Assessment of Insulin Injection Administered in Diabetic Patients: A Clinical Audit

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Screenshot of Approval

Dissertation report & PPT approved

SS **Sumant Swain <sumant@iihmrdelhi.edu.in>**
10:50

To: Sheetal Yadav

Dear Dr Sheetal

Your PPT and report have been approved for presentation. After the presentation, incorporate the inputs of the expert panel and submit the final report.

Regards
Sumant

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Introduction

- **Clinical Audit** is a quality improvement process that seeks to improve patients care and outcomes through systematic review of care against explicit criteria & implementation of change.
- The aim of the clinical audit is to measure the gap between ideal practice (determined from evidence & guidelines) and actual practice. The clinical audit process comprises of 8 steps cycle:
- Select audit topic
- Defining aims and objectives
- Selecting standards
- Methodology: type of study, sampling, source of data
- Data collection and data analysis
- Making improvements
- Sustaining improvements
- Re-audit, if required

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- Diabetes also known as diabetes mellitus, is a chronic health condition that effects how the body uses blood sugar and turns it into energy.
- The burden of diabetes is high & increasing globally, according to WHO reports more than 420 million people worldwide live with diabetes. And in developing countries like India, mainly fueled by the increasing prevalence of overweight/obesity and unhealthy lifestyles. It was reported in 2019 that an estimate of 77 million individuals in India are diabetic, & which is expected to rise to over 134 million by 2045.
- Approximately 57% of these individuals remains undiagnosed. India contributes approx. 15% to the global diabetes burden & contributes 1% of the world's research on diabetes. India with a population of 1.2 billion leads the world with earing the dubious distinction of being called as **"Diabetes Capital of the World"**.
- Major two types of diabetes are Type I diabetes that makes upto to 5-10% of all the cases whereas Type II diabetes makes 85-90% of all the cases. Diabetes is the 8th leading cause of death.
- Diabetes is a major cause for blindness, amputation, kidney failure and cardiovascular diseases & can also result into multiorgan complications. These complications are a significant cause for increased morbidity and mortality among individuals with diabetes.
- What is insulin? And how it works??
- Insulin is a hormone which is produced by the beta cells of the pancreatic islets. It is an essential hormone produced by the pancreas that helps in controlling the glucose level of our bodies.

- The Pancreas secretes insulin into the bloodstream
- Then the insulin circulates and enables sugar to enter the body cells
- Insulin lowers the amounts of sugar in the bloodstream
- As the sugar level drops, so does the secretion of insulin from the pancreas also drops.

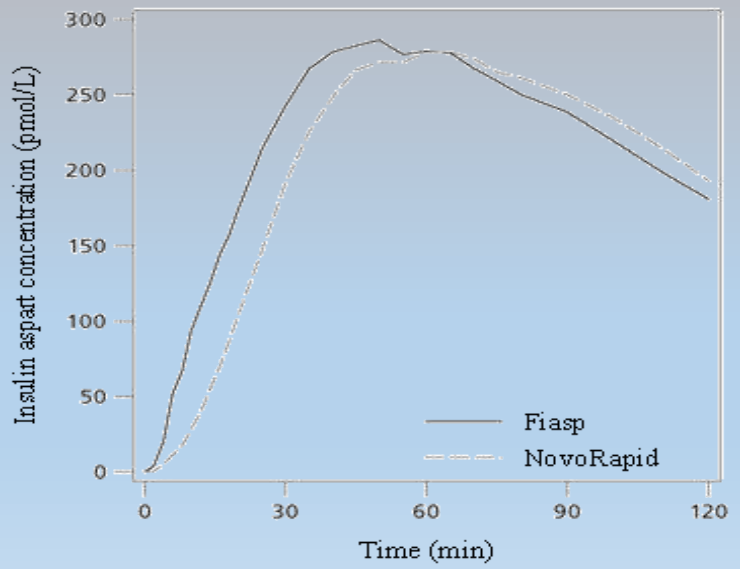
Incase of diabetes, the body either doesn't make enough insulin or the cells can't utilize the insulin it makes as well as it should.

When there is not enough insulin or the cells stop responding to insulin, it results in accumulation of sugar into the bloodstream

which results into hyperglycemia and further leads to serious health conditions such as, heart disease, neuropathy, nephropathy, etc.

In this study we have taken insulin therapy as a line of treatment for diabetic patients

- During the audit period we assessed the patients who were taking **Novorapid insulin** injections. Novorapid is a **rapid acting insulin** – it is advised to be injected 15-20 minutes before a meal rather than just before a meal.
- Whereas the other alternative to this is **Fiasp Insulin**, it is an **ultra rapid insulin**. It is the latest evolution in the ultra-rapid mealtime/bolus insulin.
- Fiasp can be taken immediately before a meal & can even upto 20 minutes after you have started eating.
- It is same as Novorapid with addition of 2 ingredients – Niacinimide (vit B3) & amino acid L-arginime – which increases the speed at which Fiasp is absorbed into the blood.



This graph shows the comparison between insulin Novarapid & insulin Fiasp.

Fiasp is 2 times faster than Novarapid

It is the first and only mealtime insulin which enters the bloodstream within 2.5 minutes and reaches its peak in its first hour.

Literature Review

- In a Clinical Review by Hyon Kwon, PharmaD, MPH – States that Fiasp was approved in the U.S. for subcutaneous and intravenous administration to improve glycemic control in adults with diabetes mellitus on September 29, 2017. On 21st October, 2019, Fiasp was approved for administration to adults with diabetes mellitus via continuous subcutaneous insulin infusion in the U.S (sNDA 208761-008). It also reviewed the efficacy of Fiasp in pediatric patients with T1DM with clinical trials. The trials evaluated the efficacy and safety of meal-time Fiasp and post-meal Fiasp compared to meal-time Novolog in paediatrics patients from 2-7 years of age.
- Fiasp has got the approval in Australia, for use in patients with type I diabetes over the age of 18 years for both injectable and pump form. The FDA, on 6th January gave a green flag for administrating Fiasp in children as young as 2 years to treat diabetic patients Studies says that Fiasp can be used by the pregnant women also but there are not enough clinical trial data to support the recommendation of Fiasp to pregnant.
- Department of Internal Medicine and Diabetology, Medical University of Lodz, Poland – Conducted a clinical trial for assessing the pharmacokinetics parameter of Fiasp. The trial was conducted under the acronym onset, in both T1DM & T2DM patients. The results showed comparable or better diabetes control with Fiasp groups as compared to Novarapid groups. Fiasp showed 2 times faster onset of action.

Objectives of Your Study

Aim:

- To assess the effective use of Insulin injections & finding better alternatives to improve care of Insulin dependent patients.

Objectives:

- To study timely administration of insulin injections.
- To suggest improvement, the care of patient on insulin.
- To find the better alternative that is not time bounded.

Methodology

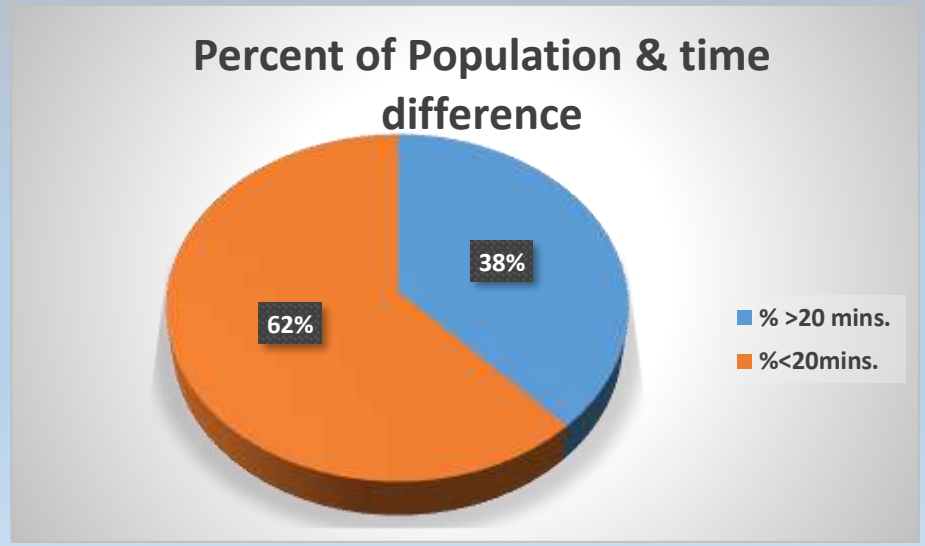
- ***Study Design**: A* Prospective and Observational study
- ***Study Period:*** from 1st April to 15th June 2021.
- ***Study Area:*** Endocrinology Department, Artemis Hospital, Gurugram, Haryana.
- ***Sample Size:*** Random sampling according to solvent formula (Screening Population – 200; Sample size – 133)
- When it is not possible to study the entire population, a smaller sample is taken using a random sampling technique and solvin's/solvent formula allows a researcher to sample the population with a desired degree of accuracy. Solvin formula is used to calculate the sample size necessary to achieve a certain confidence interval when sampling a population.
- **Solvent Formula = $n = N/(1+Ne^2)$**
- For example, for a screening population of 200 samples a margin of error of 0.05 is considered sufficiently accurate, therefore, n = 200/1+200*0.05*0.05 = 133 (The result equals the number of samples required to evaluate the population)
- *Hence 133 patients will be included in the study to assess the effectiveness of insulin injections*
- ***Research Instrument:*** Audit tool which will include Patients Name and Unique ID number, Admitting Consultant, Prescribing Consultant, Drug Administered, Drug Administration Date, Drug Administration time and Food intake time etc.
- **Staff involved**: Endocrinologists, Nurses, Pharmacists, F&B, Medical Services

Results

- Total of 133 patients who were diabetic were administered the insulin Novarapid & were asked to record the time of insulin administration and the time of meal intake.

Month	Total no. of patients Administered insulin (Novarapid)
April 2022	100
May 2022	33
Cumulative	133

- Then, as reported by the patient the data was recorded in the excel & the time difference between the insulin administration and food intake was calculated.



- Out of total 133 Patients audited, who were administered Novorapid insulin
- 62% patients had their meal within the given time after drug administration (i.e. after 15-20 min. of insulin administration), whereas
- 38% patients exceeded the time limit of 20 minutes after drug administration.

- **Finding:** Due to lack of coordination between the nursing, dietetics and kitchen staff there was delay in food servings to patients, therefore resulted in exceeding the time limit beyond 20 minutes.

- **Corrective and Prevention Action Taken** – Introduction of insulin Fiasp (The standard for introduction of Fiasp was set for a limit if 30-40% patient exceeds the time limit of 20 minutes after insulin administration)
- After the introduction of Fiasp Insulin, timing constraints were taken off and patient care in terms of timely medication administration improved.

Limitations of the Study

- Fiasp is not recommended in pregnancy as there is not enough clinical trial data to support it.
- Fiasp not administered in children below age of 18 years.
- Fiasp insulin Pump have reported to have unexplained high blood glucose after around 48 hours (in Australia, but used overseas)
- No direct observation, details were recorded as per the patient's statements.

Conclusion

- Diabetes a chronic condition & the disease burden is high, approx. 463 million people globally are living with diabetes from the latest data released by International Diabetes Federation in 2019.
- The high incidence is attributed to number of factors such as – combination of genetic susceptibility, adoption of high calorie diet, low activity lifestyle by growing middle class. Along with this other factors like obesity/overweight, age, inactivity, stress, family history, race & ethnicity also increase the likelihood for possessing diabetes later in life.
- WHO has taken an initiative to support and stimulate the adoption of effective measures for the surveillance, prevention and control of diabetes and its complication, especially in low & middle income countries.
- WHO has also released a global report on diabetes which provides an overview of the disease burden, interventions to prevent and manage diabetes, recommendations for government, individuals, and the society. WHO has also released a module on diagnosis and management of type 2 diabetes.
- In April 2021, WHO launched the Global Diabetes Compact, an initiative aiming for sustained improvements in diabetes prevention and care. In May 2021, the World Health Assembly agreed a resolution on strengthening prevention and control of diabetes.
- Diabetic patients must take responsibilities for their day to day care,& regardless of the type of diabetes, blood sugar monitoring, physical activities, keeping weight and stress under control & take medications regularly.

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Thank You

Suggestions to the Organization where the Study was Conducted

- Better patient's identification tools.
- Timely blood sugar testing.
- Training for insulin injections administrations and correct sites.
- Improved coordination between the nursing, dietetics and kitchen staff to avoid any delay in food servings.

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Dissertation Experiences

What did you learn (skill/ topic)?

- As Diabetes Mellitus is increasing as a global burden disease, choosing this topic helped in better understanding of the various causes, signs & symptoms and available treatment of the disease.
- Also, better learning of managing it well and ways to prevent it.
- Learning about the various insulin injections, types of it.
- Skill enhancement on data collection and analysis.

Overall self comments on Dissertation

- The dissertation helped in better understanding of the disease and specifically about the various insulin injections and their action time.
- Patients cooperating well during the trail and their privacy was assured.
- The various tools used during the data collection and analysis were effective in concluding the differences.
- The final conclusion helped in understanding the effectiveness of the injections and making the right choice according to the patient's

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Pictorial Journey