Improvement in Glycemic Control of Diabetic Patients Provided with Counseling by Clinical Pharmacist – A Review

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ABSTRACT:

Diabetes Mellitus is a chronic debilitating condition which has affected more than 150 million people worldwide and this number is increasing rapidly. In 2000 32 million people are affected with DM in India and India is leading the world with this number. Diabetes is a condition which, if not controlled adequately may result in serious complications. Pharmaceutical care is a practice in which the practitioner takes responsibility for a patient's drug-related needs and is held accountable for this commitment. Patient counseling is the process of providing information, advice and assistance to help patients use their medications appropriately. The information and advice is given by the pharmacist directly to patient or to patient's representative which is not only limited to medications, it also includes information about patient's illness, or life-style changes recommendations. The information is usually given verbally, but it may be aided with a written material as well. The literature review of the year 2008 to 2013 revealed that many published articles give the evidences that pharmaceutical care programs relating to patient counseling including the information on disease, drugs and life-style modifications such as food, self-care, exercise, etc. reduces the glycemic indices of diabetic patients. This results in better care of patients with chronic disease and helps them improving their daily living with diseases. Counseling helps achieving the personalized therapeutic goal of each individual patient. Evidences suggest that integrated pharmaceutical care by clinical pharmacist results in reduction of glycemic control of diabetic patients.

KEYWORDS:Glycemic Control, Clinical Pharmacist, Patient Counseling, Pharmaceutical Care, Diabetic Patients, Glycated Hemoglobin, India.

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INTRODUCTION:

Diabetes Mellitus (DM), a disorder of endocrine and metabolism. It is not a single disease; rather it is a syndrome consisting of various subtypes of diabetes with hyperglycemia. [1] DM is a chronic debilitating condition which has affected more than 150 million people worldwide and this number is increasing rapidly. [2] Approximately, 20.8 million Americans have DM, yet, only two-thirds of them have been diagnosed. [3] Several definitions of diabetes are in existence. Few of them are, "diabetes mellitus is a group of metabolic disorders of fat, carbohydrate and protein metabolism that results from defects in insulin secretion, insulin action (sensitivity) or both." [3] Another one is "diabetes is a chronic metabolic disorder in which body cannot metabolize carbohydrates, fats and proteins because of defects in insulin secretion and/or action of insulin." [4] One more definition suggests that diabetes is a chronic condition caused by relative or absolute lack of insulin. Its hallmark clinical characteristic is symptomatic glucose intolerance resulting in hyperglycemia and alterations in lipid and protein metabolism. [5]

As noted earlier, 20.8 million American people are suffering from DM. In 2005, more than 1.5 million new cases in adults were diagnosed. World-wide the prevalence of DM for all ages was approximately to be 2.8% in the year of 2000 and this number is projected to increase to 4.4% by the year of 2030. The incidences of DM are now considered epidemic with alarming increase in prevalence in both adults and children. [5]

In India, there was an exploding rated increase in the number of Diabetic people observed in recent years. India is the country which leads the world with its largest diabetic population of 32 million in the year of 2000. This number is predicted to rise to 80 million by year of 2030. It has also been observed that the prevalence is higher and rapid in urban areas from 2% in 1970s to 12% in 2000, as well in rural areas; this is also increasing. [6]

The economic burden of DM approximated $ 132 billion in 2002, which includes direct medical and treatment cost, as well as indirect cost related to disability and mortality. This disorder is the leading cause of blindness in adults aged to 20 to 74 years and the leading contributor of development of End-Stage Renal Disease (ESRD). Approximately 82,000 lower extremity amputations annually are attributed to DM, in United States. Also, cardiovascular events are responsible for two-thirds of deaths in individuals with DM. [3]

Types of DM:

As now we know, DM is a metabolic disorder which is characterize by either resistance to insulin action, or insufficient insulin secretion or both together. These manifestations results in hyperglycemia, clinically. Majority of the diabetic patients are classified in to two broad categories: Type – 1 diabetes, which is cause by absolute deficiency of insulin, or Type – 2 diabetes, which is defined by the presence of insulin resistance with an inadequate compensatory increase in insulin secretion. [3]

The classification of DM is based on the Etiology of it. [1, 3] This is described below:

- Type – 1 DM (AKA: IDDM/Juvenile onset DM)
- Type – 2 DM (AKA: NIDDM/Maturity onset DM)
- Miscellaneous:
  - Genetic defects of β-cell function
  - Genetic defects in insulin action
  - Disease of exocrine pancreas
  - Endocrinopathies
  - Drug or chemical induced
  - Infection induced
  - Uncommon forms of immune-mediated diabetes
  - Other genetic syndromes sometimes associated with diabetes
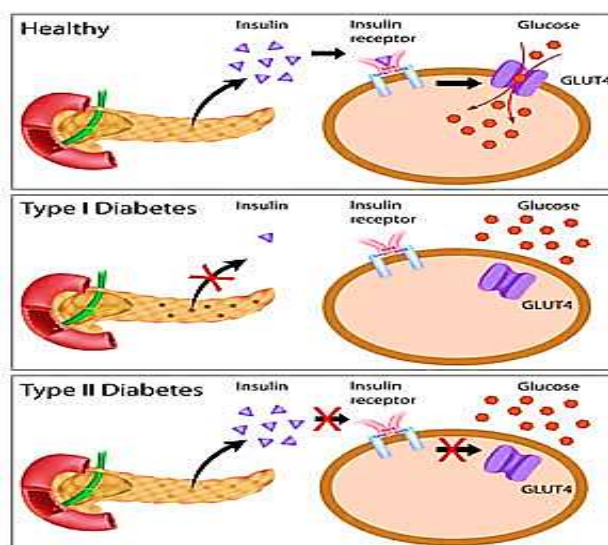- Gestational diabetes (AKA: GDM)

Figure 1: Pictorial presentation of types of DM.

Diagnostic parameters used: [6]

For diagnosis of DM different laboratory tests are employed: -

- FBS (Normoglycemia - < 110 mg/dl)
- PPBS (Normoglycemia - < 140 mg/dl)
- RBS (Normoglycemia - ≤126 mg/dl)
- HbA1c (Normoglycemia - < 6.5 %, 5.7 – 6.4 % is pre-diabetic)

Parameters	NICE (UK) [7]	ADA (USA) [8]	WHO [9]	ICMR (India) [6]	Australia [10]	Canada [11]
Year updated	**December 2014**	January 2014	2006	2005	August 2012	April 2013
FBS	Not given	≥ 126 mg/dL (7.0 mmol/L).	≥ 7.0 mmol/l (126mg/dl)	≥ 126 mg/dL	4.0–6.0 mmol/L	≥ 7.0 mmol/L
PPBS	Not	≥ 200 mg/dL	≥ 11.1 mmol/l	≥ 200 mg/dL	≥ 11.1	≥ 11.1

	given	(11.1 mmol/L)	(200mg/dl)		mmol/L	mmol/L
RBS	Not given	≥ 200 mg/dL (11.1 mmol/L).	≥ 11.1 mmol/l (200 mg/ dl)	Not available	> 11.1 mmol/L	Not given
HbA1c	≥ 6.5%.	≥ 6.5%.	Not in 2006, ≥ 6.5% in 2011	≥ 6.5%.	≥ 6.5%.	≥ 6.5%.
Method for HbA1c *	*DCCT	*DCCT	*DCCT	HPLC / Immuno-turbidimetry	Not given	*DCCT
Limitations of HbA1c	Disturbed erythrocyte turnover, abnormal hemoglobin type, hemoglobinopathies, certain anemia, and disorders associated with accelerated red cell turnover such as malaria, severe Hepatic or Renal disease.					
Screening in asymptomatic patients	No	Yes	No	Yes	Yes	Yes
Correlation of A1c with average glucose	No	Yes	No	No	No	Yes
Medical nutrition therapy (Diet)	Yes	Yes	No	Yes	Yes	Yes
Self-management education and support / role of educator defined	Yes	Yes	No	Yes	Yes	Yes
Details of DM complications and their management	Yes	Yes	No	Yes	Yes	Yes

*DCCT: Diabetes Control and Complications Trial

Sign and Symptoms at presentation:

- Polyuria, polydipsia and polyphagia are considered as classic triad.
- Type – 1 and some Type – 2 patients with comorbid conditions can present with diabetic ketoacidosis: symptom includes nausea, vomiting, abdominal pain, hyperventilation, lethargy and fruity breath.
- Blurred vision, which occurs when glucose molecules in the lens is converted to sorbitol which produces an osmotic change and results in lens swelling.
- Type – 2 diabetics can present as an incidental laboratory finding without sign or symptom: yet some patients with type – 2 DM can present with long-term complication such as neuropathy, dermopathy and retinal or renal pathology. [2]

Complications of Diabetes [1]

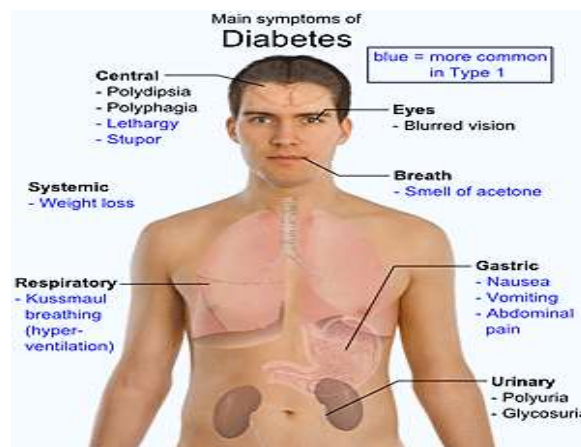Complications of diabetes can be divided into acute complications and chronic complications.

Figure 2: Pictorial presentation of symptoms of DM.

The main acute metabolic complications of diabetes are:

1) Hypoglycaemia
2) Diabetic keto acidosis and coma
3) Non ketotic hyperosmolar hyperglycemic state (NKHH)
4) Lactic acidosis

Chronic complications are usually seen in patients with long history of diabetes and poorly controlled diabetes. These are sub-classified in to:

a) Microvascular Complications:
1) Diabetic Retinopathy
2) Diabetic Nephropathy
3) Diabetic Neuropathy including Autonomic Neuropathy
b) Macrovascular Complications:
1) Diabetic foot
2) Coronary artery disease
3) Peripheral vascular disease
4) Cerebrovascular disease
5) Hypertension
6) Hyperlipidaemia
7) Hyperinsulinaemia (rarely)

Patient Counseling

"Pharmaceutical care is a practice in which the practitioner takes responsibility for a patient's drug-related needs and is held accountable for this commitment. In the course of this practice, responsible drug therapy is provided for the purpose of achieving positive patient outcomes." [12] It is the 'Heart' of pharmaceutical care practice. It is the combination of everyday activities that pharmacists perform when interacting with patients in pharmaceutical care practice. The purpose of patient care process are to attain the most effective, appropriate, safe and convenient drug therapy for the patient; to identify, resolve and prevent any drug therapy problems that could hinder in this attainment; and to ensure positive patient outcomes. The patient care process involves three steps: assessment, pharmaceutical care plan and follow up evaluation. This process is comprehensive and systemic problem solving process. [13] To achieve the goal of pharmaceutical care process, the interpersonal communication plays a major role. This communication comprises of Patient Counseling.

Patient counseling is defined as "the process of providing information advice and assistance to help patients use their medications appropriately." The information and advice is given by the pharmacist directly to patient or to patient's representative. This information is not only limited to medications, it also includes information about patient's illness, or life-style changes recommendations. The information is usually given verbally, but it may be aided with a written material as well. [14]

Communication skills are key parameters which greatly influence the patient counseling. Pharmacist must use proper communication skills during the counseling for effective counseling. This plays important role in medication adherence of the patient. [15]

Steps of patient counseling: [14]

As counseling is a two-way communication process, it is must to have interaction between pharmacist and patient for effective patient counseling. There are four steps involved in the process of counseling namely: Preparing for the session, Opening the session, Counseling content and Closing the session.

Preparing for the session:

Knowledge and skills of the counsellor are the basis for the success of counseling. The pharmacist should know as much as possible about the patient as well as his/her treatment details. This may be achieved by referring the case notes of the patient in the hospital setting. In the community setting, the information can be obtained via patient, their prescriptions and sometimes, a record of the previous dispensing for the patient.

Opening the session:

The pharmacist should introduce himself to patient and greet them by name. The pharmacist then should tell the purpose of the session very clearly. Then, the pharmacist gathers the information from the patient about his/her understanding of the disease, drugs and alternative therapies. Other relevant information includes, known allergies, family, social and medical history, personal habits, etc. here, the pharmacist can use open-ended as well as close-ended questions depending upon the information required.

Counseling content:

This part of the session is the 'Heart' of counseling process. In this part pharmacist explains the medications, treatment regimen, life-style changes and disease related information. Generally the topics are:

- Name and strength of medication
- Indication of the medication
- How much and how often to take the medication
- Expected duration of treatment
- Expected benefits of treatment
- Possible ADRs
- Possible medication or dietary interactions
- Storage recommendations
- What to do if a dose is missed

＋ Special monitoring requirements

Closing the session:

It is important to check the patient understanding before closing the session. This is generally assessed by feedback questions. It is also important to give a chance to patient to ask their doubts and queries regarding the counseling and any other questions regarding their disease or drugs. If it is appropriate, the pharmacist may give his/her contact details to the patient to encourage the patient that they can ask the pharmacist if they have any further questions or if they need any further advice or information. [14]

Patient counseling is very essential parameter of clinical pharmacy practice. This enhances patients' understanding of their illness and treatment. Counseling may also improve the patients' adherence and subsequently therapeutic outcome. [14]

Counseling and glycemic control:

After referring to different literature on the said topic of effect of counseling on glycemic control of diabetic patients; it was found that counseling does affect positively in control of diabetes along with drugs. It is of course that counseling alone is not studied, although along with drugs when the values of blood sugar are abnormal, the additions of counseling and life-style modifications do reduce the blood glucose levels significantly.

In 2008: Rosin J, et al. conducted a research in which patients were randomly assigned to the intervention or usual care arm. Laboratory data (glycosylated hemoglobin, fasting blood glucose, lipid panel, micro-albumin) systolic and diastolic blood pressure) and Diabetes Empowerment Scale short form (DES-SF) score were collected at baseline and at 6 months. It was concluded in their research that involvement of a pharmacist in diabetes type-2 management results in greater detection of DRP- drug related problems and referral to other health care professionals. It also promoted diabetes related self-efficacy and appropriate self-care behavior. Pharmacists can play an important role in the management of diabetic patients. [16]

In 2009; Turnacilar M, et al. conducted a research with the objective of impact of short pharmaceutical care program conducted in community pharmacy setting, on the indices of diabetes care of type-2 diabetic patient. They conducted the research in eight different community pharmacies in Istanbul. Total numbers of patients were 67 and pharmaceutical care was provided to the patients over total of 3 months of period. It was concluded from the short-course pharmaceutical program that pharmacists can be beneficial in integrated care for patients with type-2 diabetes. The main outcome measured was improvement in glycemic control and blood pressure control. This can be motivating for all community pharmacists to provide counseling to the diabetic patients. [17]

Another research in 2009 by Satpute DA et al. conducted in India with the aim of assessment of impact of patient counseling, nutrition and exercise in patients with type – 2 DM, included total of 35 patients and after providing counseling on emphasizing Disease understanding, Medication, Diet/ Nutrition and Exercise. After 3 months the significant reduction in HbA1c was observed as well as greater significant reductions were observed in case of FPG, total cholesterol, serum triglyceride and LDL cholesterol in intervention patients. The study concluded that glycemic control of type-2 diabetic patients can be improved through patient counseling regarding their disease, medication, personal hygiene, diet and exercise. The study also provides an economically feasible model for those programs that aim to improve the health status of people with type-2 diabetes. [18]

Two more studies conducted in 2009 by Mazroui NR, et al. and Doucette WR, et al. also showed similar results stating that pharmaceutical care program resulted in better control of glycemic indices among type – 2 diabetic patients. Pharmacists were effective at increasing the number of days the patients spent engaging in healthy diet and self-care activities. Addressing lifestyle and self-care behaviours can be a major component of a pharmacist-provided extended diabetes care service benefit. [19, 20]

Siddiqui A, et al. in 2010 conducted a study for evaluating the compliance to dietary counseling at a tertiary care hospital of Pakistan. In this study the authors provided counseling to 72 patients of type – 2 DM, and were assessed through comparison of food habits at first and second visit (made after three months). Compliance was assessed by decrease in number of dietary modifications needed in diet at second visit as compared to that of first visit. On the first visit 66.7% had very inadequate and 29.2 % had poor diets while at 2nd visit only 19.4% had very inadequate and 1.4 % had poor diet. It was concluded that rates of compliance were

sufficiently high to make positive changes in diets of diabetic patients. [21]

One of the studies in 2010 by Gavgani RM, et al. showed that increasing motivation and teaching Behavioral skills according to the individual life styles are extremely beneficial for the diabetic patients. IMB model can be an appropriate procedure for improving the self-care behaviours in patients suffering from type 2 diabetes. [22] In 2010, one of the Ph.D. thesis from University of Southern Denmark by Minet LK revealed that the benefit from promoting self-care behaviour in patients with type 2 diabetes in glycemic control and thereby hopefully also reduces morbidity and mortality. Also the role of intervention technique seems to be of less importance, although their results suspect an advantage for educational techniques. [23]

Few studies from the year of 2011 also suggest the positive impact of counseling on glycemic control. A study by O'Donovan DO et al. concluded that pharmacist intervention in type 2 Diabetes Mellitus patients is helpful to reduce mortality, morbidity and cost of treatment. [24] One study performed in India by Ramanath KV, et al. stated that pharmacist plays an important role in educating the patients about their disease to maintain their quality of life. [25] A randomized control trial conducted by Mehuys E, et al. provided new evidence, about the beneficial effect of pharmacist intervention in the clinical management of type 2 diabetic patients. [26] More evidences on the same are given by two more studies by Al-Qazaz HK, et al. and Adepu R, et al. Both of these studies conclude that patients' knowledge about their diabetes results in better glycemic control. The post-discharge counseling provided by pharmacist results in better therapeutic outcomes and health related quality of life. This was evident by reduction in blood glucose levels of counseled patients as compared to non-counseled patients. [27, 28]

Similar results are also presented in the year of 2012. One randomized control trial by Jarab AS, et al. concluded that clinical pharmacist provided pharmaceutical care to patients showed reduction in HbA1c at 6 months. [29] Interestingly, a study by Mersal FA, et al. found that counseling was more effective rather than web-based education strategies with less statistically significant difference between them in all items except for the self-care activities. [30]

In 2013, Henry TM, et al. conducted a research whose purpose was to describe the impact of pharmacist services in a collaborative practice providing care to primarily Medicaid and indigent patients. The services were provided by pharmacists including pharmacy residents and pharmacy students. In the total duration of 8 months of study, total of 93 patients were provided services and the results were observed. A significant decrease in the HbA1c, systolic blood pressure and decrease in LDL in diabetic patients were observed. They have concluded that Pharmacists were impactful in improving surrogate outcomes for patients with diabetes type 2 and in assisting physicians to address all standards of care. [31]

In 2015, a research conducted by us, based on the same literature evaluation, produced similar results to those of others mentioned above. To check the effect of counseling on glycemic control, total of 30 patients were included in the study. For which the permission was obtained from human ethics committee. Pre-counseling HbA1c test was performed to ensure the baseline results. Afterwards, patients were provided counseling regarding their disease, drugs and life-style modifications. 3 months later, post counseling HbA1c was performed on same 30 patients. The mean difference between pre and post-counseling was observed to be 0.41% (8.37% baseline – 7.96% end-point). Applying T-test and significance, it was observed that there was a significance difference existed in pre and post-counseling groups. Which signify that there is a positive effect of counseling on reduction of glycemic indices of diabetic patients. [32]

General recommendation for counseling on diabetes is given as below:

First, patient must be told of his/her condition, what is diabetes, types and causes of it in general. Also what is the possible cause of diabetes for this particular patient. Then, counseling must be given on proper use of drug. How to, when to, with what to, with what not to take the medications prescribed. Emphasis must be given on adherence to therapy and possible benefits of continuing the therapy. Possible drug-drug, drug-disease, drug-food interactions. Now, counseling must be provided regarding life-style modifications required. Patients' regular life-style habits has to be assessed during the history interview, based on that particular modifications must be given. Such as, food habits, exercise, monitoring of hypoglycemia symptoms during exercise, self-care activities, complications prevention for which, foot-care, eye-care, kidney, heart, etc. advices must be given. Regular check-up with health-care provider, and regular full body check-up at least twice-a-year should be advised. Now, if patients have any queries, satisfactory

answers must be given. Repeat the main points of counseling as a summary. It is useful to ask them closed-ended questions regarding what is told during counseling. This is to assess patient understanding towards counseling.

In addition to counseling, it is very helpful to give a daily record diary, or a daily food and exercise chart for patients to fill in every day. This helps patients remember, as well realize what they are eating, or how much they are exercising. If there is a need to improve or not. Also, this may include noting of abnormal symptoms during exercising, which helps patient's healthcare provider in assessing their course of therapy. Along with verbal information, patients' may be provided with written information such as informative leaflets, or videos regarding diabetes and its management in their regional languages.

Conclusion:

The review of published literature from the year 2008 to 2013 reveals the role of clinical pharmacists in care of chronic disease like diabetes mellitus. It is evident that even short pharmaceutical care programs relating to patient counseling including the information on disease, drugs and life-style modifications such as food, self-care, exercise, etc. reduces the glycemic indices of diabetic patients. This results in better care of patients with chronic disease and helps them improving their daily living with diseases. Counseling helps achieving the personalized therapeutic goal of each individual patient. Evidences suggest that integrated pharmaceutical care by clinical pharmacist results in reduction of glycemic control of diabetic patients.

Facts about Diabetes

Can diabetes be cured?

No. However, diabetes can be treated and controlled by proper management, to lead normal lives.

What are the symptoms of low blood sugar?

When your blood sugar is low (<60 mg/dl), your body gives out signs that you need food. Different people have different symptoms. You will have to learn to know your symptoms. Early symptoms include feeling weak, dizzy, hungry, shaky, trembling, excessive sweating, pounding heart, pale skin. While late symptoms include feeling confused, cranky, lack of concentration, numbness of mouth and tongue, headache, unconsciousness.

Can I take both tablets and insulin to control my blood sugar?

Yes. When taken as directed by your doctor, combination is very safe and effective in controlling blood sugar. A typical combination therapy consists of taking an oral medication during the day and insulin at night. Once you begin taking insulin, you will need to monitor your blood sugar more often to reduce the risk of low blood sugar reactions. If you have been taking an oral medication, your doctor may change your treatment plan to include insulin injections. This change is often made to help people with type 2 diabetes gain better control of their blood sugar.

Diet

Can I still eat sweets with diabetes?

Yes. Sweets in moderate amount can be enjoyed by people with diabetes. You just have to work them into your meal plan…not in addition to your normal meals!

How many carbohydrates per meal should I eat?

It varies by the individual's age, size, and activity level. In general, adult women usually range from 45-60 grams of carbohydrate/meal. Men can range from 60-75 grams of carbohydrate/meal. There are always exceptions, but these are safe starting points.

Is there a simple way to eat so I don't have high blood sugars?

There is no simple solution to eating to avoid raising blood sugars. A dietitian who specializes in diabetes is the best person to work with, but there will be times when sugars are high no matter what you eat.

Exercise and Living with Diabetes

How does stress affect blood glucose?

In general, stress raises blood sugar levels. It is generally temporary. When people are under prolonged stress, they may be less likely to follow through on all the tasks involved in healthy diabetes management i.e.; (forget to check blood sugar, forget to take diabetes tablets, or insulin, overeat for comfort).

How often, how long, and what times of day should I exercise?

The best time is the time you will do it! 30-45 minutes of aerobic exercise, 5-7 days a week is a great goal. Some examples are swimming, walking, tennis, bike riding, and dancing. A minimum of 30-45 minutes, 3 days a week is recommended by their physician. It is alright to break the exercise into 3 or 4 smaller 15-20 minute segments throughout the day. Remember to check your blood sugar then warm up, and cool down for 5-10 minutes. This will help you avoid sore or injured muscles.

Why do I have to test my blood – the doctor does a blood test when I see him?

Testing your own blood gives you feedback on what your blood sugars do at various times of day and how they react to your medications, exercise, food intake, etc. By testing your own blood you help the medical provider make decisions to improve the glucose control and to decide if the medications are working properly.

Why do my feet feel tingly and numb? Is this from diabetes?

Feet feeling tingly and numb may be due to elevated blood sugars from diabetes affecting the nerves. Feet should be checked by a medical provider at each visit.

Medication

Once you start diabetes medication, can you ever come off of it (and control diabetes with just diet and exercise)?

Some people are able to stop taking some diabetes medications if the blood sugars can be controlled by weight loss and increased activity. That should only be done with the medical provider's guidance.

Is there a way to take insulin without giving injection/s?

At present the only way to get insulin is to take it by injection (syringe or an insulin pump). Insulin is a protein and is digested in the body if taken by mouth. There are many scientists working to see if insulin can be taken in other ways than injection

Myths:

There are different myths related to diabetes which are to be clarified by the physician or diabetic counselor:

- **People with diabetes must eat different foods from the rest of the family.**
- **Diabetic patients do not have to worry about eating fat because it doesn't have much of an effect on blood glucose.**
- **Taking insulin will cure diabetes.**
- **People with diabetes should not eat sweets.**
- **People with diabetes cannot participate in sports.**
- **Only kids suffer from type 1 diabetes.**
- **Kids do not get type 2 diabetes.**
- **Women with diabetes should not get pregnant.**
- **No matter what you do, a person with diabetes for years will eventually get co-morbidities.**
- **Diabetes is a death sentence.**
- **Eating too much sugar can causes diabetes.**
- **I know when my sugar is low or high.**
- **You are more likely to get colds or the flu if you have diabetes.**

Future recommendations:-

- ❖ As now insulin pens are becoming available in market, teach patients its proper use and monitoring, care while taking insulin via pen.
- ❖ Diabetes education should become an integral part of management along with pharmacologic therapy.

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