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RESEARCH ARTICLE

DIABETES MELLITUS: OVERCOMING CHALLENGES WITH TECHNOLOGY

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ABSTRACT

Diabetes mellitus is a chronic disease. The worldwide of persons afflicted with the disease is increasing. The incidence of the disease has increased manifold particularly in the South- East Asian Region. Although lifestyle modification and pharmacotherapy is particularly important in the management of the disease, compliance of the patient is often compromised owing to the chronic nature of the disease. This is where the role of technology comes into being. Technology, if used judiciously, can be of great benefits in the management of the disease. Many of these tools are still in the clinical trials or in the conceptual phase. But these tools hold great potential in shaping the future course of management of the disease.

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INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder with a common underlying biochemical abnormality of hyperglycemia. The disease can be broadly classified into two categories- DM type 1 and DM type 2. While the former is due to beta-cell destruction, the latter is due to insulin resistance. (Fauci *et al*., 2008) Previously, DM type 1 was associated with childhood while DM type 2 was associated with adulthood. But with rising incidence of childhood obesity, this differentiation of DM type 1 and 2 has been blurred. (Santoro, 2013)

Epidemiological patterns

The world wide prevalence of DM has risen from a humble figure of 30 million cases in 1985 to a staggering 177 million cases in 2000. (Fauci *et al*., 2008) The International Diabetes Federation estimated that around 415 million people worldwide have diabetes as in 2015 out of which 78 million people are in South- East Asian Region (SEAR). By 2040, this figure is likely to rise to 140 million in SEAR. There were 69.1 million cases of diabetes in India in 2015. (International Diabetes Federation South East Asia. Diabetes in India-2015)

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Challenges with the classical approach

The management of DM is by large based on pharmacological approach. This approach is successful in controlling the symptomatology of DM, but is fraught with its own set of challenges. For example,

1.Use of needles to administer insulin and in checking blood glucose levels is cumbersome for most patients. It leads to compromise in the adherence of patients to the therapy. (Aronson, 2012)
2.The chronic nature of the disease and high treatment costs is yet another hurdle in the management of the disease. (Perez *et al*., 2013)
3.The complexity of dosing regimens and the risk of forgetfulness in patients especially the children and the elderly makes them prone to miss the doses of the medications or even take multiple doses. (Adisa *et al*., 2009)
4.The risk of hypoglycemia is always present in the patients who are on insulin. (Fauci *et al*., 2008)
5.The need of regular consultation with the treating physicians, dieticians and labs makes the treatment schedule hectic. (Divya and Nadig)

Role of technology

Technology can play a major role if applied judiciously in conjunction with the pharmacological treatment. Strategically

used, it can be used in the management of DM at the different levels:

- At the level of diagnosis
- At the level of treatment

Role of technology at the level of diagnosis

1.Measurement of blood glucose levels:

a. "Smart lens" technology: Alcon (eye care division Novartis) along with Google is in the process of making a "smart lens". The basis of this innovative technology is to measure glucose levels in the tear fluid and predict the blood glucose level. The lens has non- invasive sensors, microchips and other miniaturized electronics embedded inside it. The transparent nature of the lens will prevent the occlusion of the vision. The lens can help in the management of various other ocular conditions as well e.g. refractive errors. (Novartis to license Google "smart lens" technology, 2014)
b. HemoLink device: Tasso Inc. has introduced an innovative wearable blood collection device called HemoLink. The device is based on the principle of capillary action. It is placed on the skin surface for about two minutes. Inside is a vacuum, which enables a small sample of blood to be drawn from tiny open channels into a small tube. About 0.15CC of blood can be drawn. It can be used to measure blood glucose levels. The device is yet to get FDA approval. (http://www.tassoinc.com; Lavars, 2015)

2.**Diagnostic ease to differentiate between DM type 1 and DM type 2**

Scientists at Stanford University have developed a microchip to diagnose the patients of DM type 1. The working of the microchip is based upon the fact that the patients of DM type 1 have auto-antibodies in their blood. These auto-antibodies are directed against the beta cells of the pancreas. These immunologic markers are present in the blood long before the disease becomes clinically overt. The test is much cheaper than the conventional tests and requires much less expertise. The test involves a microchip on which a patient's blood is mixed with an antibody that gives off a fluorescent signal when it detects the antibody connected to Type 1 diabetes. (Researchers invent nanotech microchip to diagnose type-1 diabetes. Stanford University 2014; Lee *et al*., 2014)

3.Mobile based technological tools

a. Gmate SMART mobile diabetes monitoring system: The product was approved by FDA in 2014. The product was manufactured by Philosys. It is a small, portable blood glucose meter that can be plugged into the headphone jack of a smartphone. It can provide accurate blood glucose test results. The Gmate SMART mobile application allows the user to store a lifetime of results. It also enables to user to mail the test results to the healthcare provider. (http://www.fda.gov/Medical Devices/Products and Medical Procedures/DeviceApprovalsandClearances/510kClearances/ucm412599.htm; Gmate, 2014)
b. Another product similar to Gmate SMART is Jana Care. Jana Care has unique dual- pronged strategy: the Aina mobile- compatible blood test device and the online Habits platform. The blood test device can perform five different tests- HbA1c, Glucose, Lipid Profile (Total Cholesterol, HDL, LDL, Triglycerides), Creatinine and Hemoglobin. Measurement from this device then feeds the test data into the Habits program. Like Gmate, it also helps the user to share the test reports with the healthcare provider. This program includes trackers for diet, activity. It has already entered clinical trials at Narayana Hrudalaya, Bangalore, India. (Sonalibloom, 2015; Jana Care, 2015)

Role of technology at the level of treatment

1.Decreasing the risk of multiple doses due to forgetfulness:

a. NovoPen Echo: It is an insulin dispensing device which saves the information about the amount of insulin injected as well as the time passed since the last injection. It is battery based "pen type" of insulin dispenser. (NovoPen Echo, 2016)
b. Timesulin: It is "smart cap" which can be applied on the regular insulin pens and records the time since the last injection. (https://timesulin.com)

2.Bypassing the painful injections

a. Researchers at Massachusetts Institute of Technology (MIT) have made an innovative drug delivery capsule to bypass the painful injections. This new drug delivery capsule is coated with tiny needles which has the ability to inject the drug directly into the stomach after oral intake of the capsule. Further, preclinical studies have found that this device has better bioavailability than the classical subcutaneous route. (Trafton, 2014)
b. Intarcia therapeutics has completed phase III clinical trials of ITCA 650. It has been named as Medici Drug Delivery System. This device is a continuous subcutaneous delivery device for exenatide. It is an amalgamation of three unique technologies: osmotic mini-pump, mini-pump placement technology and temperature stabilization system. It is intended to be a once or twice annually injection system. The first part osmotic minipump is a matchstick sized pump that is placed beneath the skin. It delivers a continuous and consistent flow of medication. The temperature stabilization technology is for stabilization of proteins, peptides, antibody fragments, and other high-potency small molecules. Once the device is placed beneath the skin, water from the extracellular fluid enters the pump device at one end – by diffusing through a semi-permeable membrane directly into a salt osmotic engine – that expands to drive a piston at a controlled rate. This forces the drug within the pump to be released in a steady, consistent fashion at the distal end of the device. (http://www.intarcia.com/pipeline-technology/)
c. Insulin jet: It is an innovative drug delivery device with an operating system based on pressure. By means of a

spring system, the insulin is pressed at high speed through a small orifice in the nozzle, creating a fine stream of insulin that easily penetrates the skin. The insulin diffuses in the subcutaneous tissue. A randomized double- blind double dummy crossover study found the pharmacological profile of insulin administration by jet injection more favorable than the conventional insulin pen. (Engwerda *et al*., 2013; Insujet- for optimal Insulin therapy, 2015)

3.Decreasing the frequency of insulin injections: To achieve the dream goal of decreasing the frequency of insulin injections in DM type 1 patients, the concept of "Smart Insulin" has been introduced. The tentative pharmacokinetic basis of smart insulin is that the insulin moiety is attached to a "binding element" which prevents it from exerting its action. But once the blood glucose level rises, the "binding element" separates and the insulin molecule becomes active. With the normalization of the blood glucose levels, further release of insulin stops. The idea of "Smart Insulin" is quite impressive, but the concept is still in its infancy. (http://www.jdrf.org/wp-content/uploads/2013/07/Smart-Insulin-White-Paper-Final.pdf)

4. Bionic pancreas: iLet Bionic pancreas is yet another technological advancement in the management of DM type 1. It is wearable, bihormonal and automated device which mimics the physiological glucose control mechanisms. The device has a continuous glucose monitoring (CGM) system. Based on the blood glucose levels and an inbuilt mathematical algorithm, it can administer the required doses of insulin and glucagon as and when required. A random order, crossover study found that this device provided better glycemic control as compared to an insulin pump with lesser chances of hypoglycemic episodes in patients of DM type 1. Another randomized, open label, crossover study found this device to be useful in preadolescent children as well. Currently, Beta Bionics (a public benefit corporation) is working on the FDA approval of the device. (Russell *et al*., 2014; Russell *et al*., 2016; Brown *et al*., 2016)

5. Continuous glucose monitoring (CGM) systems: One of the most important part of strict glycaemic control requires a continuous glucose monitoring system. Various currently available tests are (A) Dexcom SEVEN Plus, (B) Dexcom G4TM, (C) Guardian REAL-time, (D) FreeStyle Navigator, (E) FreeStyle Navigator II, (F) HG1-c and (G) GlucoTrack. The reason which limits its use is their extremely high cost. (Vashist, 2013)

6. Mobile based technological tools: (Shah and Garg, 2015)

a. Insulin dose calculators: Mobile apps like Insulin calculator, Bolus calc, etc. help to overcome the challenging task of dose calculation of insulin. The limitation of these apps is that most of them are not FDA approved.
b. Calorie Counter: A challenging task for the diabetic patients is to monitor their calorie intake. To do this, the calorific value of all the commonly taken has to be remembered. To ease this process of calorie counting, apps like GoMeal, Glucose Buddy, etc. are available. Their extensive databases cover the calorific value of most of the food items.
c. Quantifying physical activity (Fitness related apps): To keep a track of physical activity, mobile apps like pacer, Map my Walk, etc. play a key role. These apps monitor the frequency, intensity, time and type of activity.
d. Medication adherence: Every chronic disease faces the challenge of non- adherence among the patients. Most of medication adherence apps like MyMedSchedule, My Meds, etc. are easy to use and cost effective.

Conclusion

Diabetes mellitus is chronic disease with impaired carbohydrate metabolism. Dietary control, physical exercise, lifestyle modification and pharmacotherapy are usually sufficient for the management of the disease. Due to chronic nature of the disease, the compliance of the patient as well as adherence of the patient to the treatment is of utmost importance. In order to ensure proper compliance, the factors which compromises patient's adherence to the management schedule should be recognized and taken care of. This is where role of technology comes into picture. A perfect blend of rational pharmacotherapy and incorporation of suitable technological advancements can help in the better management of DM.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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