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Effect of Contraceptive Pill on Diabetes Patient

A Project

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Dedication

To those who lit the first light in my life.....

**To those who exerted the effort of years in generosity, and make from
days stairs for me to rise.....**

my mother and my father.

To everyone whom taught us anything ever, our teachers.....

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Abstract

The prevalence of diabetes mellitus is increasing dramatically Worldwide, resulting in more and more women of reproductive Age being affected by either type 1 or type 2 diabetes.

Management of contraception is a major issue due to the specific Risks associated with pregnancy and those potentially induced by Hormonal contraceptives in diabetic women. This review Emphasizes the urgent need to improve the use of contraception In women with diabetes.

The glucose level in blood is maintained within a fairly narrow range Under diverse conditions (feeding, fasting, or severe exercise) by Regulatory hormones such as insulin, glucagon, or epinephrin. Measurement of glucose is one of the most frequently performed Procedures in clinical chemistry laboratories in conjunction with other Tolerance testing (Glucose tolerance test, Glucose 2h post-prandial...).

We collected the serum sample of 60 patients with diabetes Mellitus from the Children's and Maternity Hospital during two months.30 of these patients without use combined contraceptive pill while the remaining 30 patients with combined contraceptive pill,we measure the fasting blood glucose and found that pills increase risk for impaired glucose tolerance.

Chapter one

1. Introduction:

Contraception is a critical issue in women affected by diabetes mellitus. It is crucial to achieve a balance between the specific risks associated with pregnancy and those potentially induced by the contraceptive itself in diabetic women. It is well recognized that unplanned pregnancy can result in severe outcomes in women with diabetes, from the fetal to the neonatal period. Diabetes with poor metabolic control favors congenital abnormalities, spontaneous abortion, in utero death, fetal overgrowth leading to macrosomia, neonatal hypoglycaemia and hyperbilirubinemia, as well as many other deleterious effects for the fetus or newborn child. Unplanned pregnancy can also lead to dramatic complications for pregnant diabetic women, including an increased risk of hypertension and preeclampsia, as well as the worsening of pre-existing degenerative complications such as retinopathy or nephropathy.

The potential side-effects of certain contraception regimens frequently expose diabetic women to risk factors for cardiovascular events such as thromboembolic and cardiovascular risk. Thus, vascular safety represents a major concern for the orientation of contraception strategy in diabetic women.[1]

1.1 Diabetes Mellitus:

Diabetes Mellitus (DM), the most common of metabolic disorder[1] is a global public health concern. Three hundred and eighty three million adults are currently diagnosed with DM and another 175 million are estimated to be living with the condition but are as yet undiagnosed. [2] By 2035, numbers are set to increase by 55% with 592 million people becoming affected worldwide.[2] The rise in cases includes increasing numbers of women of reproductive age whose reproductive health and contraceptive needs must be carefully considered as DM has serious implications for pregnancy. It is the most common medical condition complicating pregnancy and affects up to 10% of women of a reproductive age in developed countries.[3]



1.2 There are three main types of DM(table 1) :

1_Type 1 DM is an autoimmune, chronic condition occurring in both adults and children, often before 40 years of age, and accounting for 10% of cases in adults and 98% of cases in children.[4] In type 1 DM, the primary beta cells of the pancreas do not produce insulin resulting in hyperglycemia. The propensity to develop autoimmune diseases, such as diabetes, may be familial. Treatment involves careful glucose monitoring and administration of insulin.

2_Type 2 DM, accounting for 90% of cases In adults and 2% of cases In children,[4] is sometimes known as mature onset diabetes. This occurs when the amount of insulin produced by the pancreatic beta cells Is insufficient or if the body develops a resistance to the insulin produced. As this condition is often associated with obesity, treatment involves diet and exercise, oral medication, and occasionally insulin. Recently, more cases of type

2_ DM have been diagnosed in younger age groups due to increasing obesity [1]

3_Gestational DM (GDM) develops during pregnancy in women without previously diagnosed DM. It Is caused by increased blood glucose levels in

Prevalence of diabetes (2014)^{2,4}
Table 1: the prevalence of diabetes.

Adults aged 20–79 years worldwide	affected in 2014. This figure was calculated to rise to 592 million by 2035 ²
Undiagnosed type 2 diabetes	179 million people were calculated to have undiagnosed type 2 Diabetes ⁴
Type 1 and type 2 diabetes	Type 1 diabetes – 10% of those affected Type 2 diabetes – 90% of those affected ⁴
Global estimations	The International Diabetes Federation (IDF) documents the countries with the highest number of diabetic patients: People’s Republic of China, India, USA, Russia, Brazil ²

pregnancy and is treated with diet or Insulin. GDM usually disappears after pregnancy but women are at risk of developing type 2 DM in the future .

1.3 Symptoms:

Symptoms of diabetes may occur suddenly. In type 2 diabetes, the symptoms can be mild and may take many years to be noticed Symptoms of diabetes include:

- Feeling very thirsty
- Needing to urinate more often than usual
- Blurred vision
- Feeling tired
- Losing weight unintentionally

Over time, diabetes can damage blood vessels in the heart, eyes, kidneys and nerves.

People with diabetes have a higher risk of health problems including heart attack, stroke and kidney failure.

Diabetes can cause permanent vision loss by damaging blood vessels in the eyes


Many people with diabetes develop problems with their feet from nerve damage and poor blood flow. This can cause foot ulcers and may lead to amputation



1.4 Diagnostic Testing:

The diagnosis of diabetes can be made when classic signs and symptoms of hyperglycemia are associated with a single random plasma glucose measurement of 200 mg per dL (11.1 mmol per L) or greater. Alternatively, the diagnosis can be made with an A1C level of 6.5% or greater, a fasting plasma glucose level of 126 mg per dL (7.0 mmol per L) or greater, or a two-hour plasma glucose level of 200 mg per dL or greater during an oral glucose tolerance test with 75-g glucose load (in table 2); however, testing should be repeated on a subsequent day to confirm the diagnosis.[5,6] If testing results do not match the clinical picture or are inconsistent, repeat testing or testing with another modality may be helpful.[6]

DIABETES



	Normal	Diabetes
Fasting Glucose	<100 mg/dL	>126 mg/dL
Non-Fasting Glucose	<200 mg/dL	>200 mg/dL
Oral Glucose Tolerance	<140 mg/dL	>200 mg/dL
HbA1c	<5.7%	>6.5%

Table 2: diagnosis test value

1.5 Contraceptive pill:

Birth Control Pills or Oral Contraceptive Pills are one of the most popular hormonal contraceptives taken daily orally. They contain synthetic hormones that resemble female hormones in a woman's body. These hormones protect against unplanned pregnancy, and may also be used for other medical purposes. [7]

Birth control pills work to protect against pregnancy by preventing the sperm from meeting with the egg to fertilize it, thus preventing pregnancy, through the following methods: [8]

- Preventing the ovulation process monthly by Inhibiting the work of the pituitary gland, which releases hormones that stimulate ovulation.
- Increasing the thickness of cervical mucus to Impede sperm from reaching the uterus and then to the egg to fertilize it.
- Reducing the thickness of the uterine lining to prevent the implantation of a fertilized egg Into it.

Types of birth control pills

There are many types of birth control pills based on the hormones present in them and their concentration. Types of birth control pills include the following: [9]

1_ Combined birth control pills

Combined birth control pills contain a synthetic form of the hormones estrogen and progesterone. They are available in different packages of 21 or 28 pills, including 21 active pills taken over a period of three weeks, and 7 placebo pills taken during days of rest and menstruation. [9] Extended-cycle pills are also available, with active pills taken continuously for 12 weeks and a week of placebo pills during which menstruation occurs, or packs of 365 pills taken throughout the year. [10] Types of combined birth control pills based on their hormone concentrations over the course of the month include: [10]

*Monophasic birth control pills: All active pills contain the same level of hormones.

* Biphasic birth control pills: The hormone level in active pills changes once midway through the cycle.

* Triphasic birth control pills: The hormone level in the active pills changes twice a month to mimic a woman's natural menstrual cycle.



Table 3: side effects of combined contraceptive pill [11,12,13]

Adverse effect	Action needed	Pill Suggestions
Acne	Increase oestrogen Reduce progestogen or change to less androgenic progestogen	Marvelon Femodene Yasmin Estelle 35 ED* Mercilon
Amenorrhoea	Increase oestrogen Decrease progestogen	Norimin* Brevinor-1*
Breakthrough bleeding • Early to mid cycle	Increase oestrogen	Levlen*, Monofeme*, Microgynon 30 Marvelon
• Late cycle	Increase progestogen or change type	Femodene Trifeme*, Triphasil, Triquilar
Breast soreness	Decrease oestrogen Decrease progestogen	Loette, Microgynon 20 Mercilon
Depression, moodiness or irritability	Decrease progestogen	Norimin* Loette, Microgynon 20 Trifeme*, Triphasil, Triquilar
Headache in pill-free week	Tri-cycle pills (skip two pill-free weeks in every three months)	
Menstrual cramps	Increase progestogen or tri-cycle pills	
Nausea	Decrease oestrogen	Loette, Microgynon 20 Mercilon
Weight gain	Decrease oestrogen Decrease progestogen	Loette, Microgynon 20 Mercilon

Progesterone-only pills



These birth control pills contain one hormone, progesterone, and are available in a package containing 28 active pills to be taken throughout the month. Menstruation may occur at the end of the month or stop in some women. [14]

1.6 Diabetes and contraceptive pill:

Most [birth control](#) is safe for people with [type 1 and 2 diabetes](#). However, contraceptives that contain hormones may need further evaluation by your healthcare provider.

Effective birth control is an important issue for people with diabetes, as unplanned [pregnancies](#) can result in complication.[¹⁵] For people with diabetes, weighing the benefits against the risks is essential in choosing the right birth control.

1.6.1 Effect of birth control on blood sugar:

Birth control that contains hormones can elevate some people's blood glucose levels. Hormonal contraceptives increase the female sex hormones estrogen and progesterone. In addition to preventing pregnancy, a rise in these hormones can also increase blood sugar. However, contraception containing less than 35 micrograms of ethinyl estradiol (synthetic estrogen found in hormonal contraceptives) may not affect blood sugar or insulin resistance.[16]

1.6.2 Using Birth Control to Prevent High-Risk Pregnancy:

One study found diabetic females use less effective contraception than non-diabetic females. Common causes for this finding were inadequate contraception counseling, lack of consistent contraception use, not planning pregnancies, and not seeking preconception care[17] The consequences of an unplanned diabetic pregnancy affect both the pregnant person and the fetus.

Risks faced by a newborn if born to a female with diabetes include:[16]

Stillbirth: A fetus is five times more likely to die in utero (in the uterus), especially if the pregnant person's A1C level (how well your body controls blood sugar) is 10% or greater.[18]

Perinatal death: Infants are three times as likely to die within the first few months of life.

Congenital abnormalities: Babies are twice as likely to have a significant congenital anomaly (unusual body structure or function present at birth).

Risks to a diabetic pregnant person include:[19]

Cesarean birth: Diabetic people can have large babies due to uncontrolled blood sugar levels. A large baby can increase the risk of cesarean delivery (C-section).

High blood pressure: Pregnant people with type 1 or 2 diabetes are at higher risk for hypertension during pregnancy (preeclampsia).

Stroke: Hypertension can result in a stroke during labor and delivery.

1.6.3 Oral contraception and incidence of diabetes in women:

From epidemiological data, it can be concluded that oral contraception in healthy women is not associated with an increased risk of developing diabetes. As a first demonstration, among the 98,590 women participating in the Nurses' Health Study, the incidence of diabetes was not increased in current or past users of oral contraceptives.[20,21]After a four year follow-up, the OR for diabetes occurrence was 1.6 (0.9–3.1) in current users, and 1.2 (0.8–1.8) in past users, after adjusting for age.

1.6.4 Oral contraception in women with a history of gestational diabetes:

Contraceptive options in women who experienced gestational diabetes also represent an important matter of discussion according to the high risk of developing type 2 diabetes in this particular population. Indeed, numerous studies reported a 7fold increase in diabetes incidence in the 5–10 years following gestational diabetes.[22]After gestational diabetes, it is crucial to systematically check the glucose tolerance status in the immediate post-partum period and to organize a systematic .

1.6.5 The progestogen-only pill (POP):

is regarded as a safe option for women with DM of any age with or without complications. Advantages of using the method generally outweigh the theoretical or proven risks [23]. The POP needs to be taken within a daily set time period but compliance is likely to be good if scheduled with routine insulin or oral hypoglycemic medication. Desogestrel has the benefit of inhibiting ovulation in 97% of cases and a 12 hours dosing period,[24] and therefore may be a more reliable choice especially for younger people with DM.

Chapter Two

2.1 Method and material:

The list result obtained by special device called spectrophotometer. we take the serum sample of 60 patients have diabetes Mellitus for two months ,30 of these patients that companied contraceptive pill while the remaining of 30 patients without use any pill and measure fasting blood glucose for these patients we observid that the contraceptive pill increase risk for impaired glucose tolerance and increase the level of glucose sugar in the blood.

The kit used is **GLUCOSE GOD -PAP**

The manufacturer name of kit is **BIOLABO SAS**



2.2 Procedure:

- Detailed Kenza 240TX procedure is available on request
- Wavelength: 505 nm o Temperature: 37°C
- Let stand reagents and specimens at room temperature.
- Mix. Let stands for 10 minutes at 37°C or 20 minutes at room Temperature .
- Read absorbance at 500 nm (460-560) against reagent blank .
- Coloration is stable for 15-20 minutes at 37°C, and then slowly decrease .



Chapter Three

3.1 The results:

The Result Shaw in this table

	NO.of patients	Fasting blood glucose	t-test
Patient with pills	30	122±43	0.05<p
Patients with no pills	30	110±41	

3.2 discussion:

According to descriptive statics and T.test samples mean and Anova two factors, there is a significance difference between groups of patients Combined estrogen-progestin high-dose oral contraceptives increase the risk of impaired glucose tolerance.

3.3 consultion:

Birth control pills cause a change in blood sugar levels for users compared to non-users

References:

- 1_ D.R. McCance. Pregnancy and diabetes, Best Practice & Research: Clinical Endocrinology & Metabolism
- 2_ Gourdy, P. (2013). Diabetes and oral contraception. Best Practice & Research Clinical Endocrinology & Metabolism, 27(1), 67-76.
- 3_ Han Cho, N. (2014). International Diabetes Federation (IDF). IDF Diabetes Atlas.
- 4_ Dunlop, A. L., Jack, B. W., Bottalico, J. N., Lu, M. C., James, A., Shellhaas, C. S., ... & Prasad, M. R. (2008). The clinical content of preconception care: women with chronic medical conditions. American journal of obstetrics and gynecology, 199(6), S310-S327.
- 5_ American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2004;27(suppl 1):S5-S10
- 6_ American Diabetes Association. (2) Classification and diagnosis of diabetes. Diabetes Care. 2015;38(suppl):S8-S16.
- 7_ Lindsay Boyers. Your Guide to Birth Control Pills: Types, Effectiveness, and Safety. Retrieved on the 21st of December, 2023.
- 8_ Alexandra Benisek. Birth Control Pills. Retrieved on the 21st of December, 2023.
- 9_ Diabetes, U. K. (2014). Diabetes: facts and stats. Diabetes UK, 3(1-21), 5.
- 10_ Dawn Stacey. What Are Combination Birth Control Pills? Retrieved on the 21st of December, 2023.

11_ National Prescribing Service Newsletter. Hormonal contraceptives: tailoring for the individual. Available from: http://www.nps.org.au/resources/NPS_News/news54/news54.pdf. Accessed February 2008

12_ Shoup D, Kjos SL. The handbook of contraception: a guide for practical management. Totowa: Humana Press; 2006.

13_ Gallo MF, Nanda K, Grimes DA, Schulz KF. 20 mcg versus >20 mcg estrogen combined oral contraceptives. Cochrane Database Syst Rev 2005; 2.14_Centers for Disease Control and Prevention. Diabetes and pregnancy.

15_ 9_Kidshealth.org. Birth Control Pill. Retrieved on the 21st of December, 2023.

16_ Centers for Disease Control and Prevention. Type 1 or type 2 diabetes and pregnancy.

17_ Robinson, A., Nwolise, C., & Shawe, J. (2016). Contraception for women with diabetes: challenges and solutions. Open Access Journal of Contraception, 11-18.

18_ Britton, L. E., Hussey, J. M., Berry, D. C., Crandell, J. L., Brooks, J. L., & Bryant, A. G. (2019). Contraceptive use among women with prediabetes and diabetes in a US national sample. Journal of midwifery & women's health, 64(1), 36-45.

19_ Bloomgarden, Z. T. (2000). American Diabetes Association 60th Scientific Sessions, 2000: diabetes and pregnancy. Diabetes Care, 23(11), 1699-1702.

20_ L.M. Lopez et al. Steroidal contraceptives: effect on carbohydrate metabolism in women without diabetes mellitus

21_ S.L. Kjos et al. Evaluation of routine diabetes and lipid screening after age 35 in candidates for or current users of oral contraceptives

22_ World Health Organization. Reproductive Health. (2010). Medical eligibility criteria for contraceptive use. World Health Organization.

23_ Hussain, S. F. (2004). Progestogen-only pills and high blood pressure: is there an association?: A literature review. *Contraception*, 69(2), 89-97.

24_ . Shawe, J., Mulnier, H., Nicholls, P., & Lawrenson, R. (2008). Use of hormonal Contraceptive methods by women with diabetes. *Primary care diabetes*, 2(4), 195-199.