International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Pattern of Pharmacotherapy and Glycemic Control Status in Diabetic Patients with Different Stages of CKD in A Tertiary Care Centre in Kerala

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Received: 01-01-2026
Accepted: 25-01-2026
Available online: 26-02-2026

ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is a leading cause of Chronic Kidney Disease (CKD), with approximately 20–30% of diabetic patients developing moderate-to-severe renal impairment. Management of diabetes in CKD is clinically challenging due to altered insulin metabolism, reduced renal clearance of anti-diabetic drugs, and increased risk of both hyperglycemia and hypoglycemia. Although guidelines such as ADA, KDIGO, and KDOQI recommend an HbA1c target of <7% to retard CKD progression, optimal glycemic targets in advanced CKD remain controversial.

Aim: To assess the pattern of pharmacotherapy and glycemic control status in diabetic patients with different stages of CKD attending a tertiary care center in Kerala, and to evaluate the association of CKD severity with microvascular and macrovascular complications.

Methods: This cross-sectional study included 104 patients with T2DM and established CKD (eGFR <60 mL/min/1.73m²) attending endocrinology and nephrology outpatient departments. Data collected from electronic medical records included demographic variables, laboratory parameters (HbA1c, hemoglobin, serum creatinine), comorbidities, diabetic complications, imaging findings, and treatment details. Statistical analysis was performed using SPSS version 21.0. A p-value <0.05 was considered statistically significant.

Results: The mean age was 69.89 ± 5.46 years, with a mean diabetes duration of 15.09 ± 6.4 years. Mean HbA1c was 8.31 ± 1.79%, indicating suboptimal glycemic control. The mean eGFR was 26.06 ± 16.00 mL/min/1.73m², with 32.7% of patients in stage 5 CKD (<15 mL/min). Systemic hypertension was present in 94%, dyslipidemia in 67%, coronary artery disease (CAD) in 56%, diabetic retinopathy (DR) in 67.1%, and peripheral vascular disease (PVD) in 67% of patients.

When categorized by treatment modality, 13 patients were on oral hypoglycemic agents (OHA) alone, 48 on insulin alone, and 43 on combination therapy. Insulin use increased significantly with declining eGFR. Sulfonylureas were the most commonly prescribed OHA, followed by gliptins, metformin, and SGLT2 inhibitors. Premixed insulin was the most frequently used insulin regimen. Better glycemic control was observed in the OHA-only group compared to insulin-treated groups. Among insulin regimens, basal insulin showed relatively better HbA1c control.

Patients with eGFR <30 mL/min had significantly higher prevalence of dyslipidemia (p=0.037) and diabetic retinopathy (p=0.009). CAD also showed a higher prevalence in advanced CKD, though statistical significance was borderline.

Conclusion: This study highlights suboptimal glycemic control among diabetic CKD patients in a tertiary care outpatient setting, with increasing reliance on insulin therapy in advanced stages. Sulfonylureas and premixed insulin were the most commonly prescribed agents. Screening gaps for end-organ complications and underutilization of ACE inhibitors and statins were observed. Despite limitations including small sample size and retrospective design, this study provides a cross-

sectional overview of real-world management patterns in diabetic kidney disease and underscores the need for guideline-based comprehensive care.

Keywords*: Pharmacotherapy, Glycemic, Diabetic, CKD, hyperglycemia .*

INTRODUCTION

Around 20–30% of patients with type 2 diabetes mellitus (T2DM) have moderate-to-severe CKD (glomerular filtration rate (GFR) <60 mL/min/1.73m2)

(1). the combination of diabetes and CKD is coupled with increased morbidity and mortality, mainly due to increased cardiovascular risk (2).

Treatment of Diabetes in patients with diabetic kidney disease can be difficult, because of renal failure-related changes in insulin signalling, glucose transport and metabolism, favouring both hyperglycaemic peaks and hypoglycaemia. the decline in eGFR impairs the clearance of anti diabetic agents and insulin, frequently requiring modification of prescriptions.

Rigorous glucose control decreases the risk of microalbuminuria
and macroalbuminuria, but evidence is missing as to whether intensive glycemic control reduces the risk of clinically significant renal outcomes, such as doubling of creatinine, ESRD or death from renal disease during the years of follow-up(3).

To address these controversies, the Standards of Medical Care in Diabetes of the American Diabetes Association (ADA) , the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines (6), and the Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease and the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for the management of diabetes with CKD recommend a target A1C of<7.0% to prevent or retard the progression of CKD.

Still, none of these guidelines specified the goals for glycemic control in patients with renal impairment and a GFR of <45 mL/min. also, several studies have questioned the precision of A1C as a reliable marker of the blood glycemic average, and extreme values for A1C, whether below 6% (42 mmol/mol) or above 9% (72 mmol/mol), have been correlated with the worst prognosis in individuals with significant loss of renal function (6,7).

Aim of this study was to assess the pattern of pharmacotherapy and glycemic control status in diabetic patients with different stages of ckd in a tertiary care centre in Kerala. The association of ckd with other micro vascular and macro vascular complications were also assessed .

Research design

It is a Cross sectional study conducted in patients with CKD & diabetes who visited endocrinology and nephrology OPD. Data collected from EMR included, Personal details (Age, weight, DM duration) Labs (Creatinine, Hb, HbA1C) Co-morbidities (HTN, CAD, DL) Micro &macro vascular complications(DR , POVD) Imaging (Echo, USG abdomen) and treatment details (Diabetes treatment, erythropoietin use, Haemodialysis)etc . Patients with type 2 DM and Established CKD with eGFR<60 mL/min/1.73m2 were included.

Statistical analysis

The values were expressed as the mean with SD and the number (percentage) for the categorical variables. The Kolmogorov-Smirnov test was used to test the distribution pattern. The differences in clinical characteristics between groups were analyzed using Student t test. P value, <0.05 was considered statistically significant. The statistical analyses were performed with SPSS, version 21.0, software (SPSS, Chicago, IL) .

RESULTS

Baseline characteristics

Among the 104 patients included in the study, 60 patients were males, 44 were females .Mean Age was 69.89yrs (SD 5.46),Mean Diabetes duration was 15.09 yrs (SD 6.4). Mean HbA1c was 8.31(SD1.79) and Mean Hb was 10.73 (1.34). Among all patients, 94% had systemic hypertension, 67% had dyslipidemia ,56% had coronary artery disease ,67.1% had Diabetic retinopathy (both PDR & NPDR)and 67 % had POVD

Mean EGFR was 26.06 (SD16.00). Among all population included 24% were on haemodialysis, 27.7% have used Erythropoietin.

Distribution of patients according to eGFR categories shown in table 1

Table 1

eGFR	Frequency	Male & female
45-59	14(13.5%)	9 & 5
30-45	34(32.7%)	21 & 13
15-30	22(21.2%)	12& 10
<15	34 (32.7%)	18&16
Total	104	

Percentage Distribution of systemic hypertension, coronary heart disease ,povd ,dyslipidemia ,statins and ACEI use ,proteinuria and diabetic retinopathy in each classes of ckd has shown in table 2.

Distribution of co morbidities and complications in different egfr categories

Table 2

eGFR	45-59	30-45	15-30	<15	TOTAL number with available data
Duration of dm (yrs)	14.86±6.98	15.06±5.93	14.5±6.6	14.76±6.93	
dyslipidemia	78.6%	73.5%	63.6%	50%	67
Htn	85.7%	85.3%	90.9%	97.1%	97
Proteinuria	36%	38%	78%	98%	52
CAD	35.7%	47.1%	63.6%	26.8%	58
PVD	100%	46.2%	45.5%	66.6%	23
DR	63.6%	69.2%	73.7%	100%	68
Statins	26%	12%	14%	10%	46
ACEI	22%	12%			38

Table3
Patients with ESRD in the total population

	Frequency (%)
Hemodialysis	25 (24)%
RENAL TRANSPLANT	4
ERYTHROPOITIN	29(27.7%)
ACUTE WORSENING OF RFT seen in	3

Table 4 -observation among diabetic retinopathy patients

	DR+(total-68)	NO DR (total-18)
PROTEINURIA	62	12
OBSTRUCTIVE UROPATHY	8	10
HTN	68	18

Table 5 –observation in the total population

Povd	65 not checked	23 had povd	16 without povd
DR	18 not checked	12-NPDR 56-pdr	18 no DR
hba1c	14 Patients were missing		
Usg abdomen	7 not checked	79 –MRD	18-obstructive uropathy

Among 12 patients who had proteinuria didn't have retinopathy , 12 of them were hypertensive, 8 of them had some type of obstructive uropathy (prostatomegaly underwent TURP /ureteric calculi with HUN in ultrasound)

In total population ,1 patient had ADPKD,4 patients underwent renal transplantation,3 patients reported acute worsening of renal function by infection or hepato renal syndrome .

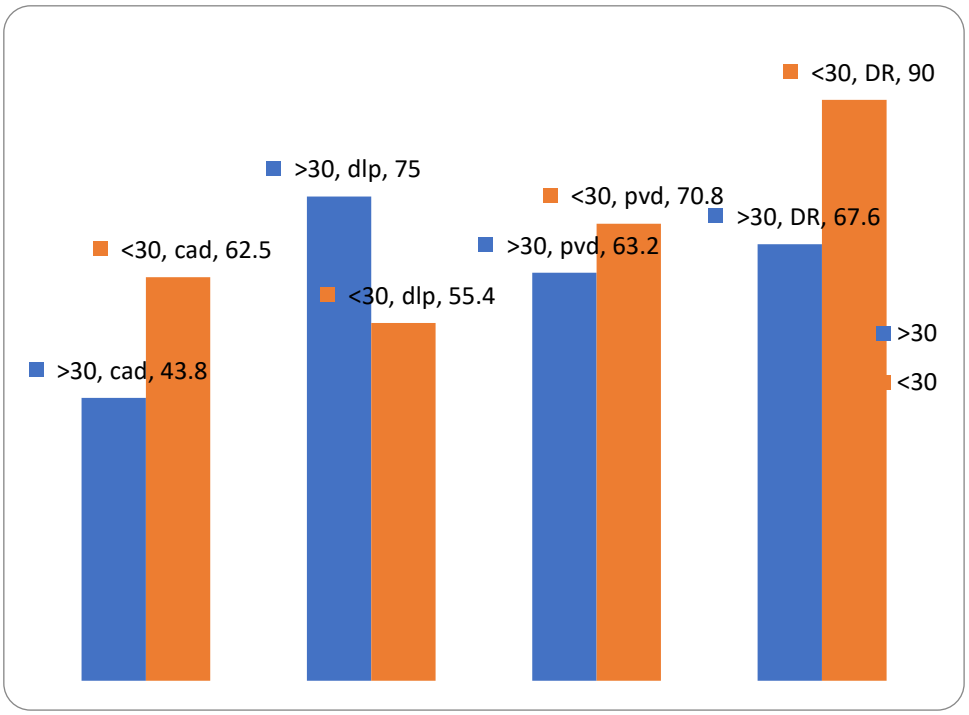
Among total population 65 patients povd status was not checked ,18 patient's retinopathy were not screened ,abdominal imaging was missing in 7 patients.

To study the distribution of complications with respect to the severity of renal disease ,Total population was divided into 2 groups with egfr>30/<30.shown in table 6 and graph 1.significance of cad ,DR, Dyslipidemia were statistically

significant except for PVD .which may be due to less screening for PVD on opd basis and less data available for the same .(table 6 ,graph 1)

Table 6

	Egfr<30	Egfr>30	P value
Dyslipidemia	31(55.4%)	36(75%)	0.037
PVD	17(70.8%)	12(63.2%)	0.837
DR	45(90%)	25(67.2%)	0.009
CAD	35(62.5%)	21(43.8%)	0.056



Graph 1

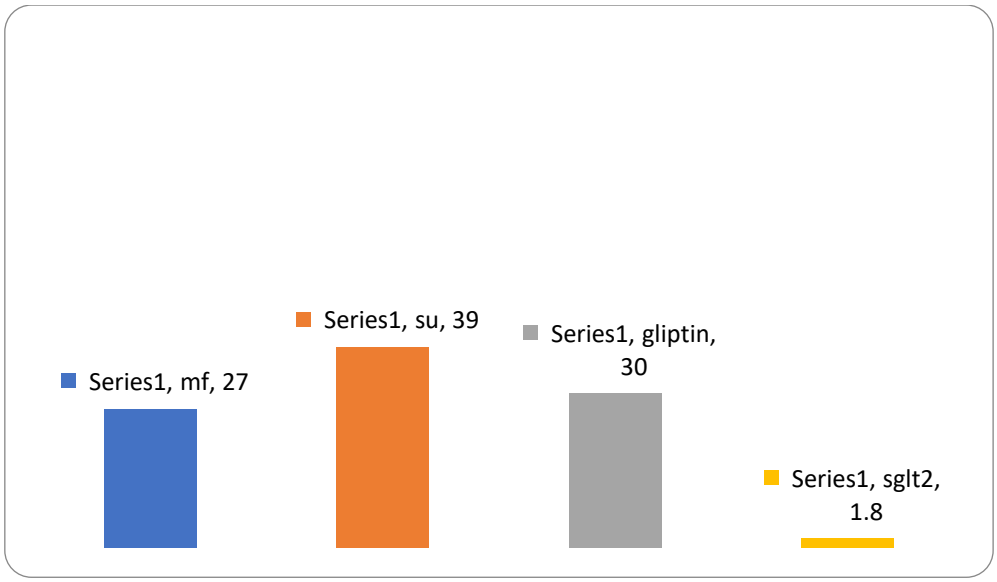
Based on Anti diabetic treatment, population was divided into OHA only used, combination of OHA and insulin used and insulin only used groups. Distribution showed in table 7.

Table 7

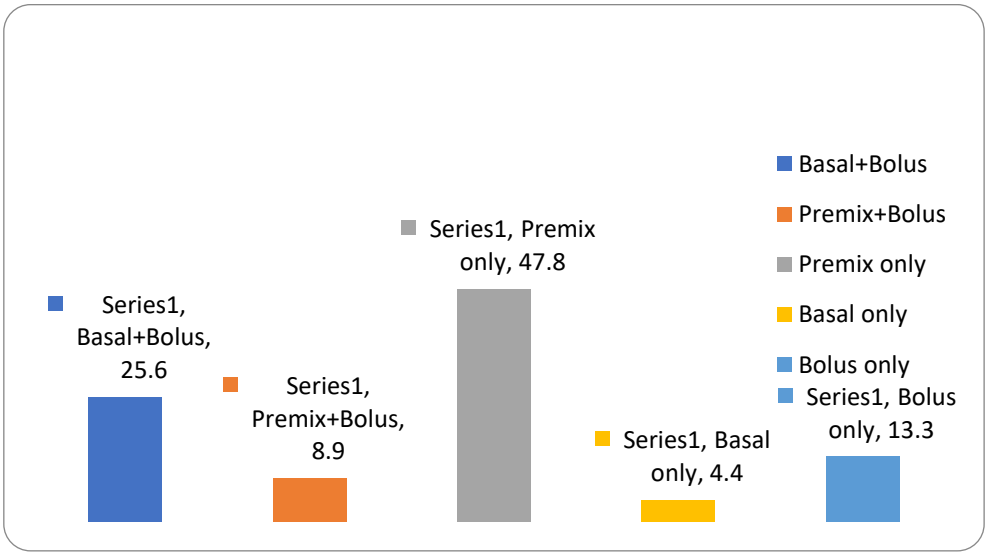
	Frequency
OHA only	13
Insulin only	48
Both	43
Total	104

Total number of patients used oha(oha alone and in combination with insulin) were 56 ,and total number of patients used insulin(insulin alone and in combination with oha) were 91.

Percentage Distribution of OHA used in the population group shown in graph 2.

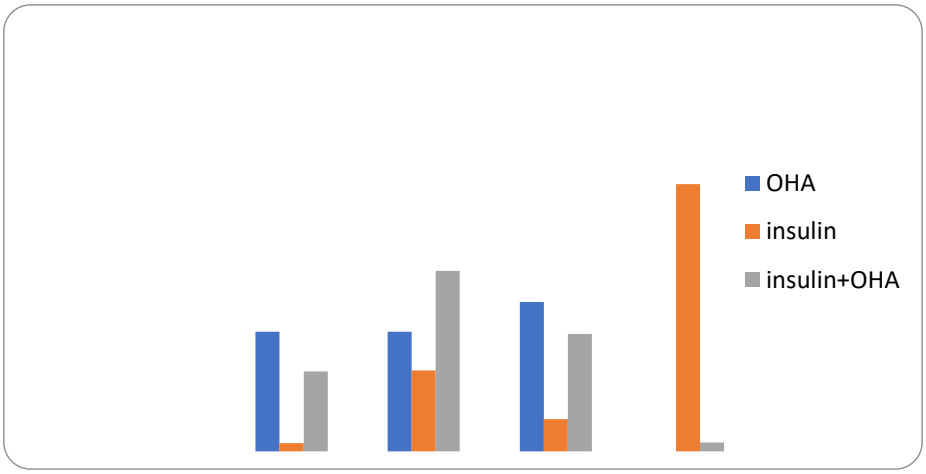


Graph 2

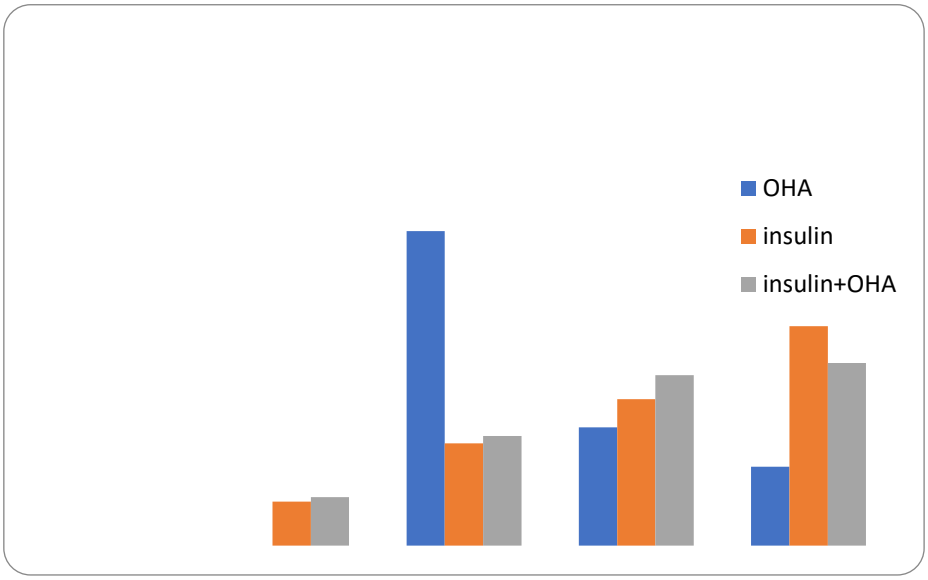


Graph 3 shows percentage distribution of types of insulin used in the population

Mean hba1c in basal +bolus group was 8.99,premix+bolus group was 9.24,premix only group was 8.09,basal only group was 7.35 and bolus only group was 8.35 .which showed better hba1c in basal only and premix group when compared to other groups .



Graph 4 shows eGFR distribution in the 3 groups



Graph 5 shows hba1c distribution in the 3 groups

Mean egfr in oha only group was 37.80,in insulin only group was 15.16 and in both oha and insulin group was 34.68 .this showed population with advanced ckd stages were treated with insulin only .

DISCUSSION

In our study predominantly were males with older population (avg 69.89yrs),and had a long duration of diabetes (15.09 yrs). this observation was seen in many Indian and abroad conducted studies.

Grandfils et al (2) study conducted in France , Patients were generally of older age with a mean age of approximately 75 years, and had a relatively long (mean 12–14 years) history of diabetes , were predominantly males.

The mean HbA1c was approximately 7.1% in his study ,In our study Mean HbA1c was much higher range (8.31) ,which shows better glycemic control in CKD patients in abroad when compared to Indian scenario .

Grandfils et al (2) in their study In patients with moderate CKD , 81% were treated with oral therapy, while 7% received insulin alone and 12% received insulin in association with oral therapy. Among patients with more severe kidney dysfunction a higher number were treated with insulin (24% alone and 11% in combination with oral agents). With regard to the choice of glucose lowering drugs , 47% were treated with sulfonylurea and 58% were treated with metformin in moderate CKD group .

In this study with moderate CKD 60.8 % were treated with oral therapy ,while 67.4% received insulin in association with oral therapy, and22.9 % received insulin alone. Among patients with more severe kidney dysfunction a higher number were treated with insulin (77.1% alone and32.5 % in combination with oral agents).

In this study among total OHA used sulfonylureas are more common than others. SU>gliptins>MF >SGLT2.AmongTotal Insulin used Premix 47.8%were more common > basal bolus 25.6%>bolus 13.3>premix+bolus 8.9%>basal 4.4%. Better hba1c observed in OHA group than >insulin +oha> insulin only. Mean hba1c in insulin group observed in this order basal (7.35)<premix (8.09)<bolus<basal bolus.

Better hba1c observed in premix insulin group may be due to non reported hypos or good compliance with premix insulin when compared to basal bolus or recently changed regimen from premix to basal bolus in uncontrolled DM. due to cross sectional study these things are not evaluated in this study .

Our study provides new qualitative information in the management of T2DMpatients with CKD. It also confirms the resultsof other published research on glucose lowering strategiesused for these patients , showing that metforminand sulfonylurea were the most prescribed glucose lowering agents.

Metformin should be used with cautionamong patients with mild-to-moderate CKD because of its renal elimination. Although there is debate on the threshold of serum creatinine or GFR, it should be avoided in severe CKD patients (GFR

< 30 mL/min/1.73m2). Most insulin secretagogues, especially glibenclamide, should be avoidedin patients with CKD, because of the risk of hypoglycaemia.

Most dipeptidyl peptidase-4 (DPP-4) inhibitors have prominent renal elimination, and thus dose reduction is necessary among patients with CKD for sitagliptin, vildagliptin, andsaxagliptin. The exception is linagliptin which is mainlyeliminated unchanged in bile and intestine. Therefore, for this product, no dosage regimen adjustment is necessary.

Yasmine et al in their study to investigate the association between albuminuria, hypertension, eGFR and CV events in diabetic kidney disease patients in a developing country found that cvd seen in 11.5 % povd in 6.6 %,use of ACE /ARB in 81 %,statin in 33.6 % ,htn in 33.6 % .

Herbert F Jelinek et al in their study 83.40% of the patients had hypertension and 93.43% had a history of dyslipidemia .The single most prevalent diabetic complication was retinopathy (13.26%), followed by CAD (10.20%)

In our study Among all patients ,94% had systemic hypertension , 67% had dyslipidemia ,56% had coronary artery disease ,67.1% had Diabetic retinopathy (both PDR & NPDR)and 67 % had POVD.

Few studies have evaluated associations between HbA1c levels and clinical outcomes in those with CKD. Shurraw et al 9 reported that HbA1c levels > 9% were associated with worse clinical outcomes, with faster kidney disease progression, increased cardiovascular events, and mortality, among patients with non dialysis-dependent CKD.

lower HbA1c levels (<6.5%) were associated with higher hazards of death from hypoglycaemia related complications. Findings from a cohortof Taiwanese adults with type 2 diabetes showed thatHbA1c levels > 7.0% were associated with increasedrisk for ESRD compared with HbA1c levels of 6% to7%.10 However, a secondary analysis of the ACCORD (Action to Control Cardiovascular Risk in Diabetes) trial reported that tighter glycemic control in patients with CKD was associated with a significant increase in cardiovascular and all-cause mortality.11

Coca et al13 reported that for those with type 2 diabetes, lower HbA1c levels were associated with reduced risk for micro- and macroalbuminuria, but its effects on ESRD were uncertain. Recently, a secondary analysis of the ADVANCE trial reported that intensive glucose control led to a long-term reduction in ESRD while not increasing the risk for cardiovascular events or death.

Can one assume that these renoprotective effects of intensive glucose control are seen in all diabetic patients with CKD or end-stage renal disease (ESRD)?
Unfortunately, results of prospective randomized controlled intervention studies are not yet available , despite the fact that diabetes is present in 25–50% of patients with ESRD

CONCLUSION

In this study among total oha used sulfonylureas are more common than others. SU>gliptins>MF >SGLT2.amongTotal Insulin used Premix 47.8%were more common > basal bolus 25.6%>bolus 13.3>premix+bolus 8.9%>basal 4.4% Better hba1c observed in OHA gp than >insulin +oha> insulin only.Mean hba1c in insulin group observed like , basal (7.35)<premix (8.09)<bolus<basal bolus.

65 patients povd status was not checked , ,18 patients retinopathy was not screened ,abdominal imaging was missing in 7 patients. Which showed strict adherence to guidelines may be missing in opd patients on evaluating end organ work up .it is shown that ,use of ACEI and statins also not much encouraged in opd patients .

There were many limitations for this study .it had small sample size .since it was a retrospective study non reported Hypoglycaemic episodes were not evaluated .however this gives an overall view of diabetic kidney disease patients attending in our opd .it gives a cross sectional picture of diabetic patients with different stages of CKD and their management pattern by physicians.

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