A NON-INTERVENTIONAL DATA COLLECTION STUDY TO DETERMINE THE RISK FACTORS ASSOCIATED WITH DIABETES AND HYPERTENSION

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Abstract

Introduction: Progesterone is a critical hormone for female reproductive health, with therapeutic uses in managing conditions like irregular cycles, endometriosis, PCOS, and infertility. This non-interventional observational study assessed real-world usage patterns and patient-reported outcomes of progesterone therapy.

Materials and Methods: A cross-sectional study of 100 females prescribed progesterone was conducted. Participants were recruited via convenience sampling and completed questionnaires on demographics, medical history, treatment details, effectiveness, and symptom relief. Physiological parameters were recorded. Data were analysed using descriptive statistics.

Results: The cohort had a mean age of 36.89 ± 9.51 years. Most participants were menstruating (53%), with common conditions being endometriosis (37%) and PCOS (26%). Treatment was primarily oral (84%), with perfect adherence reported. A high proportion (84%) found progesterone somewhat or very effective. Key benefits included improved menstrual regularity, increased fertility (31%), reduced period pain (31%), and reduced bleeding (22%). Furthermore, 62% reported improved pregnancy outcomes.

Conclusion: This real-world evidence confirms the importance of progesterone in effectively managing a spectrum of reproductive health disorders, with high patient satisfaction and adherence. It highlights its role in alleviating symptoms and improving fertility, supporting its continued use in clinical practice. Further investigation into long-term outcomes is warranted.

Keywords: A cross-sectional, Progesterone, endometriosis, PCOS, and infertility, demographics, medical history.

1.Introduction:

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood glucose. Hyperglycaemia, also called raised blood glucose or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

In 2022, 14% of adults aged 18 years and older were living with diabetes, an increase from 7% in 1990. More than half (59%) of adults aged 30 years and over living with diabetes were not taking medication for their diabetes in 2022. Diabetes treatment coverage was lowest in low- and middle-income countries.

In 2021, diabetes was the direct cause of 1.6 million deaths and 47% of all deaths due to diabetes occurred before the age of 70 years. Another 530 000 kidney disease deaths were caused by diabetes, and high blood glucose causes around 11% of cardiovascular deaths

Since 2000, mortality rates from diabetes have been increasing. By contrast, the probability of dying from any one of the four main noncommunicable diseases (cardiovascular diseases, cancer, chronic respiratory diseases or diabetes) between the ages of 30 and 70 decreased by 20% globally between 2000 and 2019.[1]

What are the different types of diabetes?

The most common types of diabetes are type 1, type 2, and gestational diabetes.

Type 1 diabetes:

If you have type 1 diabetes, your body makes little or no insulin. Your immune system attacks and destroys the cells in your pancreas that make insulin. Type 1 diabetes is usually diagnosed in children and young adults, although it can appear at any age. People with type 1 diabetes need to take insulin every day to stay alive.

Type 2 diabetes:

If you have type 2 diabetes, the cells in your body don't use insulin properly. The pancreas may be making insulin but is not making enough insulin to keep your blood glucose level in the normal range. Type 2 diabetes is the most common type of diabetes. You are more likely to develop type 2 diabetes if you have risk factors, such as overweight or obesity, and a family history of the disease. You can develop type 2 diabetes at any age, even during childhood.

You can help delay or prevent type 2 diabetes by knowing the risk factors and taking steps toward a healthier lifestyle, such as losing weight or preventing weight gain.

Gestational diabetes:

Gestational diabetes is a type of diabetes that develops during pregnancy. Most of the time, this type of diabetes goes away after the baby is born. However,

1. **Association of Demographic Factors with Diabetes and Hypertension**
   Measurement: Statistical analysis (e.g., logistic regression) will assess the strength and significance of demographic factors in relation to the outcomes (diabetes and hypertension).

if you've had gestational diabetes, you have a higher chance of developing type 2 diabetes later in life. Sometimes diabetes diagnosed during pregnancy is type 2 diabetes.

Prediabetes

People with prediabetes have blood glucose levels that are higher than normal but not high enough to be diagnosed with type 2 diabetes. If you have prediabetes, you have a higher risk of developing type 2 diabetes in the future. You also have a higher risk for heart disease than people with normal glucose levels.[2]

2.Aim:

To investigate and identify the demographic, lifestyle, genetic, and environmental risk factors associated with the development and progression of diabetes and hypertension through non-interventional data collection, thereby contributing to improved prevention and management strategies.

3.Objectives:

To determine the risk factors associated with the development of diabetes and hypertension in a specified population, using observational data collection methods.

4.Methodology:

Clinical Phase: Non interventional

Type of Research: Academic Research

Study Sites: Multicenter

Study Period: Planned Enrolment Duration: Approximately 3 months.

Planned Total Duration of the Study: 6 months.

Study Visits: Single visit study

Study Population: Male and female subjects of age 18 years and above

Study Objectives: To determine the risk factors associated with the development of diabetes and hypertension in a specified population, using observational data collection methods.

Study Design: A Non interventional cross-sectional pilot study.

Number of Subjects:80 subjects.

Study End Points:

Primary Endpoints

2. **Prevalence of Diabetes (Type 2) in the Study Population**
   This will be determined by the participants' self-reported diagnosis of diabetes or confirmed through medical records or fasting blood glucose levels ($\geq$ 126 mg/dL) and/or HbA1c ($\geq$ 6.5%).

3. **Prevalence of Hypertension in the Study Population**
   Measurement: This will be determined through blood pressure measurements taken during the study visit(s).

Main Inclusion Criteria

Adults aged 18 years or older

Individuals with a history of hypertension or diabetes or who are at risk (e.g., family history, obesity, etc.)

Willingness to participate and provide informed consent

Main Exclusion Criteria

Secondary Endpoints

1. **Risk Factor Profile for Diabetes and Hypertension**
   Measurement: Analysis of lifestyle and behavioural factors via self-report surveys and clinical measurements (e.g., BMI, dietary habits, physical activity, smoking status).

2. **Impact of Family History on the Development of Diabetes and Hypertension**
   Measurement: Self-reported family medical history of diabetes and hypertension, with analysis of the correlation between familial history and individual health outcomes.

3. **Obesity (BMI ≥ 30) and its Association with Diabetes and Hypertension**
   Measurement: Body Mass Index (BMI) will be calculated for each participant (weight/height²), and its relationship with the presence of diabetes and hypertension will be analysed.

4. **Physical Activity Levels and Risk of Diabetes and Hypertension**
   Measurement: Physical activity will be assessed using self-reported questionnaires (e.g., International Physical Activity Questionnaire, IPAQ) and analysed in relation to the prevalence of the conditions.

5. **Dietary Habits and their Association with Diabetes and Hypertension**
   Measurement: Participants will complete a food frequency questionnaire (FFQ) or 24-hour dietary recall to assess dietary patterns, and this will be correlated with the occurrence of diabetes and hypertension.

6. **Alcohol Consumption and Smoking as Risk Factors**
   Measurement: Participants will self-report alcohol use (frequency, amount) and smoking status (current, former, never), and these behaviors will be analysed for their association with the two diseases.

7. **Impact of Socioeconomic Status (SES) on Health Outcomes**
   Measurement: SES will be assessed based on income, education level, and employment status. This information will be correlated with diabetes and hypertension outcomes.

8. **Sleep Patterns and its Impact on Diabetes and Hypertension**
   Measurement: Sleep duration and quality will be assessed through participant self-reporting (e.g., sleep diaries or standardized sleep questionnaires, RS Sleep Scale).

Genetic Factors Measurement: Family history of these conditions (diabetes and hypertension) will be collected, and its impact on individual health status will be analysed.

Individuals with other chronic conditions that could confound the study (e.g., cancer, severe renal disease)
Pregnant or breastfeeding women
Individuals unable to provide informed consent
Route, Dose and Dosage Form: Not Applicable.
History of all medication using and prescribed at the time of enrolment should be captured.

- Data Capturing
- Paper CRF.
- Informed Consent Form

Data Analysis: Data will be analysed using statistical methods to identify significant correlations between various risk factors and the presence of diabetes and hypertension. Logistic regression models will be used to determine the strength and significance of associations. Descriptive statistics (mean, standard deviation, percentage) will be used to summarize demographic characteristics and lifestyle factors.

Results:

TABLE-1 SUMMARY STATSTICS OF DEMOGRAPHICS		
S.no	**Parameter**	**Mean ± SD**
1	Age	56.56 ± 16.05
2	Height (mts)	1.67 ± 0.06
3	Weight	75.61 ± 9.88
4	BMI	31.89 ± 4.51

Graph-1 Summary Statstics of Demographics
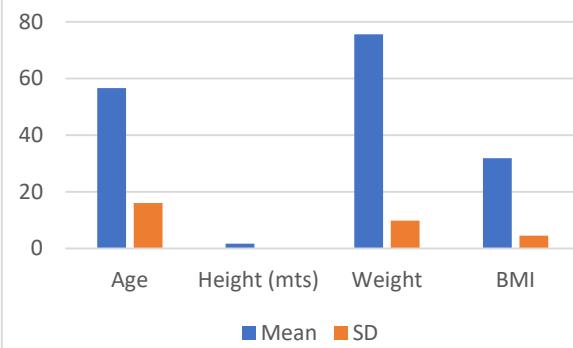
TABLE-2
SUMMARY STATSTICS OF VITAL SIGNS

S.no	Parameter	Mean ± SD
1	Pulse Rate	92.65 ± 8.73
2	SBP	125.36 ± 9.80
3	DBP	84.89 ± 7.85
4	Respiratory Rate	20.13 ± 1.29
5	Body Temperature	96.80 ± 10.01

Graph-2
Summary Statstics of Vital Signs

TABLE-3
SUMMARY STATSTICS OF PREVELANCE OF DM AND HTN

S.no	Parameter	Mean ± SD	
1	Prevalence of Diabetes (Type 2) in the Study Population (HbA1c)	7.84 ± 0.77	
2	Prevalence of Hypertension in the Study Population (Blood Pressure)	**SBP**	**DBP**
		125.36 ± 9.80	84.89 ± 7.85

Graph-3
**SUMMARY STATSTICS OF PREVELANCE OF DM AND HTN**
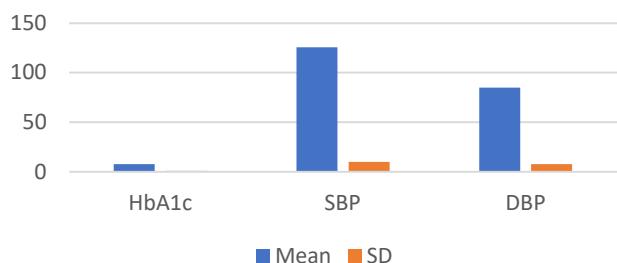
TABLE-4
SUMMARY STATSTICS OF RSIK FACTOR PROFILE FOR DM AND HTN

Parameter	Group-1(n=30) Diabetic Mean ± SD	Group-2(n=30) Hypertension Mean ± SD	Group-3(n=30) Control Mean ± SD
Age	52.43 ± 16.57	54.43 ± 17.57	64.03 ± 8.55
	p-value is 0.006908 (The result is significant at $p < 0.05$)		
Height	1.67 ± 0.06	1.68 ± 0.06	1.68 ± 0.05
Weight	74.37 ±11.75	76.60 ± 9.67	63.43 ± 4.86
BMI	31.61 ± 4.74	32.32 ± 5.15	26.64 ± 2.38
	p-value is < .00001(The result is significant at $p < 0.05$)		
Gender	Male (n=16)	Male (n=15)	Male (n=18)
	Female (n=14)	Female (n=15)	Female (n=12)
IPAQ	13.57 ± 4.24	10.60 ± 3.86	9.20 ± 3.50

Graph-4
RISK FACTOR PROFILE FOR DM AND HTN
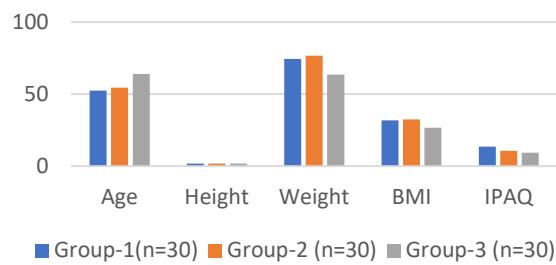
| TABLE-5 SUMMARY STATSTICS OF IMPACT OF FAMILY HISTORY ON DEVELOPMENT OF DM & HTN					
Parameter	**Group-1(n=30) Diabetic %**		**Group-2(n=30) Hypertension %**		**Group-3 (n=30) Control Healthy Subjects %**
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
Diabetic History	30 (100%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	30 (100%)
Hypertension	15 (50%)	15 (50%)	30 (100%)	0 (0%)	0 (0%)	30 (100%)
Obesity	15 (50%)	15 (50%)	22 (73.3%)	8 (26.6%)	0 (0%)	30 (100%)
Smoking History	13 (43.33%)	17 (56.66%)	11 (36.6%)	19 (63.4%)	8 (26.6%)	22 (73.4%)
Alcohol History	11 (36.6%)	19 (63.4%)	11 (36.6%)	19 (63.4%)	10 (33.3%)	20 (66.7%)
Family History DM	21 (70%)	9 (30%)	20 (66.6%)	10 (33.4%)	22 (73.3%)	8 (26.7%)
Family History HTN	13 (43.3%)	17 (56.7%)	13 (43.33%)	17 (56.66%)	11 (36.6%)	19 (63.4%)
Socioeconomic Status	16 (53.3%)	14 (46.7%)	13 (43.33%)	17 (56.66%)	22 (73.3%)	8 (26.6%)

Graph-5 SUMMARY STATSTICS OF IMPACT OF FAMILY HISTORY ON DEVELOPMENT OF DM & HTN

SUMMARY STATSTICS OF IMPACT OF FAMILY HISTORY ON DEVELOPMENT OF DM & HTN in Group-1
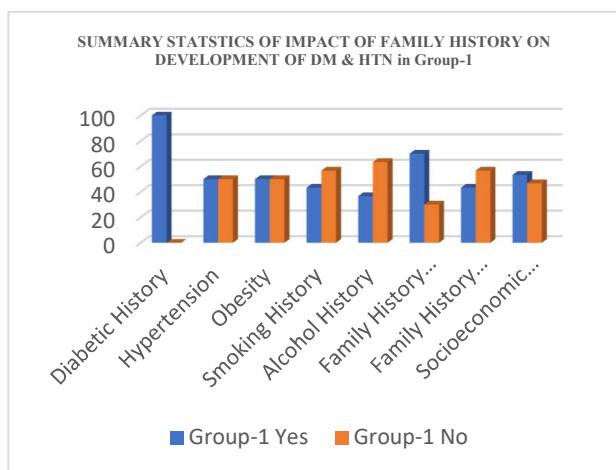
SUMMARY STATSTICS OF IMPACT OF FAMILY HISTORY ON DEVELOPMENT OF DM & HTN in Group-2
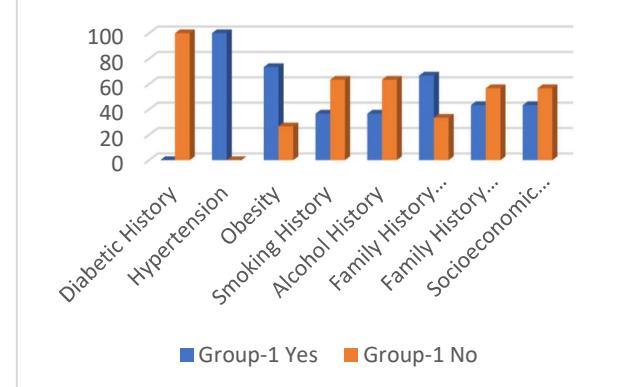
SUMMARY STATSTICS OF IMPACT OF FAMILY HISTORY ON DEVELOPMENT OF DM & HTN in Group-3
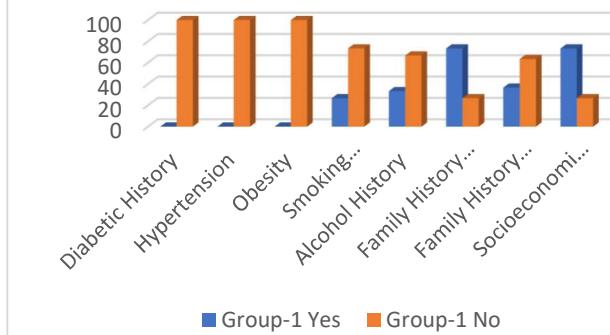
Summary and Discussion:

It was evident that From Table-1 the mean the average age of participants is 56.56 years, with a standard deviation (SD) of ±16.05 years, The mean height is 1.67 meters, with an SD of ±0.06 meters, The average weight is 75.61 kilograms, with an SD of ±9.88 kilograms, The mean Body Mass Index (BMI) is 31.89, with an SD of ±4.51. This data represents the central tendency and variability in the demographic characteristics of the sample.

It was evident that From Table-2, The average pulse rate is 92.65 beats per minute (bpm), with a standard deviation (SD) of ±8.73 bpm. The mean SBP is 125.36 mmHg, with an SD of ±9.80 mmHg.The average DBP is 84.89 mmHg, with an SD of ±7.85 mmHg.The mean respiratory rate is 20.13 breaths per minute, with an SD of ±1.29. The average body temperature is 96.80°F, with an SD of ±10. 01°F.This table outlines the typical values and variability of vital signs in the studied group.

It was evident that From Table-3, The mean HbA1c level in the study population is 7.84%, with a standard deviation (SD) of ±0.77%. This indicates a notable prevalence of Type 2 diabetes.

The **Prevalence of Hypertension, Systolic Blood Pressure with** the mean SBP is 125.36 mmHg, with an SD of ±9.80 mmHg and the mean DBP is 84.89 mmHg, with an SD of ±7.85 mmHg.This data highlights the average measurements and variability associated with diabetes and hypertension prevalence in the study group.

It was evident that From Table-4, the Mean age in **Group 1 (Diabetic)** was 52.43 ± 16.57 years, **Group 2 (Hypertension)**: 54.43 ± 17.57 years, **Group 3 (Control)**: 64.03 ± 8.55 years.

Significance: The p-value is 0.0069, indicating a statistically significant difference in age among the groups ($p < 0.05$).

Height: Similar across groups: ~1.67–1.68 ± 0.05–0.06 meters were observed

Weight: Group 1 (Diabetic): 74.37 ± 11.75 kg, Group 2 (Hypertension): 76.60 ± 9.67 kg, Group 3 (Control): 63.43 ± 4.86 kg.

Body Mass Index (BMI*)*

- **Group 1 (Diabetic)**: 31.61 ± 4.74
- **Group 2 (Hypertension)**: 32.32 ± 5.15
- **Group 3 (Control)**: 26.64 ± 2.38
- **Significance**: The p-value is < 0.00001, indicating a highly significant difference in BMI among the groups ($p < 0.05$).

Gender Distribution

- **Group 1 (Diabetic)**: 16 males, 14 females
- **Group 2 (Hypertension)**: 15 males, 15 females
- **Group 3 (Control)**: 18 males, 12 females

Physical Activity (International Physical Activity Questionnaire)

- **Group 1 (Diabetic)**: 13.57 ± 4.24
- **Group 2 (Hypertension)**: 10.60 ± 3.86
- **Group 3 (Control)**: 9.20 ± 3.50

This table illustrates key differences in age, BMI, and physical activity levels, with significant differences noted for both age and BMI among the groups.

Conclusion:

The data highlights distinct risk factor profiles across diabetic, hypertensive, and healthy control groups:

Diabetes and Hypertension Prevalence: Diabetes was exclusive to Group 1 (100%), and hypertension was universal in Group 2 (100%), confirming the focused selection of the groups & Neither diabetes nor hypertension was present in the healthy control group (Group 3).

Obesity: Obesity was significantly more prevalent in the hypertensive group (73.3%), indicating a strong association between obesity and hypertension and Half of the diabetic group (50%) was obese, while none of the control group exhibited obesity.

Smoking and Alcohol History: Smoking and alcohol use were relatively moderate across all groups, with slightly higher prevalence in Group 1 (diabetics).

Family History: A strong family history of diabetes (~70%) was observed consistently across all groups, including controls, suggesting a genetic predisposition in the studied population. Family history of hypertension (~40%) showed no significant difference among the groups.

Socioeconomic Status: The control group had the highest proportion of participants in a higher socioeconomic bracket (73.3%), which may suggest a correlation between socioeconomic status and better health outcomes.

Overall Conclusion suggest that Obesity emerges as a key modifiable risk factor, particularly in the hypertensive group. Additionally, genetic predisposition plays a significant role in diabetes prevalence, and socioeconomic factors may influence overall health. Tailored interventions targeting obesity and lifestyle modifications can significantly reduce the risk of diabetes and hypertension in at-risk populations.

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