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Research Article

# COST CONSEQUENCE ANALYSIS OF DIABETIC NEPHROPATHY MANAGEMENT IN A TERTIARY CARE HOSPITAL

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**ABSTRACT**

**Objective:** The objective of the study was to assess the overall costs incurred to patients with diabetic nephropathy (DN) and to disclose the elements that could affect them.

**Methods:** Two-year retrospective, observational study using hospital database of a tertiary care center in Mangalore. Outcomes were assessed based on the survival of patients, length of hospital stay, coexistence of risk factors, and comorbidities. Severity was identified through staging of the disease; costs and clinical outcomes assessed through the cost consequence analysis.

**Results:** Of the 156 patients who met the diagnostic criteria, it was noticed that demographic age factor for DN was declining and the minimum duration to develop DN was seen to be as less as 1–5 years. In spite of having ample evidence that angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) control the progression of disease, not many doctors were inclined to follow. Our study showed that patients of DN with chronic kidney disease (CKD) spent more and patients with CKD and end-stage renal disease (ESRD) spent double than those with CKD alone.

**Conclusion:** Overall costs in treating 156 patients of DN amounted to 10 lakh INR and the major determinant was the cost of investigations, unlike what was expected of the drug prices.

**Keywords:** Type 2 DM, Diabetic nephropathy, CKD, Pharmacoeconomics, Cost consequence analysis, Direct costs, Indirect medical costs, India.

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## INTRODUCTION

Diabetes is a major health problem, affecting millions worldwide; mostly attributed to lifestyle changes in the recent years and the resulting surge in obesity. Defined as as a 'disturbance of intermediary metabolism', diabetes is either due to a complete or relative lack of insulin [1] which when teamed with dyslipidemia, may lead to progressive tissue damage resulting in micro and macrovascular complications [1]. DN is one of the most common microvascular complications and poses a major threat on quality of life and even survival in patients with type 2 diabetes mellitus (T2DM). Persistent proteinuria together with elevated blood pressure and retinopathy without any coexisting urinary tract infection, other renal disease, or evidence of heart failure is the clinical definition of diabetic nephropathy (DN) [1]. As the condition progresses, glomerular filtration rate (GFR) in these patients further drops and kidney functions deteriorate.

Therefore, treatment modalities such as good glycemic control, prompt regulation of blood pressure, and correction of proteinuria along with lifestyle modifications such as smoking cessation, lipid control, and salt and protein restriction help prevent or retard the progression of diabetic renal disease to a certain extent. Apart from antidiabetics and antihypertensives, drugs such as erythropoietin-stimulating agents, phosphate binders, lipid-lowering agents, Vitamin B12, folic acid, and Vitamin D analogs could be used. In addition to such a complex pharmacotherapy, long latency for diagnosis, chronicity of the disease, multiorgan involvement, and necessity for long-term care make the management of DN difficult [1]. Since majority of the people (>80% of deaths were reported in developing countries) with diabetes and its complications live in socioeconomically backward countries [2], this becomes an even greater challenge.

The total cost of DN management depends on prevalence and severity, drug therapy, patients' compliance, and treatment of complications. Back in the 2000's, prevalence was around 37.76 million in India and diabetes was estimated to be responsible for 109,000 deaths, 11 lakh years of life lost and 22 lakh disability-adjusted life years (DALYs) [3]. Nearly 40% of patients with T2DM progress to DN; Statistics indicate that there are about 10 cases of ESRD per million population and more than half a million subjects are already registered on renal replacement therapy (RRT) in the US alone. Whereas in Germany, studies showed that overall estimated cost related to nephropathy was around 1332€ from the insurance provider's perspective and 2019€ from the society's perspective [4].

In a developing country like India with a meagre health budget, majority of the patients' bear their hospital expenditure from their own pockets or utilize the family's financial resources, thus draining them completely. Only about 19% of the population are covered under central and state government-sponsored health insurance. Another 25% may be placed under private insurance schemes. However, the rest of the population are left to fend for themselves. Despite this massive incidence of diabetes and gross disparities in health-care spending, there are very few studies in India exploring the same. Since pharmacoeconomics is a branch that deals with analysis of costs of prescriptions and their clinical outcomes [5], we have attempted to use pharmacoeconomic tools and analyses to address the issue herein and help bring down the associated economic burden.

## METHODS

It was a descriptive, hospital-based study conducted retrospectively with the necessary information collected from the hospital database and Medical Records Department of A.J. Institute of Medical Sciences and

Research Centre, a tertiary care center in Mangalore during the period of August 2015–July 2017, a total span of 2 years. Both male and female patients above the age of 18 years diagnosed and treated with T2DM and DN coded as per the International Classification for Disease-10, on regular treatment and follow-up were included in the study. Patients with comorbid complications (i.e., coronary artery disease, neuropathy), newly diagnosed patients (<1 year), and vulnerable population (i.e., pregnant and lactating mothers) were excluded from the study. The study synopsis was approved by the Institutional Ethics Committee, AJIMS and RC (No: AJEC/REV/61/2015-16 dated October 15, 2015).

Demographic data including name, age, sex, address, presenting symptoms, duration of disease, medications (oral antidiabetics/insulin/combinations), treatment received in the hospital, average length of hospital stay (LOS), history of comorbidities, outcomes, and cost details were collected on a standardized case record form in the beginning and during follow-up. Outcomes were assessed based on the patients' survival, LOS, coexistence of risk factors such as associated hypertension (HTN), positive family history, smoking, and development of diabetic retinopathy (DR). Disease severity was identified through staging of the disease. For any missing values, the variable for measurement was considered to be in the normal range.

For cost evaluation, consumables were categorized into three:

- CAT–1: Supplementary therapy costs, related to IV fluids, catheters, crystalloids/colloids, blood and blood products, life-saving drugs, antibiotics, etc.
- CAT–2: Antidiabetic treatment which includes primarily the cost of insulin preparations, oral hypoglycemic, and antihyperglycemic drugs, ACEI's, and ARB's which can treat DN and further prevent the progression of disease.
- CAT–3: Costs related to investigations and laboratory tests.

For the analysis of costs of various drugs and products, prices in the latest "Current Index of Medical Specialties (CIMS)" were used as reference [6]. Furthermore, differences in the cost of various brand formulations due to preferences of consultants were standardized by taking the average of three commonly used brands/branded generics. This also made sure that increase in prices of drugs due to inflation each year is adjusted therein. The three most commonly prescribed brands/generics were identified by obtaining the pharmacist's procurement list from the past 6 months. Costs related to investigations (radiology, hematology, and biochemical) were obtained from the "Hospital Price List" for the year 2017, all expressed in Indian Rupee. As much as we'd like to include, indirect costs (cost of transportation to and fro, lost wages for the patient and bystander, and loss of productivity), and indirect non-medical costs due to morbidity and mortality associated with the disease have been missed out due to the retrospective study design [7]. Intangible costs due to non-financial outcomes such as pain, suffering, or inconvenience are difficult to quantify and impossible to compare as economic or financial costs [7].

### Statistical analysis

Variables following normal distribution were expressed as mean±SD and others were considered as median along with its quartiles. For intergroup and subgroup analysis, Student's t-test was used in case of normal distribution and Mann–Whitney U-test is applied on assuming the null hypothesis [8] Costs were reported as median along with their 95% confidence interval. $p<0.05$ was considered statistically significant and data analysis was done with the help of SPSS Software version – 21.

## RESULTS

A total of 156 patients met the diagnostic criteria for DN wherein 64% were male and only 2–3% belonged to both extremes of age. The baseline characteristics are tabulated below. Table 1 deals with the demographic details of patients with DN and Table 2 includes baseline characteristics and treatment details of these 156 patients.

**Table 1: Demographic details of patients with DN**

| Parameter | No. of patients (n=156) |
|---|---|
| Male gender | 100 |
| Age | |
| 41–60 years | 85 |
| 61–80 years | 64 |
| Personal history/addictions | |
| Tobacco use | 20 |
| Alcohol | 17 |
| Both | 4 |
| Family H/o DM and CKD | 59 |
| History | |
| Hypertension | 121 |
| Hypothyroidism/heart disease | 8/9 |
| Others | 3 |
| Socioeconomic status (Kuppuswamy's scale) | |
| Upper | 35 |
| Middle | 78 |
| Lower | 43 |
| Duration of T2DM | |
| <10 years | 56 |
| >10 years | 100 |

**Table 2: Baseline characteristics and treatment details (n=156)**

| | |
|---|---|
| Presenting complaints | |
| Uremic symptoms | 40 |
| Uremic encephalopathy | 7 |
| Fluid overload | 69 |
| Uncontrolled DM | 22 |
| Diagnosis at admission | |
| DM and DN | 115 |
| ESRD | 38 |
| Coexisting DR | 58 |
| Treatment details | |
| Length of hospital stay (median) | 5–10 days (51%) |
| ICU admission (n) | 38 |
| Patients on routine dialysis | 64 |
| Antidiabetic medications (%) | |
| Metformin | 39.33% |
| Sulfonylureas (glimepiride/gliclazide/glipizide/glibenclamide) | 22%/6%/4%/8.6% |
| Gliptins | 16.66% |
| Others | 3.41% |
| Insulin prescribed | |
| Ultra short-acting insulin | 5.65% |
| Short-acting insulin | 64.34% |
| Intermediate-acting insulin | 28.26% |
| Long-acting insulin | 2.17% |

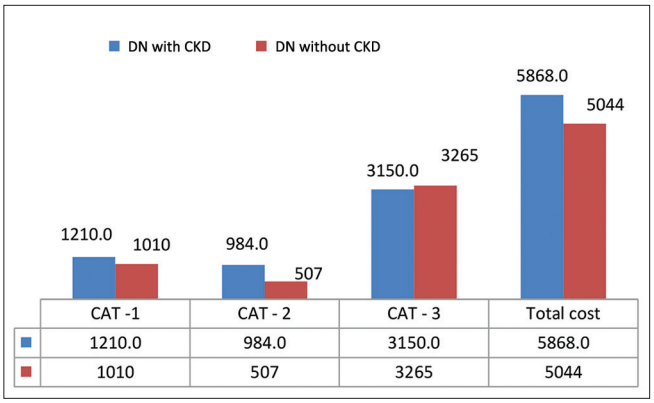


**Fig 1: Median cost distribution of diabetic nephropathy patients with and without chronic kidney disease category wise**

**Table 3: Median cost comparison and statistical significance (p value)**

| CKD | N | Mean | SD | Median | IQR | Z value | p value |
|---|---|---|---|---|---|---|---|
| CAT-1 | | | | | | | |
| Yes | 137.0 | 1805.8 | 1516.9 | 1210.0 | (727.5–2396.5) | 0.889 | 0.374 |
| No | 19.0 | 1255.8 | 780.2 | 1010.0 | (773–1572) | | NS |
| CAT-2 | | | | | | | |
| Yes | 137.0 | 1400.7 | 1259.2 | 984.0 | (502.5–1992.5) | 3.260 | 0.001* |
| No | 19.0 | 650.5 | 837.5 | 507.0 | (203–652) | | HS |
| CAT-3 | | | | | | | |
| Yes | 137.0 | 3566.1 | 2128.2 | 3150.0 | (1957.5–4765) | 0.263 | 0.793 |
| No | 19.0 | 3720.3 | 2207.6 | 3265.0 | (2140–4710) | | NS |
| Total | | | | | | | |
| Yes | 137.0 | 6772.7 | 3647.2 | 5868.0 | (4165.5–8580.5) | 1.244 | 0.214 |
| Cost | | | | | | | |
| No | 19.0 | 5626.6 | 2710.9 | 5044.0 | (3942–7071) | | NS |

HS: Highly significant, NS: Non significant. *Statistically significant value is 0.001

**Table 4: Overall cost comparison category wise**

| Category | Cost | Percent |
|---|---|---|
| CAT-1 | Rs. 270,407 | 26.59 |
| CAT-2 | Rs. 204,253 | 20.09 |
| CAT-3 | Rs. 559,734 | 55.05 |
| Total | Rs. 1,016,617 | 100.0 |

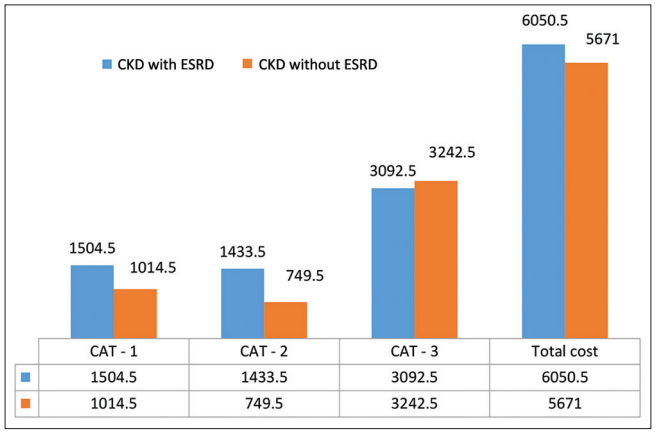


**Fig 2: Median cost distribution of chronic kidney disease patients with and without end-stage renal disease category wise**

Using Mann–Whitney U-test, the relation between CKD and the costs required for treating it was found to be statistically significant with p=0.001.

The expenditure for a patient of DN with CKD per hospital visit ranged from Rs. 1600 to Rs. 17,800 non-inclusive of direct staffing and indirect non-medical costs.

## DISCUSSION

In this era of evidence-based medicine and personalized medicine, pharmacoeconomics has an important role to play. Not just the patients, but their relatives and well-wishers are keen to know why a particular drug/procedure/investigation was performed. This is where various techniques of pharmacoeconomic analyses and models aid doctors in decision-making. Diabetes is a hormone-metabolic disease which poses a heavy economic burden, for the individual, society, and the nation. According to the latest estimates of International Diabetes Federation (IDF), every fifth person suffering from diabetes is an Indian [9] but there are hardly any studies discussing the same. The scarcity of literature in the Indian setting and the difficulty in extrapolating results from foreign literature gives relevance to this study.

In our study, majority of the patients belong to the age group of 41–60 years which disrupts the earlier notion that DN is primarily seen in elderly patients. With a declining demographic age factor, there is the need for more years of treatment, which proportionately increases number of hospital visits, drug prices, and the potential economic burden by that many years. A significant proportion (44%) of patients has presented with fluid overload and uremia or azotemia, all of which warrant emergency treatment and surge treatment costs. Furthermore, it was a common notion that DN develops after about 10–20 years of diabetes mellitus [10]. However, in this study, 64% of patients have developed DN after 10 years, but 36% have developed nephropathy and its sequelae in less than 10 years' time. This could be due to poor glycemic control, presence of coexisting HTN (86%), DR (37%), obesity, dyslipidemia, positive family history (38%), and smoking (13%). Diabetic retinopathy is a well-known precursor to micro-albuminuria and overt nephropathy [10].

Of all 156 patients, 74% were in various stages of CKD. Furthermore, 38 patients were categorized under ESRD following which the patient has to either undergo routine hemodialysis (twice/thrice weekly) or enroll themselves for renal transplantation. Hemodialysis requires creation of an arteriovenous (AV) fistula, repetitive erythropoietin injections (25 mcg = Rs 1500), HBsAg vaccinations, and blood transfusions; all these considerably increase the hospitalization costs and total expenditure. At the same time, these are not even comparable to the expenses involved in a renal transplantation procedure in terms of availability of a matching donor, medical and surgical complications that patients may develop while waiting for the transplant. According to the United States Renal Data System [11] – a website for kidney transplant services, 1 lakh patients were registered to obtain a matching donor and statistics show that at least 12 people die each day awaiting a transplant. Even after a transplant, these patients have to be put on heavy doses of immunosuppressants/"antirejection meds" and steroids which further increase the economic burden. In this study, 64 patients were on routine hemodialysis and 38 patients were admitted to the intensive care units (ICUs); there was one patient admitted for evaluation after renal transplant and his expenditures reflected a similar trend. One of the reasons for CAT 1 costs to increase is perhaps the ICU admissions and the use of higher antibiotics such as Tigecycline and Meropenem in these individuals, which increase the cost substantially. Furthermore, the median LOS for majority (51%) of patients was 5–10 days. There were 15 patients in the study whose days in the hospital went beyond 11 days and this is comparable to a previous study from Karnataka showing that diabetic patients with nephropathy or other complications have longer days of hospital stay (average 8–12 days) [12].

While observing the prescription pattern, it was found that metformin and short-acting regular insulin remained the preferred choice among oral drugs and insulin preparations, respectively. It is a relief that even after years of inflation, metformin remains the cheapest drug to be prescribed among DM patients with efficacy. Oral medications were

cost effective but in the long run, insulin helped in preventing onset of complications by having lesser hypoglycemic events. Despite the fact that ACEIs and ARBs could halt the progression of nephropathy [2], it was noticed in our study that many of the doctors did not prescribe these medications; probably, they were unaware of its efficacy or they thought that once DN has occurred, there is not much benefit seen with these drugs. Furthermore, there was latency in the diagnosis of nephropathy in many patients; this has to change. In fact, physicians should be able to anticipate diagnosis in persons with poor blood sugar control and should look out for the same. Nevertheless, the outcomes of all patients were good; no mortality was observed during the study period.

Sathyavani *et al.* observed that on an average, diabetic patients without any complications spent much lesser than patients of DN with CKD [13]. Median annual cost for a patient with CKD was Rs. 12,664 in comparison with Rs. 3214 for a patient without CKD. Furthermore, costs involved in hemodialysis for a patient of CKD are approximately four times as that of an individual with CKD alone [13] Similar observations were seen in our study as well. In our study, 77% of individuals belonged to the lower and middle socioeconomic strata indicating that most of them could not afford such high costs. The median costs for CAT-1 were as high as Rs. 1200 in a patient of DN with CKD and Rs.1500 in a patient of CKD with ESRD (Figs. 1 and 2). The median costs for CAT-2 were Rs. 984 (IQR: 502.5–1992.5; Z=3.260) in a patient of DN with CKD; it was still higher, Rs. 1433 (IQR: 478.5–2138) in a patient of CKD with ESRD (almost the double). Median costs for CAT-3 were maintained at Rs. 3200 in both the cases. The median cost required for treating a patient of CKD was found to be statistically significant with a p=0.001 (Table 4).

The overall cost of DN in this study sample amounts to a figure of Rs. 1,016,617. The expenditure for a patient of DN with CKD per hospital visit including CAT 1, 2, and 3 ranged from Rs. 1600 to Rs. 17,800. These values, although high, are definitely slighter as opposed to the previous studies conducted in the US or UK [2,4]. Furthermore, it was identified that CAT-1 accounts for about 26%, CAT-2 accounts for another 20%, and CAT-3 accounts for the major chunk of total cost, that is, 55% (Table 3). This explains to us where the cost reduction needs to be applied. There is more expenditure involved in following up a nephropathy patient rather than treating him/her. Various blood investigations and imaging modalities available today are of course, a blessing to mankind but they also require expensive equipment and regular maintenance. The CAT-3 costs alone per patient per hospital visit have ranged from Rs. 940 to Rs. 10,140 in this study.

As discussed earlier, prompt control of blood sugar not only through medications but also diet and non-pharmacologic measures is a must and this has to be a continuing process. Furthermore, other risk factors have to be managed at the outset. Apart from this, strict measures from the government's behalf to lower prices of antidiabetic medications or to include them as a part of "Essential Medicines" should be done. The Government of India and the National Pharmaceutical Pricing Authority (NPPA) have been trying to fix and control the MRP of various medicines for some time now. This should be elaborated to include at least some antidiabetics (both oral and injectable medicines) as diabetes has now acquired the status of an epidemic in India. Furthermore, existence of a specific "Antidiabetic Policy" and a common "DN Management Algorithm" recommendation to each hospital may assist different practitioners to follow a similar but cost-effective and efficacious practice. Furthermore, this study shows the requirement for some kind of discounting or standardization on expensive investigations as it is not quite possible to clinically confirm or stage CKD. Further, allocation of health budget more than a mere 2.2% is required for a population of 1.3 billion; it would be welcoming to have a national health-care system for India like UK/Canada.

**Strengths of the study**

This is one of the very few studies in India to evaluate the costs of diabetic complications, especially nephropathy management, and to deliberate the costs involved in various stages. It also is the first to categorize costs into different groups and to assess the expenditure of following up a patient, especially by including the cost of investigations. By calculating the average of any three drugs commonly prescribed to patients, the study is able to give a real-world picture on pricing of drugs and other consumables. By providing the overall costs, the study has helped to achieve a baseline figure for future reference. Since it contains a mixed population (center was frequented by patients from Kerala, Karnataka, and even Tamil Nadu as Mangalore was a known medical tourism hub), the study can be considered as generalizable to the South Indian population.

**Limitations of the study**

The study has a cross-sectional design; hence, cause and effect relationships cannot be established but it does provide a picture of the current scenario. This is a retrospective, single-center study and has included patients who could still afford treatment from a private hospital even with insurance assistance. Another limitation was that only costs related to consumables and investigations were analyzed. Other cost blocks such as in-patient and room charges, and nursing and staff consulting charges have not been included. Costs after discharge such as discharge medications also have not been considered, as those are outside the scope of this study. Finally, diabetic patients with other comorbidities such as CAD, DR, or peripheral neuropathy have also been excluded, so as to ensure homogeneity in the study.

## CONCLUSION

The study showed that age of onset in DN is declining and that it may present even before 40 years. It is disrupting the common notion that there might be an interval of 10 years before the occurrence of renal damage. With the presence of coexisting risk factors, nephropathy may present as early as 5 years of DM. Therefore, the study established that there is a need to promptly control blood sugar to delay the progression and the necessity to diagnose and manage nephropathy intensively. There is ample evidence which suggests that DN could be slowed by the use of cost-effective medications such as ACEI's and ARB's; however, this study concluded that not many physicians were inclined to follow these measures. It showed that patients of DN with CKD spent more than those without CKD; and patients with CKD and ESRD spent double than those with CKD alone. This study explained that the overall costs in treating 156 patients of nephropathy amounted to more than 10 lakh rupees and the major determinant in this was the cost of investigations, unlike what was expected of the drug prices. Hence, doctors, institutions, policymakers, and the government together need to find a way toward cost containment by employing the apt measures.

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## AUTHORS' CONTRIBUTION

Dr. Sara Kurien: Proposed the concept; carried out the data collection and tabulation of results; and performed some of the analysis with the help of other coauthors. Dr. Manohar V.R: Helped in the conceptualization and framework of the study. He was also instrumental in the choice of cost consequence analysis. Dr. Sharath Kumar and Dr. Arun Ravindran: – Verified the analytical methods and supervised the findings of this work. Also assisted in drafting the article. All authors discussed the results and contributed to the final manuscript as well as proofreading and critical revision of the article before the final submission.

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Nil.

**CONFLICTS OF INTEREST**

There are no conflicts of interest.

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