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Research Article

Comprehensive Assessment of Long-Term Safety Concerns in Antidiabetic Drug Therapy

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Abstract

Diabetes is a disease that occurs when your blood glucose, also called blood sugar, is too high. Glucose is your body's main source of energy. The human body can make glucose, but glucose also comes from the food we consume. Insulin is a hormone made by the pancreas that helps glucose get into the cells to be used for energy. If anyone have diabetes, the body doesn't make enough or any insulin or doesn't use insulin properly. There are basically 2 types of diabetes, Type 1 diabetes is where blood glucose (sugar) level is too high because body can't make a hormone called insulin. This happens because body attacks the cells in the pancreas that make the insulin, meaning is unable produce any at all. With type 2 diabetes the insulin in pancreas makes can't work properly, or pancreas can't make enough insulin. This means blood glucose (sugar) levels keep rising. Around 90% of people with diabetes in the UK have type 2. Antidiabetic drugs are medicines developed to stabilise and control blood glucose levels amongst people with diabetes. If diabetic patient will take Anti-Diabetic medication for Prolong time, the Anti-Diabetic drugs can show some adverse effect, like- Anorexia, Lactic acidosis, Mild Diarrhoea, Dyspepsia, Weight gain, Hypoglycaemia etc. But among these side effects we have observed that the major side effects are Arthralgia (joint Pain). In the present study we surveyed among 80 people and near about 50 people have diabetes at various age. Several People is used different types of medicine but among them majority used the drug is Metformin and Glimepiride. For the treatment of side effects about 87% people does not use any medication. The observed blood glucose level after taking antidiabetic medicine is around 110mg/dL. This comprehensive study will provide an idea about the various adverse effects, observed due to prolonged use of antidiabetic drugs. Though a more detailed volunteer study is further required to draw a final conclusion.

Keywords: Diabetes; Anti Diabetic Drugs; Metformin; Glimepiride; Blood Glucose Level;; Insulin

Introduction

Diabetes is a disease that occurs when blood glucose, also called blood sugar, is too high. Glucose is the body's main source of energy [1]. Human body can make glucose, but glucose also comes from the food we consume [2]. Insulin is a hormone made by the pancreas that helps glucose get into the cells to be used for energy. If anyone has diabetes, the body doesn't make enough or any insulin or doesn't use insulin properly. Glucose then stays in the blood and doesn't reach the cells [2]. Diabetes raises the risk of damage to the eyes, kidneys, nerves, and heart. Diabetes is also linked to some types of cancer [3]. Taking steps to preventor manage diabetes may lower your risk of developing diabetes health problems.

Different types of diabetes

There are mainly four Types of Diabetes as below.

- **Type 1 diabetes:** Type 1 diabetes is where the blood glucose (sugar) level is too high because human body can't make a hormone called insulin [4]. This happens because the body attacks the cells in your pancreas that make the insulin meaning you can't produce any at all. We all need insulin to live. It does an essential job. It allows the glucose in the blood to enter cells and fuel in the bodies [5]. When anyone have type 1 diabetes, the human body still breaks down the carbohydrate from food and drink and turns it into glucose. But when the glucose enters the bloodstream, there's no insulin to allow it into the body's cells. More and more glucose then builds up in the bloodstream, leading to high blood sugar levels [6].
- **Type 2 diabetes:** With type 2 diabetes the insulin in pancreas can't work properly, or the pancreas can't make enough insulin. This means the blood glucose (sugar) levels keep rising. Around 90% of people with diabetes in the UK have type 2 [7]. It is serious condition and can be lifelong. Having type 2 diabetes without treatment means that high sugar levels in the blood can seriously damage parts of the body, including eyes, heart and feet. These are called the complications of diabetes. But with the right treatment and care, one can live well with type 2 diabetes and reduce the risk of developing them [8].
- **Gestational diabetes:** Gestational diabetes is diabetes that can develop during pregnancy. It affects women who haven't been affected by diabetes before. It means high blood sugar is needed to take extra care of yourself and your bump. This will include eating well and keeping active. It usually goes away again after giving birth. It is usually diagnosed from a blood test 24 to 28 weeks into pregnancy [9].
- **Maturity onset diabetes of the young (MODY):** MODY is a rare form of diabetes which is different from both type 1 and type 2 diabetes and runs strongly in families. MODY is caused by a mutation (or change) in a single gene [10]. If a parent has this gene mutation, any child they have, has a 50 per cent chance of inheriting it from them. If a child does inherit the mutation they will generally go on to develop MODY before they're 25, whatever their weight, lifestyle, ethnic group etc. [11].
- **Neonatal diabetes:** Neonatal diabetes is a form of diabetes that is diagnosed under the age of six months. It's a different type of diabetes than the more common type 1 diabetes as it's not an autoimmune condition (where the body has destroyed its insulin producing cells) [12].
- **Wolfram Syndrome**: Wolfram Syndrome is a rare genetic disorder which is also known as DIDMOAD syndrome after its four most common features (Diabetes Insipidus, Diabetes Mellitus, Optic Atrophy and Deafness) [13].
- **Alstrom Syndrome:** Alstrom Syndrome is a rare genetically inherited syndrome which has a number of common features [14].
- **Latent autoimmune diabetes in adults (LADA):** LADA is a type of diabetes which seems to straddle type 1 and type 2 diabetes. Bits of it are more like type 1, and other bits are more like type 2. That's why some people call it type 1.5 diabetes or type 1 ½ diabetes. It's not actually classified as a separate type of diabetes at the moment, but there's some medical research going on to try and pinpoint exactly what makes it different from type 1 and type 2 diabetes [15].
- **Type 3c diabetes:** Type 3c diabetes is a type of diabetes that develops when another disease causes damage to the pancreas. The conditions related to type 3c are pancreatic cancer, pancreatitis, cystic fibrosis or haemochromatosis. You can also develop type 3c if you have part or all of your pancreas removed because of other damage [16].

- **Steroid-induced diabetes**: Some people who take steroids can go on to develop diabetes. This is known as steroid-induced diabetes, and is more common in people who are at higher risk of type 2 diabetes [17].
- **Cystic fibrosis diabetes:** Cystic fibrosis diabetes is the most common type of diabetes in people with cystic fibrosis. Although it has features of both type 1 and type 2, it is a different condition [18].
- **Monogenic diabetes:** Monogenic diabetes is a rare condition, different from both type 1 and type 2 diabetes. It's caused by a mutation in a single gene. If a parent has this mutation, their children have a 50p per cent chance of inheriting it. Since monogenic diabetes is so rare, people can often get misdiagnosed. And in some cases of monogenic diabetes, the condition can be managed with specific tablets and doesn't require insulin treatment. That's why it's incredibly important to understand rare forms of diabetes and diagnose them correctly [19].

Anti-diabetic drug

Antidiabetic drugs are medicines developed to stabilize and control blood glucose levels amongst people with diabetes.

- **Antidiabetic drugs for type 1 diabetes:** For people with type 1 diabetes, daily insulin injections are essential to maintain health. Type 1 diabetics must also eat properly, keep blood glucose levels from going too low or too high, and monitor blood sugar levels [20].
- **Antidiabetic drugs for type 2 diabetes:** For people with type 2 diabetes, diet and exercise may be enough to control blood glucose levels in some. However, when diet and exercise is no longer efficient, anti- diabetic drugs may be prescribed. Medication will either be taken orally in the form of tablets (oral hypoglycemics), or be injected (insulin and GLP-1 receptor agonists) [21]. Biguanides, such as Metformin, are commonly prescribed as a first antidiabetic medication. If biguanides are not effective on their own you may be given alternative medication either instead of, or in addition to, biguanides. The type of medication you are offered could depend on a variety of factors as different medication have different advantages and disadvantages [22].

Adverse effect of anti-diabetic drug

If diabetic patient will take Anti-Diabetic medication for Prolong time, the Anti- Diabetic drugs can show some adverse effect, like-

- **Anorexia (Weight Loss):** Anorexia can happen for Prolong use of Anti-Diabetic drug, actually it is an eating disorder that causes people to weigh less than is considered healthy for their age and height, usually by excessive weight loss [23].
- **Lactic Acidosis (Muscle Cramp, Body Aches):** Due to prolonged use of Anti-Diabetic Drug Lactic Acidosis can happen, it is a type of metabolic acidosis that occurs when lactic acids build up in your blood. Your body produces more lactate when your tissues are deprived of oxygen. Lactate can also build up if your livers and kidneys aren't able to metabolize it efficiently [24].
- **Mild Diarrhea:** Prolong use of Anti-Diabetic Drug can happen Mild Diarrhoea. The main symptom of diarrhea is passing loose, watery stools three or more times a day. People with diarrhoea may also have one or more of the following symptoms: an urgent need to use the bathroom [25].
- **Dyspepsia (Indigestion):** Due to prolong use of Anti-Diabetic Drug dyspepsia can happen, an ingredient called simethicone may provide some relief by reducing intestinal gas. Examples of gas relieving remedies include Mylanta and Gas-X. Medicines to reduce acid production. These medicines are called H-2-receptor blockers and are available without a prescription [26].
- **Arthralgia (Joint Pain):** Arthralgia (Joint Pain) can happen for Prolong use of Anti-Diabetic drug, joint stiffness, among its many causes are overuse, sprains, injury, gout, tendonitis and a few infectious diseases, including rheumatic fever and chickenpox.
- **Weight Gain:** Long term use of Anti-Diabetic drug can Causes Weight Gain, an increase in body weight. This can involve an increase in muscle mass, fat deposits, excess fluids such as water or other factors. Weight gain can be a symptom of a serious medical condition [27].
- **Hypoglycemia (Low Blood Sugar Level):** Hypoglycemia can happen for Prolong use of Anti-Diabetic drug; it is a condition in which your blood sugar (glucose) level is lower than the standard range. Glucose is your body's main energy source. Hypoglycemia is often related to diabetes treatment. But other drugs and a variety of conditions many rare can cause low blood sugar in people who don't have diabetes [28].

- **Skin Inflammation (Rashes):** Long term use of Anti-Diabetic Drug can Causes Skin Inflammation, It is also known as dermatitis. Signs that imply skin inflammation are primarily rash, red patches or even a breakout like blisters or abscess. A rash caused by inflammation is usually stinging, burning or itching when touched [29].
- **Increase Heartbeat**: Antidiabetic drug can increase heartbeat, and it can causes heart-related conditions such as high blood pressure (hypertension) Poor blood supply to the heart muscle due to coronary artery disease (atherosclerosis), heart valve disease, heart failure, heart muscle disease (cardiomyopathy) [30].

Materials and Methods

The study was implemented by a set of questions, in an online application and distributed through electronic social media, like WhatsApp, Facebook, Gmail, etc. throughout North 24 Parganas, West Bengal, India. To conduct the present study, first of all, a questionnaire including various information is circulated and information gathered. The table below provides all the questions.

Sl no	Question
1	Name
2	Age
3	Gender
4	Place you belong to
5	Are you diabetic patient?
6	If yes then which type of diabetes you have?
7	Any family history with diabetes?
8	If yes then who has diabetes in your family?
9	If you are a diabetic patient then at which age it is observed?
10	Which type of Medication you take , Name it
11	If you observed any side effects then what are those side effects?
12	If any others side affects you observed, then name it.
13	Do you take any medication for the side effects?
14	If yes, what are the medication?
15	What is the Blood Glucose Level (Fasting) during Diabetes? [If You don't have diabetes, what is your normal Blood Sugar level]
16	What is the Blood Glucose level (Fasting) after taking diabetic Medications?

Table 1: The questionnaire included in the survey form.

Results and Discussion

The below pie chart represents the percentage of gender respondents in the survey. It was observed that there were 47.4 % male, and 51.3 % female volunteer were responded during the survey.

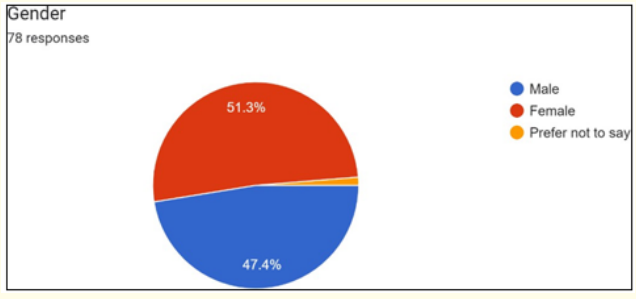

Figure 1: Different Percentage of gender represents in the survey.

The below pie chart represents the percentage of diabetic patient respondent in the survey. Our survey report revealed that out of all respondents 62.8 % of people are suffering from diabetes and 37.2 % are not.

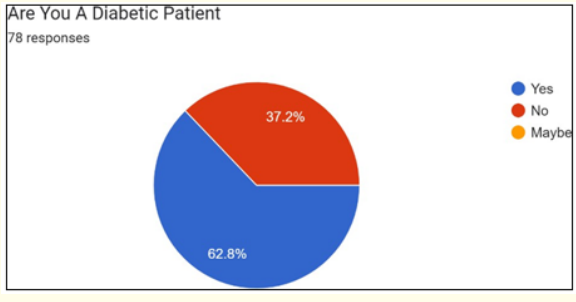

Figure 2: Percentage of diabetic patient respondent in the survey.

The below pie chart represents the percentage of DM Type 1 is 65.3 % and DM Type 2 is 34.7%

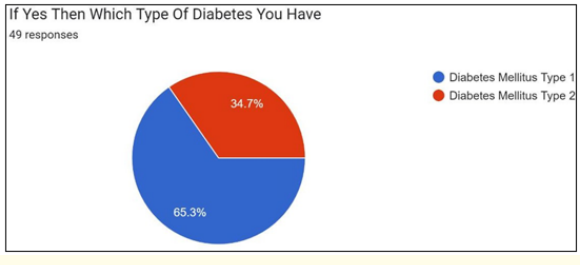

Figure 3: Percentage of types of Diabetes in graphical representation.

The below pie chart represents the percentage of family history with Diabetes respondent inthe survey. Our survey report revealed that out of all respondents 45.9 % of family membersare suffering from diabetes and 54.1 % are not diabetic.

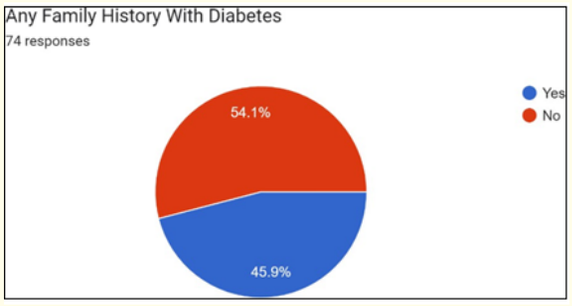

Figure 4: Percentage of family history with Diabetes.

From the graphical representation below we can notice that there is diabetes of family members in most cases.

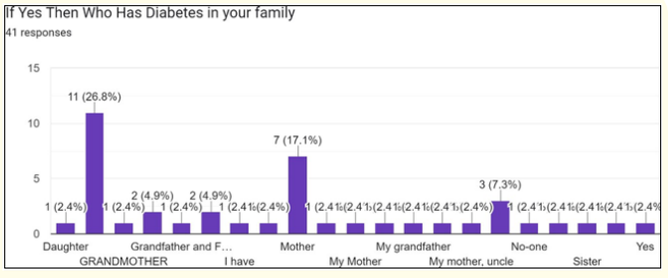

Figure 5: Graphical representation of Family members with Diabetes.

The below graphical representation chart represents the age at which diabetes is observed by the patients. From the above pie chart, we can identify that people, age group of 41-50 are more prone to diabetes.

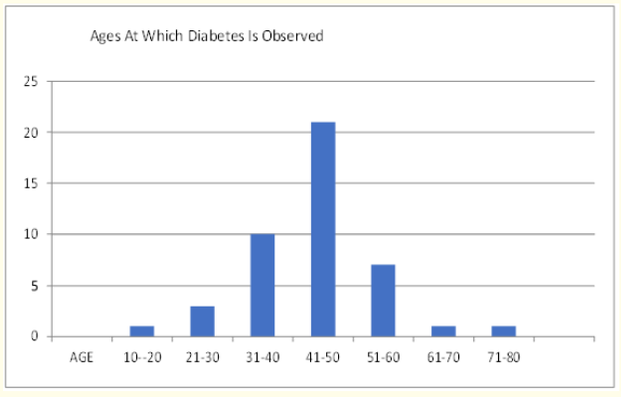

Figure 6: Graphical representation of age at which diabetes is observed.

The chart below represents the graphical representation of medication which is used. From that we observe that Metformin is widely used medication during diabetes followed by Glimepiride, Biguanides and insulin therapy.

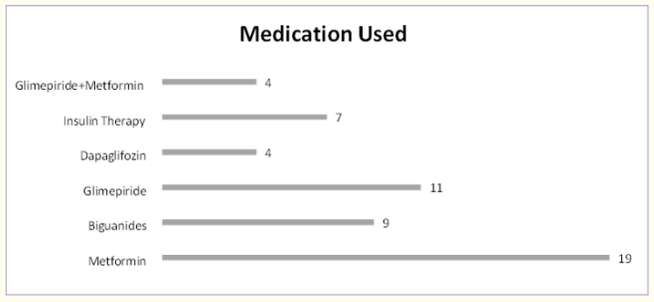

Figure 7: Graphical representation of medication takes for diabetes.

The below chart represents the side effects due the used of anti-diabetic drugs. From that we observed that among various types of side effects Arthralgia (joint Pain) is more common, followed by Anorexia, Lactic acidosis and weight gain.

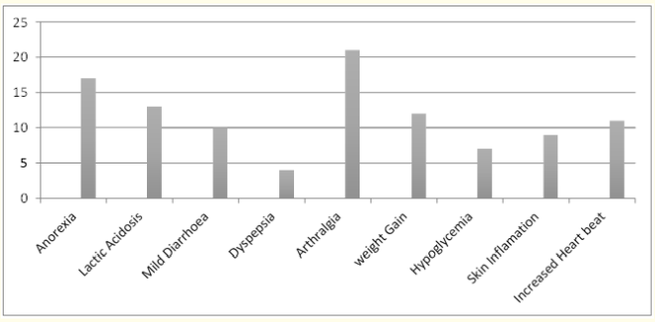

Figure 8: Graphical representation of Side Effects observed due to antidiabetic drug.

The below chart represents other side effects observed in the people after taking anti diabetic drugs. In which some are Hair fall, Stress, Muscle pain etc.

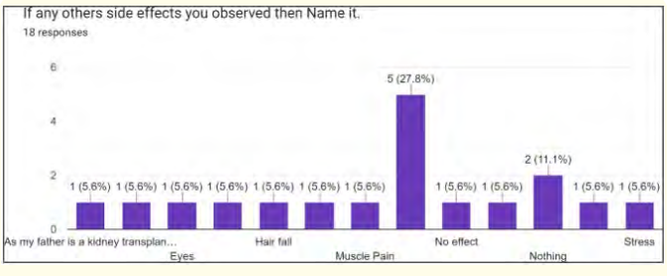

Figure 9: Graphical representation of others side effects.

From the below pie chart, we can identify that 86.3% of people surveyed did not take any medication foe side effects which is showed due to the anti-diabetic drug.

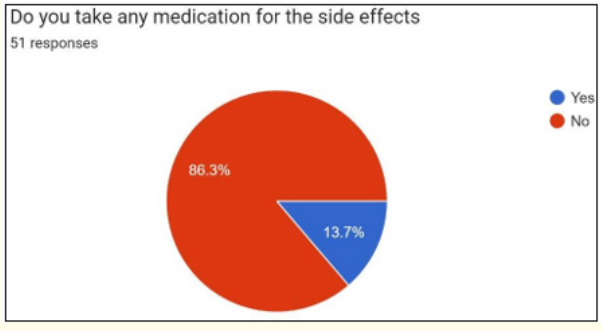

Figure 10: Percentage of whether medication taken for side effects.

From this below chart we can notice that people are taking different types of medication for various side effects. Some of the drugs are Norfloxacin, Ostocalcium Plus, Cilnidipine etc.

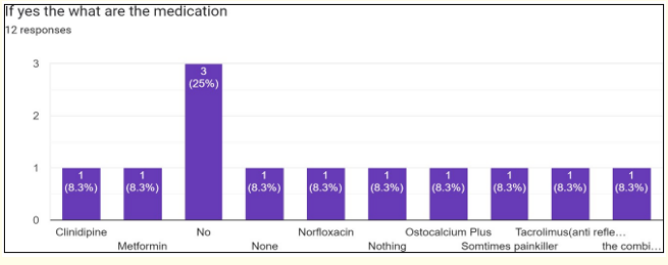

Figure 11: Percentage of types of medication taken to treat side effects.

From the chart below we can conclude that after taking the diabetic medication, the blood sugar level comes down to a range of 100-120 mg/dL.

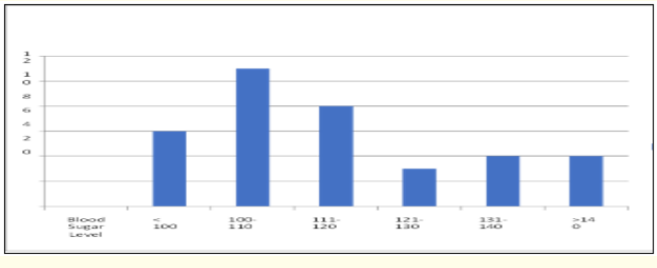

Figure 12: Graphical representation of blood glucose level (fasting) after taking diabetic medications.

Conclusion

Assessment of ADRs helps in understanding the relationship of drug and the adverse effect, severity and preventability of the reactions reported. This can gain confidence and improve adherence to the treatment given. Finally, we can conclude that diabetes is mostly seen in the age group of 41-50 and the medication which is mostly used is Metformin. The side effects which are mostly seen is Arthralgia. The Blood glucose level is between 100-120 mg/dL after taking the Antidiabetic Medication. The present study established the adverse drug reaction profile and causality assessment of antidiabetic drugs in a group of volunteers in mainly West Bengal region of India. It was found that the present study arthralgia was the most commonly experienced ADR by diabetic patients. Blood glucose level maintenance without inducing hypoglycaemia is important in reducing progressive complication with DM including risk of coronary vascular accident disease and death. Importance must be given while prescribing drugs for other co-morbid conditions. The second most common ADR reported was anorexia which is again in accordance with the previous study done on antidiabetic drugs. This study also exhibited that combination of sulphonylureas with biguanides, metformin were responsible for most of the ADRs. ADR monitoring is essential to protect the diabetic patient from use of new antidiabetic drugs. Ensuring that risk in drug use are anticipated and can be managed by the treating physician will extend confidence in the health service provided. Hence can improve compliance and reduce hospital admission due to adverse effects.

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Conflict of Interest

The authors declare that they have no competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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