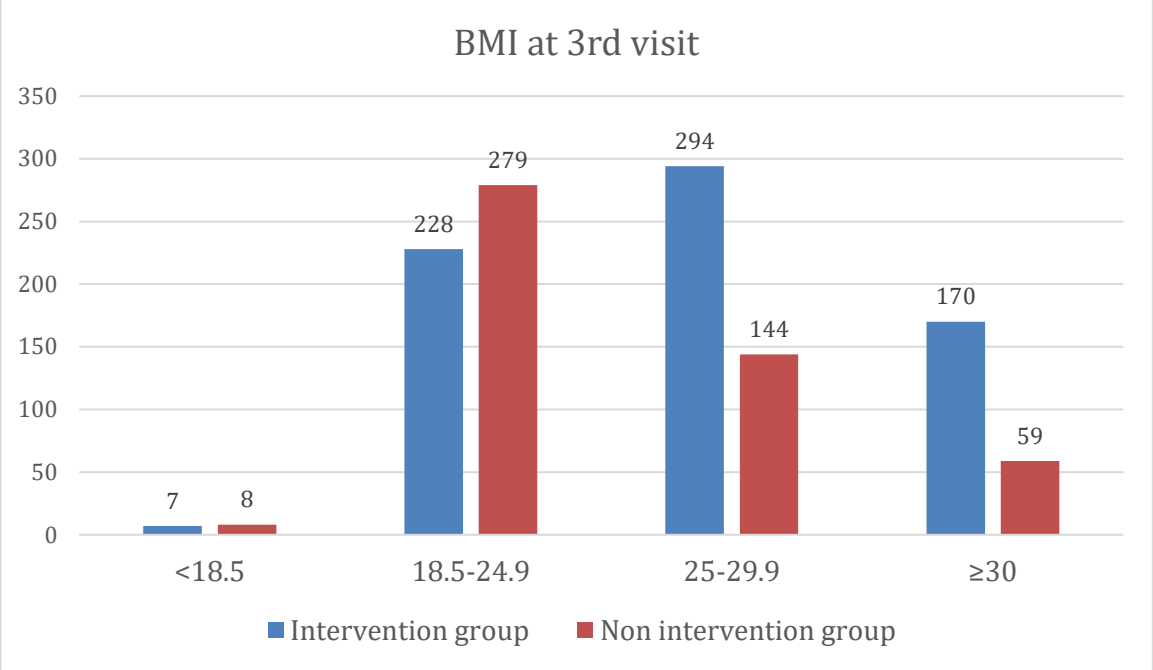


Fig. 9: BMI levels of patients at 3rd visit

The above figure 9 shows the body mass index of patients from interventional and non-interventional group at 3rd visit. Among interventional group, 7 (1%) were under-weight, 228 (32.6%) were normal, 294 (42.1%) overweight and 170 (24.3%) were obese.

Among non-interventional group, 8 (1.6%) were under-weight, 279 (57%) were normal, 144 (29.4%) overweight and 59 (12%) were obese.

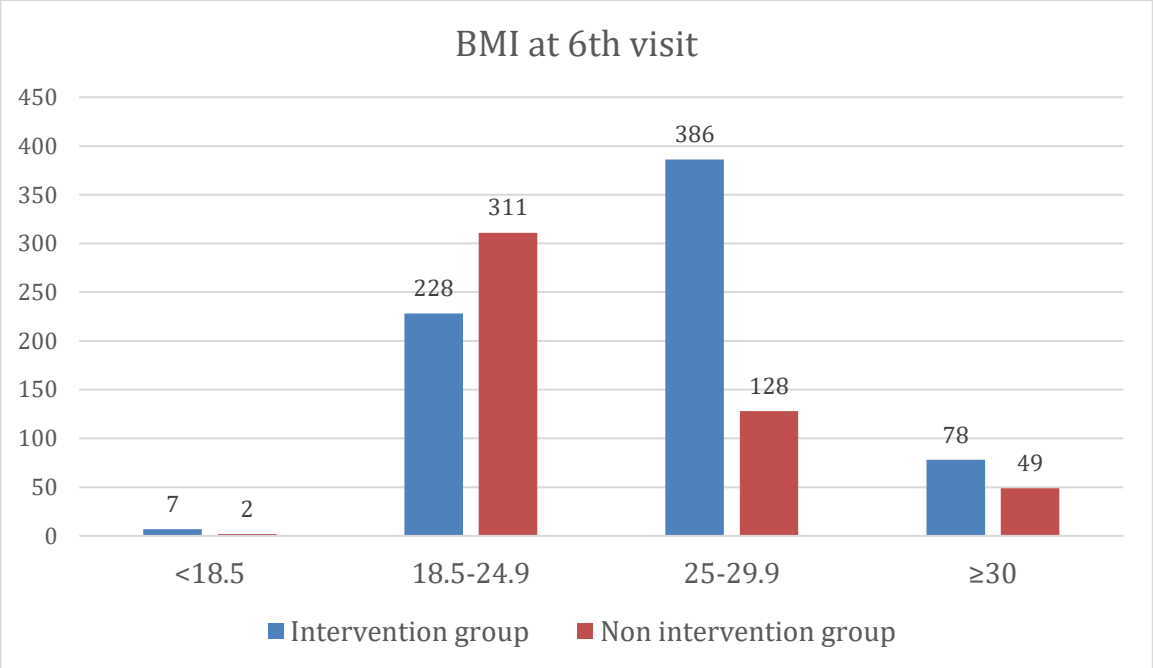


Fig. 10: BMI levels of patients at 6th visit

The above figure 10 shows the body mass index of patients from interventional and non-interventional group at 6th visit. Among interventional group, 7 (1%) were under-weight, 228 (32.6%) were normal, 386 (55.2%) over weight and 78 (11.2%) were obese.

Among non-interventional group, 2 (0.4%) were under-weight, 311 (63.5%) were normal, 128 (26.1%) over weight and 49 (10%) were obese.

Table 3: HbA1C levels of patients

HbA1C (%)	Intervention group N=699, n (%)	Non-intervention group N=490, n (%)	P value
HbA1C at baseline (0 visit)			
≤7	111 (15.9)	73 (14.9)	0.644
>7	588 (84.1)	417 (85.9)	
HbA1C at 3rd visit			
≤7	201 (28.7)	111 (22.6)	0.012
>7	498 (71.3)	379 (77.4)	
HbA1C at 6th visit			
≤7	332 (47.5)	184 (37.6)	0.0006
>7	367 (52.5)	306 (62.4)	

Chi-square test used. P value<0.05 is significant

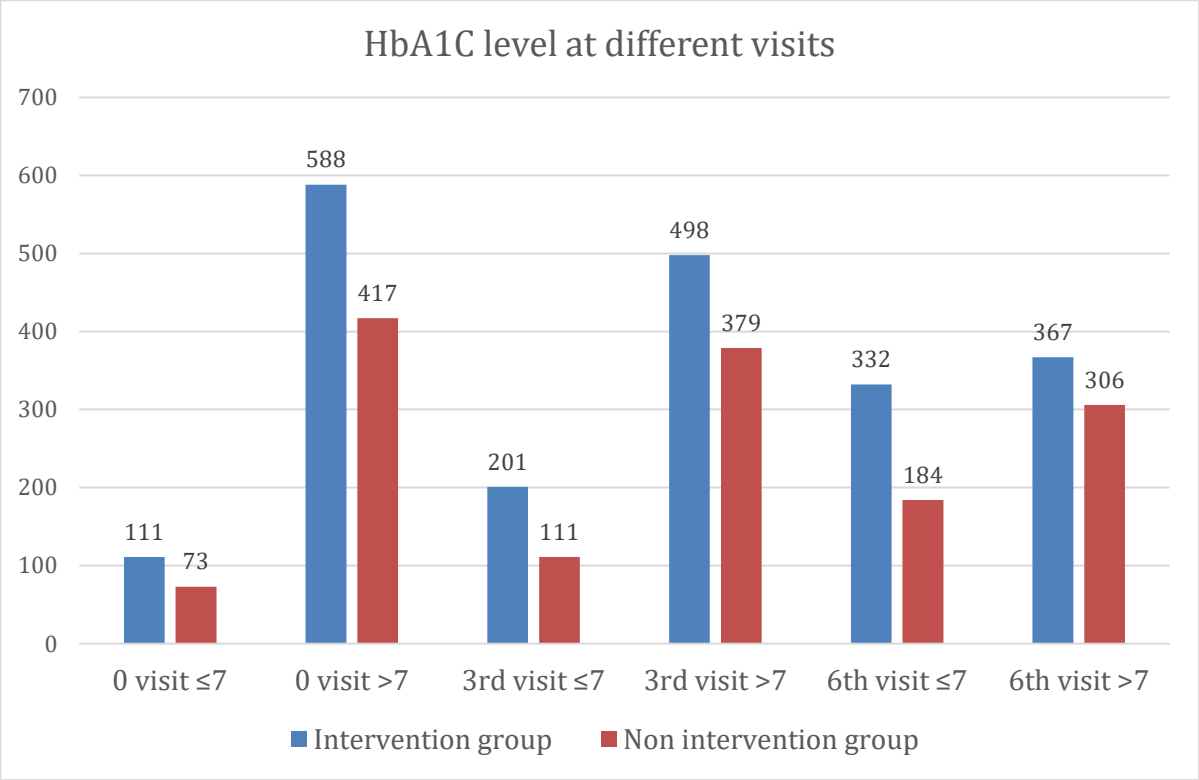


Fig. 11: HbA1C levels of patients

The above figure 11 shows the HbA1C levels of patients At baseline, 111 (15.9%) patients from interventional and 73 (14.9%) non-interventional group had HbA1C value ≤7. 588 (84.1%) patients from interventional and 417 (85.9%) non-interventional group had HbA1C value greater than 7.At 3rd visit, 201 (28.7%) patients from interventional and 111 (22.6%) non-interventional group had HbA1C value ≤7. 498 (71.3%) patients from interventional and 379 (77.4%) non-interventional group had HbA1C value >7.

At 6th visit, 332 (47.5%) patients from interventional and 184 (37.6%) non-interventional group had HbA1C value ≤7. 367 (52.5%) patients from interventional and 306 (62.4%) non-interventional group had HbA1C value greater than 7.

At baseline, 111 (15.9%) patients from interventional and 73 (14.9%) non-interventional group had HbA1C value ≤7. 588 (84.1%) patients from interventional and 417 (85.9%) non-interventional group had HbA1C value greater than 7.

At 3rd visit, 201 (28.7%) patients from interventional and 111 (22.6%) non-interventional group had HbA1C value ≤7. 498 (71.3%) patients from interventional and 379 (77.4%) non-interventional group had HbA1C value >7.

At 6th visit, 332 (47.5%) patients from interventional and 184 (37.6%) non-interventional group had HbA1C value ≤7. 367 (52.5%) patients from interventional and 306 (62.4%) non-interventional group had HbA1C value greater than 7.

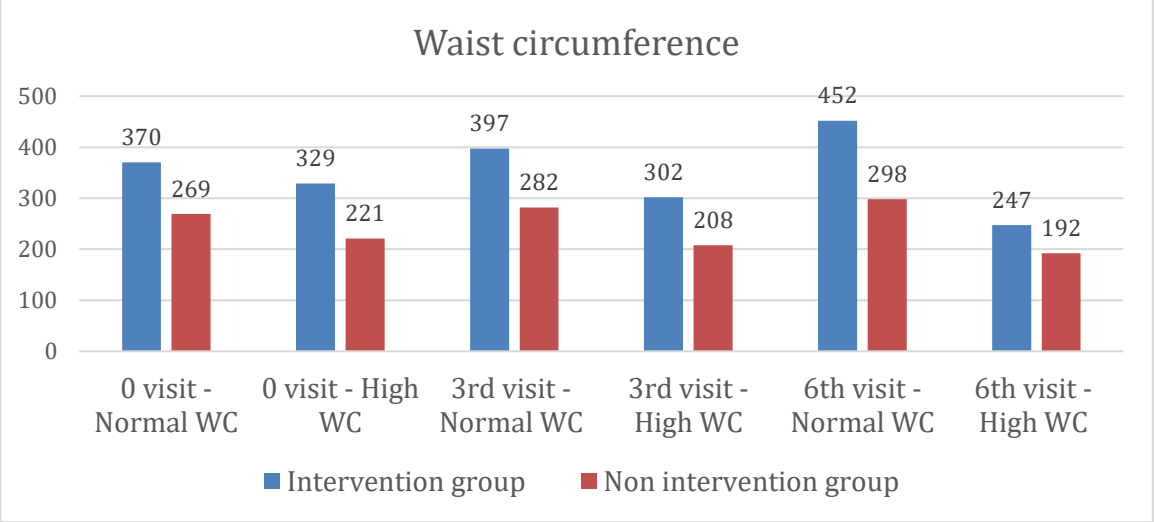


Fig. 12: Waist circumference of patients

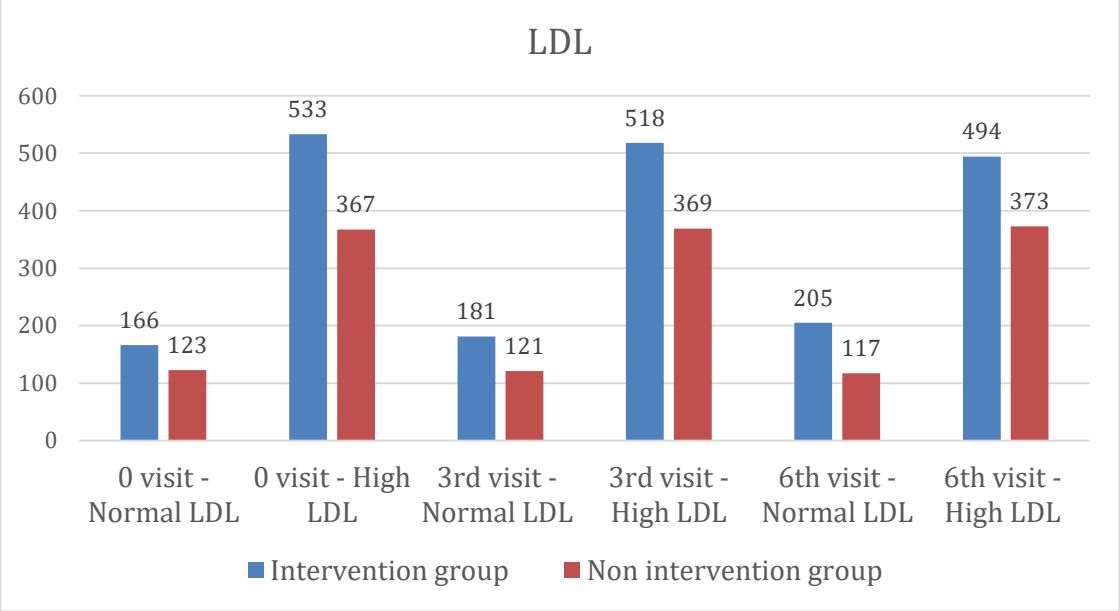


Fig. 13: LDL levels of patients

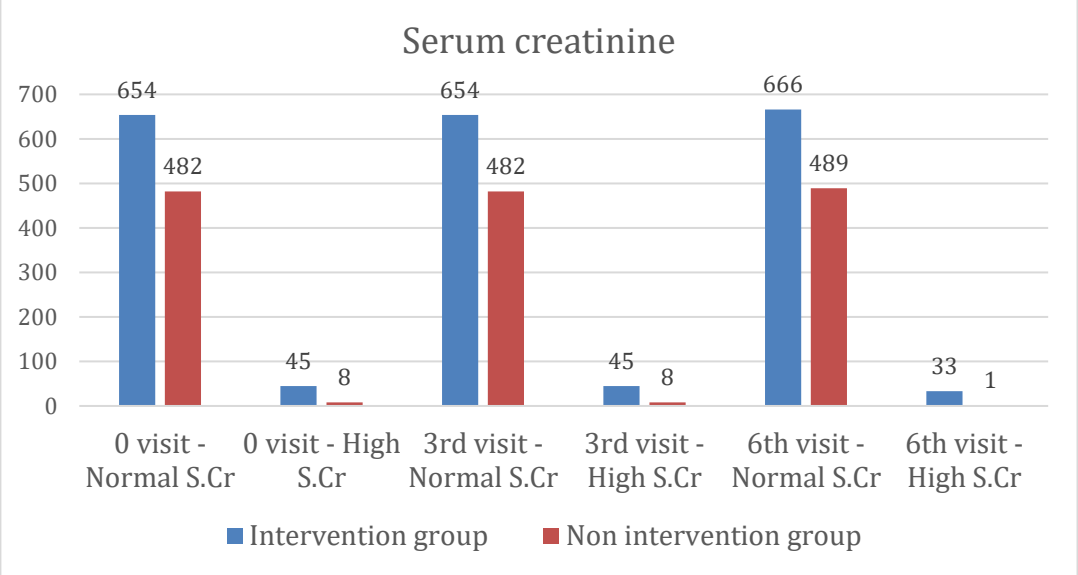
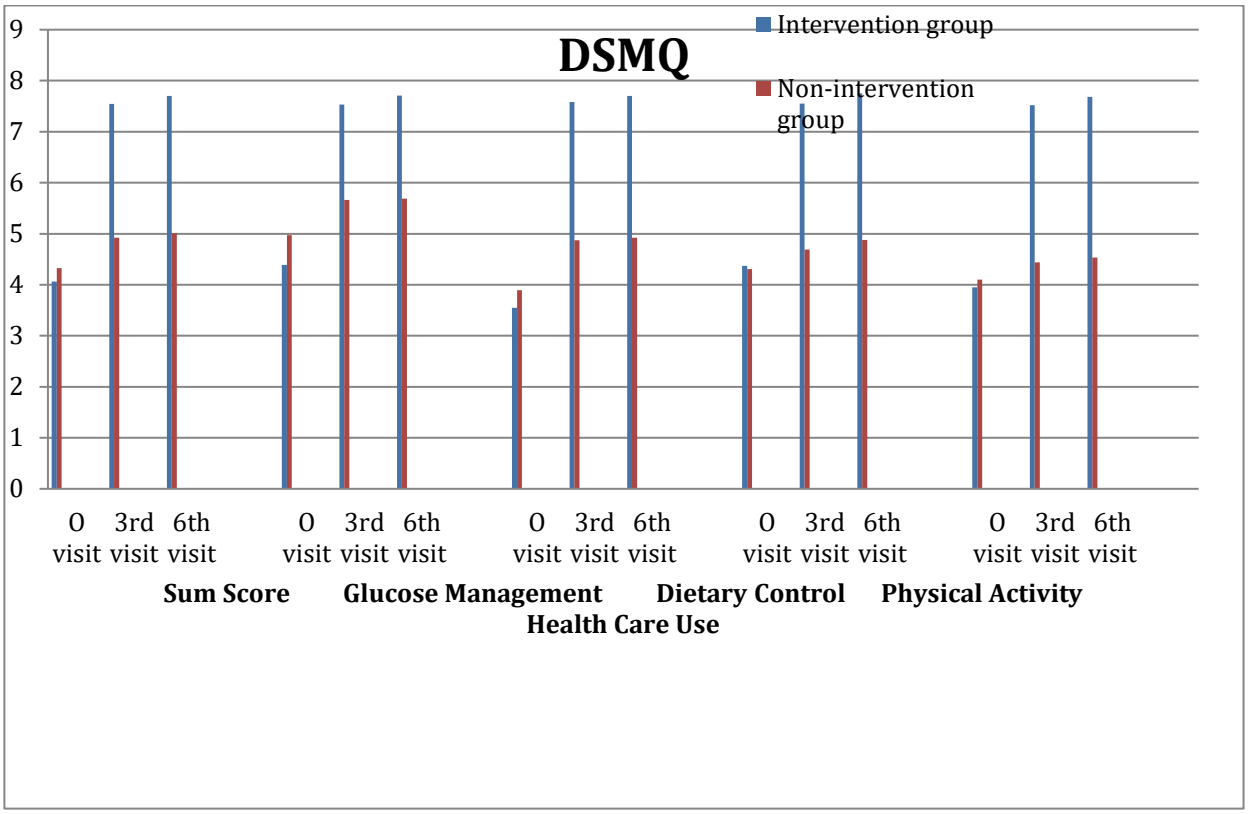


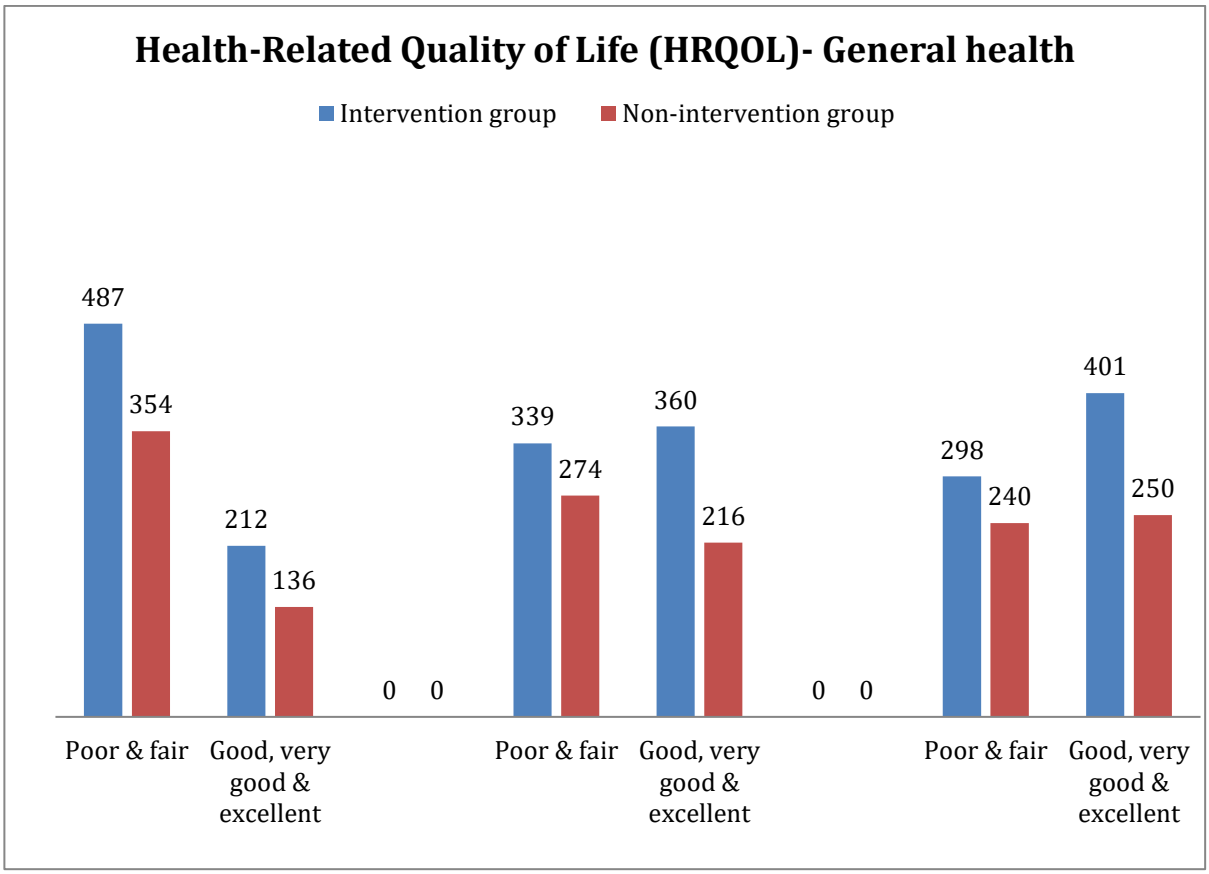
Fig. 14: Serum creatinine levels of patients

Questionnaires



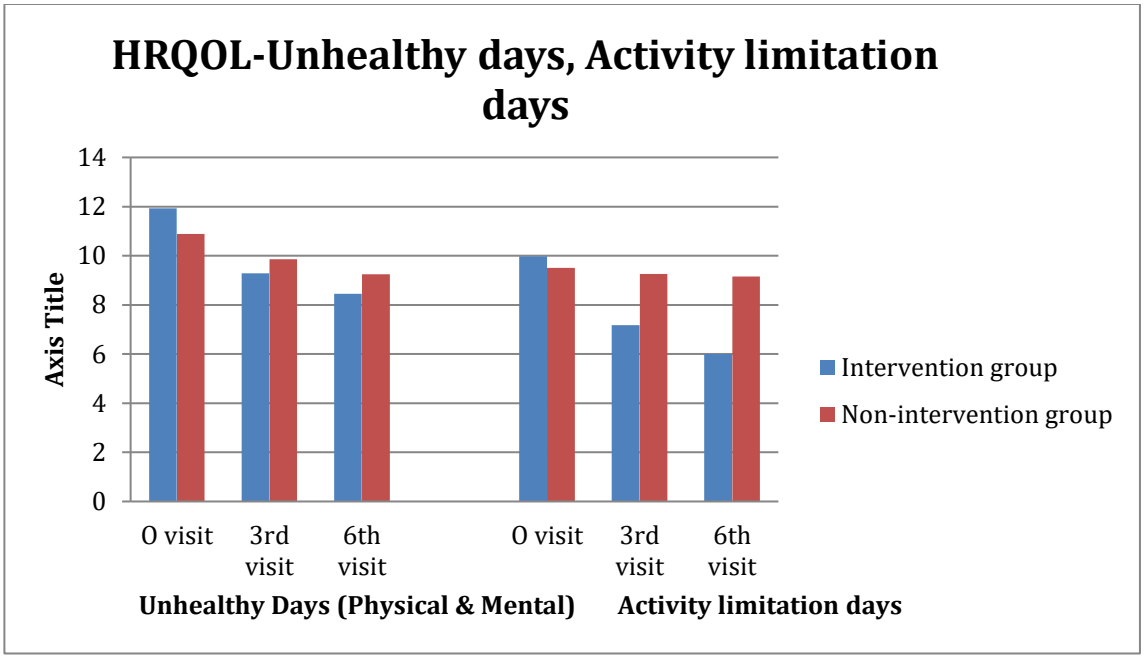
Independent-t test used. P value<0.05 is significant

Fig. 15: Diabetes Self-Management Questionnaire (DSMQ)



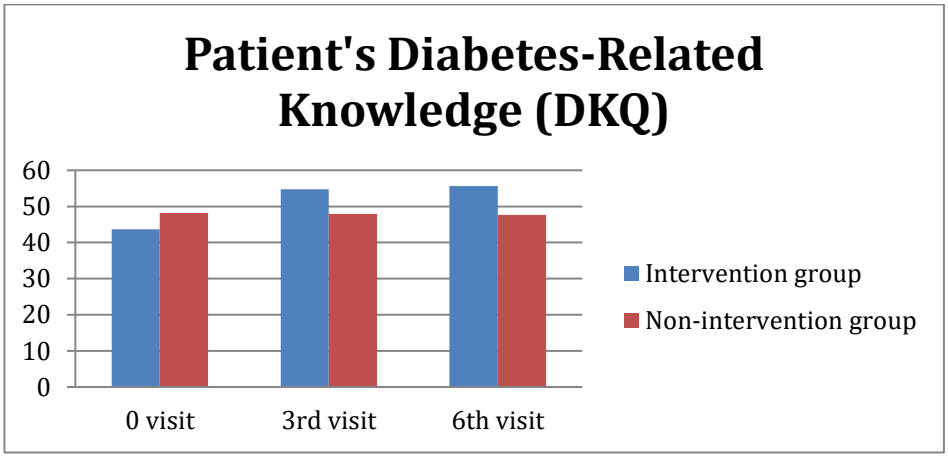
Chi-square test used. P value<0.05 is significant

Fig. 16: HRQOL- General health



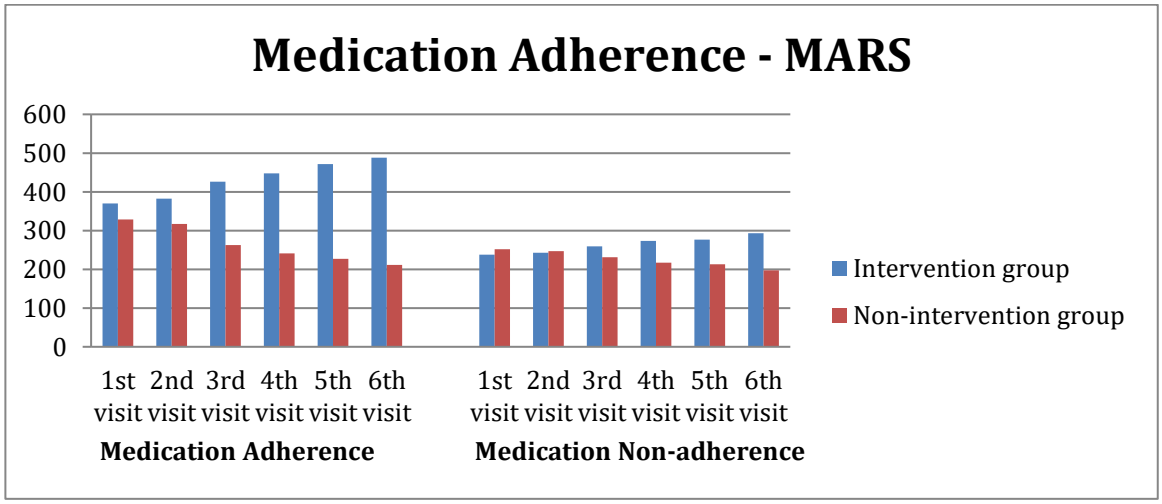
Independent-t test used. P value<0.05 is significant

Fig. 18: HRQOL–Unhealthy and activity limitation days



Independent-t test used. P value<0.05 is significant

Fig. 19: Diabetic Knowledge Questionnaire (DKQ)



Chi-square test used. P value<0.05 is significant

Fig. 20: Patients medication adherence

While comparing the mean difference values of indicators using independent-t test, the current study shows a significant improvement between interventional and non-interventional groups.
Mean difference of HbA1C (0 visit- 6th visit) for interventional group is 0.648±0.713 and non-interventional group is 0.378±0.619, which is significant (P-value=0.0001).

Discussion

While comparing the mean difference values of indicators using independent-t test, the current study shows a significant improvement between interventional and non-interventional groups. Mean difference of HbA1C (0 visit- 6th visit) for interventional group is 0.648±0.713 and non-interventional group is 0.378±0.619, which is significant (P-value=0.0001). The study found a significant mean difference of VAI between interventional (0.3583±1.7114) and non-interventional group (0.0029±0.0736) from 0 visits to 6th visit (P- Value=0.0001). The study results show a significant mean difference of waist circumference (WC) between interventional (4.08±7.36) and non-interventional group (0.98±16.45) from 0 visits to 6th visit (P-Value=0.0001). In this study, the mean difference of LDL (0 visit- 6th visit) for interventional group is 30.39±33.91and non-interventional group is -1.16±11.58, which is significant (P-value=0.0001). Our findings are consistent with those found in the existing literature, which demonstrate that pharmacist-led treatments of various types increased HbA1c and adherence in diabetic patients. According to meta-analyses, pharmacist-led comprehensive education programs result in a 1% HbA1c decrease, whereas treatments combining both counselling and effective medication management result in a 1% HbA1c reduction. [8,9,10,11,12,13,14,15]

Conclusion

The findings of this study show that pharmacists can have a significantly positive influence on medication adherence, glycaemic control, and patient satisfaction. In an outpatient context, a pharmacist-led intervention can assist patients with type 2 diabetes improve their HBA1c, BMI, blood pressure levels, total cholesterol, and medication adherence.
A clinical pharmacist who is also a qualified diabetes educator can be involved in diabetes care to help patients better control their disease by providing knowledge about disease management, encouraging them to achieve therapeutic and lifestyle goals, and assisting them in sticking to their medication regimens.

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