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A Non-Interventional Study on Importance of Usage of Progesterone in Females

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Abstract:

Introduction: Diabetes and hypertension are major chronic diseases with rising global prevalence, contributing significantly to morbidity and mortality. This study aimed to investigate and identify demographic, lifestyle, genetic, and environmental risk factors associated with the development and progression of diabetes and hypertension through a non-interventional, observational approach.

Materials and Methods: A non-interventional, cross-sectional pilot study recruited 80 adults ($\geq$18 years) at multiple sites over six months, collecting all data during a single visit. It gathered demographic, medical, lifestyle, vital sign, and anthropometric data. Diabetes was diagnosed via self-report, records, or HbA1c $\geq$6.5%; hypertension by blood pressure measurement. Analysis used descriptive statistics and logistic regression.logistic regression.

Results: Participants averaged 56.56 ($\pm$16.05) years old with a BMI of 31.89 ($\pm$4.51). Mean HbA1c was 7.84% ($\pm$0.77) and BP was 125.36/84.89 mmHg. Groups differed significantly in age (p=0.0069) and BMI (p<0.00001). Hypertension group had 73.3% obesity. ~70% reported diabetic family history. Smoking/alcohol use were moderate, slightly higher in diabetics. Controls had higher socioeconomic status (73.3%).

Conclusion: Obesity, family history of diabetes, and socioeconomic status emerged as significant factors associated with diabetes and hypertension. The findings underscore the importance of targeted lifestyle interventions, particularly weight management, in at-risk populations. Genetic predisposition also plays a notable role, especially in diabetes. Further studies with larger sample sizes are recommended to validate these observations and inform public health strategies.

Keywords: A non-interventional, cross-sectional, Diabetes and hypertension, morbidity and mortality, socioeconomic status, Smoking/alcohol

1.Introduction:

Progesterone is a naturally occurring steroid hormone that plays a crucial role in the female reproductive system, particularly in regulating the menstrual cycle and supporting pregnancy. It is synthesized primarily in the ovaries, adrenal glands, and placenta, and its levels fluctuate throughout a woman's life, particularly during the menstrual cycle, pregnancy, and menopause. In recent years, progesterone supplementation has been studied for its potential benefits in various aspects of female health, including menstrual disorders, fertility treatments, and hormonal replacement therapy.

3.Objectives:

To assess the common medical conditions in females that require progesterone supplementation.

To evaluate the effectiveness of progesterone in managing reproductive health issues, such as irregular menstrual cycles, endometriosis, polycystic ovary syndrome (PCOS), and infertility.

To understand the benefits and challenges associated with progesterone usage from the perspective of patients.

To explore the impact of progesterone on pregnancy outcomes and symptom relief (e.g., menstrual pain,

A growing body of evidence suggests that progesterone can have significant therapeutic effects, especially in conditions like luteal phase defects, endometriosis, and polycystic ovary syndrome (PCOS), where hormonal imbalance plays a pivotal role. Additionally, progesterone has been recognized for its neuroprotective, anti-inflammatory, and mood-stabilizing properties, which may have broader implications for women's health, including the management of premenstrual syndrome (PMS), menopausal symptoms, and even mental health issues such as anxiety and depression.

This non-interventional study aims to explore the significance of progesterone usage in women, focusing on its physiological roles, therapeutic applications, and potential impact on overall health. By examining real-world data and clinical observations, this study seeks to further understand the benefits and challenges associated with progesterone therapy, offering valuable insights into its role in modern medical practices and women's health.

2.Aim:

The aim of this study is to evaluate the importance of progesterone usage in females, focusing on its impact on managing various reproductive health conditions, improving fertility, regulating menstrual cycles, and enhancing overall quality of life. Specifically, the study aims to

Assess the prevalence of medical conditions in females that necessitate progesterone supplementation, such as irregular menstrual cycles, endometriosis, polycystic ovary syndrome (PCOS), and infertility.
Evaluate the effectiveness of progesterone in addressing these reproductive health issues and improving pregnancy outcomes.
Examine the benefits of progesterone usage in terms of symptom relief, such as reduced menstrual pain, bleeding, and other discomforts.
Investigate patient adherence to progesterone therapy and identify factors influencing compliance with treatment regimens.
Gather real-world patient experiences and perceptions of progesterone's role in managing reproductive health and enhancing fertility.

Data Collection:
Questionnaires will be administered to collect data from participants. The questionnaires will cover:
Demographic information (e.g., age, height, weight, reproductive status)
Medical history (e.g., diagnosis of endometriosis, PCOS, fibroids, hormonal imbalances)
Details of progesterone use (e.g., dosage, administration route, frequency)
Patient-reported effectiveness of progesterone (e.g., perceived improvement in fertility, menstrual regularity, symptom relief)
Experiences with progesterone (e.g., side effects, satisfaction, perceived benefits)
Adherence to treatment (e.g., frequency of missed doses, treatment compliance)

Observational Nature:
Since this is a non-interventional study, researchers will only observe and document the patients' existing treatment

bleeding).
To investigate patient adherence to progesterone therapy and factors influencing compliance.

4.Methodology:
This is a non-interventional observational study, meaning no experimental interventions were applied, and the participants' existing treatment regimens were observed and documented. The study involved 100 female patients who were using progesterone for various reproductive health issues, such as menstrual irregularities, hormonal imbalances, and fertility problems. Data were collected through questionnaires regarding patient demographics, medical history, medication usage, effectiveness of progesterone, and personal experiences with the treatment

Study Design:
This study follows a non-interventional, observational design, meaning that no experimental manipulation or changes to treatment plans were made. The aim is to observe and document the natural usage of progesterone among female patients for managing various reproductive health conditions.

Population:
•The study will involve 100 female participants who are currently using progesterone for reproductive health issues.
•Participants will be selected from various healthcare settings (e.g., clinics, hospitals) where progesterone is prescribed for conditions such as irregular menstrual cycles, endometriosis, polycystic ovary syndrome (PCOS), fibroids, infertility, and menopausal symptoms.

Sampling Method:
A convenience sampling method will be used, where patients who meet the eligibility criteria and consent to participate will be included in the study.
The study will aim for a diverse range of ages, reproductive stages (e.g., menstruating, perimenopausal, post-menopausal), and medical conditions to ensure comprehensive data on progesterone usage across different groups.

regimens and outcomes, without altering or influencing the treatment in any way.

The study will focus on real-world data, capturing the lived experiences and results of using progesterone in routine clinical practice.

Outcome Measures:

Primary Outcomes:

Effectiveness of progesterone in improving menstrual regularity, reducing menstrual pain, and alleviating other symptoms (e.g., reduced bleeding, improved fertility).

Patient satisfaction with treatment and perceived benefits.

Secondary Outcomes:

Pregnancy outcomes (improvement in conception rates or pregnancy success following progesterone usage).

Symptom relief (such as reduction in period pain, improvement in hormonal imbalances). Adherence rates to prescribed progesterone therapy.

Data Analysis:

Descriptive statistics (mean, median, standard deviation) will be used to summarize demographic and clinical characteristics of the participants.

The effectiveness of progesterone and patient-reported outcomes will be analysed using frequency distributions and percentages to quantify the most common experiences and perceptions.

Comparisons will be made between different groups (e.g., those with menstrual irregularities vs. those with infertility) to evaluate if progesterone shows differential effectiveness across various conditions.

Ethical Considerations:

All participants will provide informed consent, understanding the nature of the study and their voluntary participation.

The study will ensure the confidentiality and privacy of participant data, in accordance with ethical guidelines and regulations (e.g., HIPAA or GDPR, depending on location).

As this is a non-interventional study, no medical procedures or treatments will be altered as part of the research. Participants will continue their treatment as prescribed by their healthcare providers.

It was evident from Table-2 the mean Pulse Rate of overall study population was 84.16 ± 7.49 beats/min which was Normal, the mean SBP was 120.35 ± 7.01 mm/hg, the mean DBP was 75.8 ± 7.64 mm/hg which was, Respiratory Rate16.4 ± 1.55 breaths/min and Body Temperature 97.7 ± 0.650 F both were recorded as normal values.

Results:

TABLE-1

SUMMARY STATSTICS OF DEMOGRAPHICS

S.no	Parameter	Mean ± SD
1	Age	36.89 ± 9.51
2	Height	1.601 ± 0.11
3	Weight	61.45 ± 9.93
4	BMI	28.77 ± 4.18

GRAPH-1
SUMMARY STATSTICS OF DEMOGRAPHICS
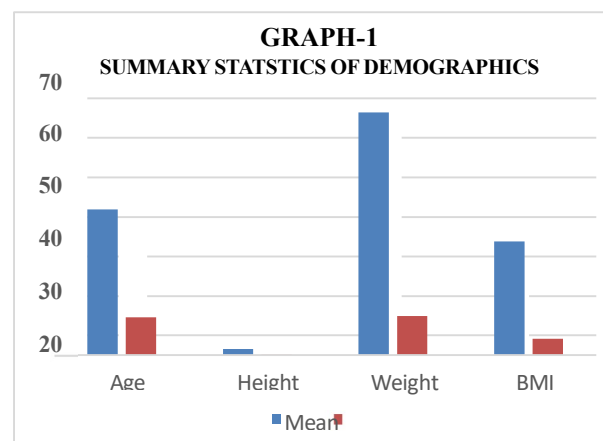
It was evident from Table-1 the mean age group of overall study population was 36.89 ± 9.51 yrs, the mean height was 1.601 ± 0.11 mts, the mean weight was 61.45 ± 9.93 kgs and the mean BMI of all over study population was 28.77 ± 4.18 kg/m2.

TABLE-2

SUMMARY STATSTICS OF VITAL SIGNS

S.no	Parameter	Mean ± SD
1	Pulse Rate	84.16 ± 7.49
2	SBP	120.35 ± 7.01
3	DBP	75.8 ± 7.64
4	Respiratory Rate	16.4 ± 1.55
5	Body Temperature	97.7 ± 0.65

GRAPH-2
SUMMARY STATSTICS OF VITAL SIGNS

TABLE-3

SUMMARY STASTICS OF PROGESTERONE USAGE QUESTIONNARIES

Reproductive Status		
S.no	**Parameter**	**(n= 100)**
1	No of Patients with Menopause	27
2	No of Patients with Mensurating	53
3	No of Patients with Post Menopause	20
Hormonal Therapy		
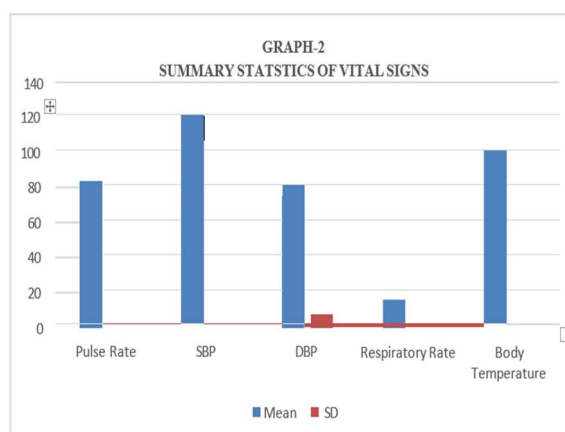
S.no	Parameter	Yes	No
1	No of Patients with Hormonal Therapy	84	16

Birth Control

S.no	Parameter	Yes	No
1	No of Patients using Birth Control	0	100

Hormonal Medical Conditions

S.no	Parameter	(n= 100)
1	Endometriosis	37
2	PCOS	26
3	Fibroids	21
4	No Medical History/No Abnormalities	16

Progesterone Usage

S.no	Parameter	Yes	No
1	Usage of Progesterone Usage	84	16

Progesterone Usage Medical Conditions

S.no	Parameter	(n= 100)
1	Infertility	8
2	Hormonal Imbalance	13
3	Irregular Menstrual Cycle	33
4	Support Pregnancy	16
5	Fibroids	14
6	No of patients with No Usage	16

Route of Administration & Frequency

S.no	Parameter	Usage	Non-Usage
1	Oral	84	16
2	Frequency	84	16

Missed Doses

S.no	Parameter	Usage	Non-Usage
1	**Missed Doses**	0	0

Effectiveness of Progesterone

S.no	Parameter	Effectiveness
1	Some What Effective	41
2	Very Effective	43
3	No Effective	16

Rating of Progesterone post Usage

S.no	Parameter	Effectiveness
1	Some What Effective	45
2	Very Effective	39
3	No Rating	16

Improving rate of pregnancy

S.no	Parameter	Yes	No
1	Rating on Improvement in pregnancy post usage	84	16

Relief Progesterone post Usage

S.no	Parameter	Relief rating
1	Significant relief	43
2	Some relief	41
3	No Rating	16

Experience Progesterone post Usage

S.no	Parameter	Yes	No
1	Experience Progesterone post Usage	84	16

Progesterone usage experience

S.no	Parameter	Usage Experience
1	Increased Fertility	31
2	Reduced Menstrual Bleeding	22
3	Reduced Period Pain	31
4	No Experience	16

It was evident from Table-3 i.e. post assessment of Progesterone Usage Questionaries we found the Reproductive Status of patients using Progesterone out of 100 patients 27 are with Menopause stage, 53 with Mensurating and 20 are with Post Menopause and the major share of patients with usage of progesterone are Mensurating. Post assessment of Progesterone Usage Questionaries we found That the total no of patients with Hormonal Therapy are 84 and with No hormonal Therapy are 16 and major share of patients with hormonal Therapy Post assessment of Progesterone Usage Questionaries, out of 100 patients we found No patients are using Birth Control. Post assessment of Progesterone Usage Questionaries, out of 100 patients we found the past medical conditions using Progesterone are diagnosed with Endometriosis (37), PCOS (26), Fibroids (21), No Medical History/No Abnormalities (16). The major share of patients with usage of progesterone are diagnosed with Endometriosis. In over all 100 patients (84) are using progesterone and (16) are not on any medication and out of 100 patients the Progesterone Usage Medical Conditions are with history of

pulse rate (84.16 ± 7.49 beats/min), systolic blood pressure (120.35 ± 7.01 mm Hg), diastolic blood pressure (75.8 ± 7.64 mm Hg), respiratory rate (16.4 ± 1.55 breaths/min), and body

Infertility (8), Hormonal Imbalance (13), Irregular Menstrual Cycle (33), Support Pregnancy (16), Fibroids (14) and no of patients with no medical history (16) and the majority of patients using progesterone are with medical history of Irregular Menstrual Cycle. Out of 100 patients we found that the route of administration was oral (84) and with frequency Once a day

(84) and rest of the study population not using any medication and no missed doses recorded. Among 100 patients we assessed the Effectiveness of Progesterone using questionnaires and (41) patients reported usage of progesterone shows Some What Effective, (43) patients reported usage of progesterone shows Very Effective and (16) not reported the Effectiveness as they not used any medication. And the majority of patients reported usage of progesterone shows Very Effective. Among 100 patients we assessed the Rating of Progesterone as follows. (45) patients reported usage of progesterone shows Some What Effective, (39) patients reported usage of progesterone

shows Very Effective and (16) not reported the Effectiveness Among 100 patients we assessed the Improving Rate of Pregnancy Post Usage of Progesterone (62) patients showed Improvement in pregnancy post usage and (38) showed no improvement. Among 100 patients we assessed the Relief Progesterone post Usage and (43) patients showed Significant relief, (41) patients showed Some relief and (16) Not reported as they not used medication. Among 100 patients we assessed the Progesterone usage experience and (31) patients showed Increased Fertility, (22) showed Reduced Menstrual Bleeding, (31) showed Reduced Period Pain, (16) had no Experience they not used medication and the majority of patients beneficial post usage of progesterone was Increased Fertility and Reduced Period Pain Conclusion: The study provided comprehensive insights into the characteristics and outcomes of patients using progesterone. The demographic data revealed that the mean age of the study population was 36.89 ± 9.51 years, with a mean height of $1.601 \pm$

0.11 meters, weight of 61.45 ± 9.93 kg, and BMI of 28.77 ± 4.18 kg/m², indicating a relatively healthy and diverse cohort. Physiological parameters assessed showed normal values for

In terms of effectiveness, a majority of patients (84%) reported that progesterone was somewhat effective or very effective, with the latter group comprising 43% of the total participants. This is a strong indication that progesterone therapy may be providing significant benefits for those in the study. Additionally, 62% of patients noted an improvement in pregnancy outcomes following progesterone treatment, a key finding that underscores the potential role of progesterone in supporting fertility.

As for symptom relief, 43% of patients experienced significant relief, while 41% reported some relief. Among those who noted specific benefits, many highlighted increased fertility (31%), reduced menstrual bleeding (22%), and reduced period pain (31%) as the most common positive effects of progesterone. These findings align with the use of progesterone for treating menstrual irregularities and supporting pregnancy, and they further emphasize the medication's role in improving reproductive health.

The study's demographic data indicates a relatively young and diverse group of patients, with an average age of just under 37

temperature ($97.7 \pm 0.65°F$), which supports the overall well-being of the population. Regarding reproductive health, most patients using progesterone were in the menstruating phase (53%) followed by menopause (27%) and post-menopause (20%). A significant majority (84%) of the patients were undergoing hormonal therapy, with no patients using birth control. Common medical conditions associated with progesterone usage included endometriosis (37%), polycystic ovary syndrome (PCOS) (26%), fibroids (21%), and hormonal imbalances (13%). The predominant use of progesterone was oral (84%) with once-a-day administration, and there were no reports of missed doses. The majority of patients (84%) reported progesterone to be somewhat effective or very effective, with 43% considering it very effective. The most common medical conditions treated with progesterone were irregular menstrual cycles, infertility, and support for pregnancy. When assessing the impact of progesterone usage, 62% of patients reported improvement in pregnancy outcomes post- treatment, and 43% experienced significant relief from their symptoms, with 41% noting some relief. The treatment was associated with increased fertility (31%), reduced menstrual bleeding (22%), and reduced period pain (31%).

Discussion:

The data collected from the study offers valuable insights into the usage of progesterone among a cohort of 100 patients, revealing various demographic, physiological, and medical factors that influence its effectiveness.

Firstly, the participants in the study had a mean age of 36.89 years, and were relatively healthy with normal physiological measures, such as pulse rate, blood pressure, respiratory rate, and body temperature. These findings provide a solid baseline for evaluating the effects of progesterone, as the study population's health status appears to be within a typical range.

When it comes to reproductive health, most of the patient's using progesterone were in the menstruating phase (53%), followed by those in menopause (27%) and post-menopause (20%). This suggests that progesterone is commonly used by women in the reproductive stages of life. Interestingly, the vast majority (84%) of patients were undergoing hormonal therapy, with no patients on birth control. The usage of progesterone among patients with specific medical conditions like endometriosis (37%), PCOS (26%), and fibroids (21%) is also notable, as these conditions are often linked to hormonal imbalances and irregularities in the menstrual cycle.

The study also looked at the mode of progesterone administration, with most patients (84%) using oral progesterone once daily, and no missed doses were reported. This high adherence rate to the prescribed dosage is important, as it reflects the study population's commitment to their treatment regimens.

Interestingly, the study found that a vast majority of the participants (84%) were using progesterone orally, with once-a-day administration being the most common regimen. The simplicity of this administration route might explain the high adherence rate, as daily oral administration is easy to

years. This is noteworthy because progesterone usage is common in women during their reproductive years, especially for managing conditions like irregular menstrual cycles, PCOS, or infertility. However, it's also important to recognize that a substantial portion of the population was in menopause or post-menopause (47%), which aligns with the growing understanding of how progesterone can be utilized not just for fertility-related issues, but also to manage menopausal symptoms. The fact that nearly half of the patients in the study were either in menopause or post-menopause suggests that progesterone's role in managing hormone imbalances during these stages is a key area of interest.

Additionally, the physiological parameters of the study population were consistently within normal ranges, which strengthens the argument that progesterone was being prescribed and used by individuals who are relatively healthy and not exhibiting major complications from their baseline health. This is important because it highlights that the findings may reflect the typical response to progesterone treatment in a relatively healthy population, rather than a group with more complex health conditions.

When looking at the reproductive health conditions tied to progesterone usage, the findings suggest that progesterone is most commonly prescribed for managing irregular menstrual cycles (33%), followed by conditions like endometriosis, PCOS, and fibroids. Irregular menstrual cycles are a prominent issue among women with hormonal imbalances, and the effectiveness of progesterone in regulating these cycles is supported by the significant proportion of patients reporting improvements in menstrual symptoms like reduced bleeding and pain. This is a key finding because it speaks directly to progesterone's potential in improving quality of life for women with these common reproductive health issues.

In conclusion, this study reinforces the notion that progesterone is an effective treatment for a range of reproductive health concerns, particularly in women with irregular menstrual cycles, endometriosis, and infertility. The positive outcomes reported by the majority of patients, including improved fertility, symptom relief, and menstrual regulation, suggest that progesterone could play a significant role in improving the quality of life for women facing these challenges. However, more research is needed to fully understand the long-term benefits and potential risks of progesterone, especially for those in menopausal and post-menopausal stages.

Conclusion:

In conclusion, this study provides compelling evidence supporting the effectiveness of progesterone in managing various reproductive health conditions. The majority of participants, particularly those with irregular menstrual cycles, endometriosis, and infertility, reported significant benefits from progesterone therapy, including improved fertility, symptom relief (such as reduced menstrual pain and bleeding), and improved pregnancy outcomes. The study also highlighted that most patients adhered to the prescribed regimen, with oral administration being the most common method.

integrate into routine schedules. Additionally, the fact that there were no reports of missed doses suggests that patients were committed to their treatment plans, which may have contributed to the positive outcomes reported.

One of the most significant results of the study was the high level of effectiveness reported by patients. A combined 84% of participants considered the progesterone treatment somewhat effective or very effective, with 43% categorizing it as very effective. This is a strong indication that progesterone has a positive impact on those using it, especially considering the diverse range of reproductive health conditions that were treated. The fact that 62% of patients reported improved pregnancy outcomes post-treatment further emphasizes the role of progesterone in supporting fertility. The improvement in pregnancy rates, alongside the other benefits, supports the therapeutic value of progesterone for a range of reproductive issues.

The relief of symptoms, such as menstrual pain and bleeding, also stands out as an important result. The fact that 43% of patients felt significant relief and 41% experienced some relief highlights progesterone's effectiveness in managing discomfort associated with menstrual cycles, a common concern among women with conditions like fibroids or endometriosis. Reduced period pain (31%) and reduced menstrual bleeding (22%) were reported by patients as key benefits, which suggests that progesterone could offer an alternative or complementary approach to traditional treatments for these conditions.

Another interesting point is the absence of any patients using birth control, which could suggest that the population in this study was more focused on fertility-related treatments rather than contraceptive use. This reinforces the idea that progesterone is viewed as a therapeutic option to address reproductive health issues beyond just contraception. It also raises the question of whether progesterone is being used as a first-line therapy for fertility, or if there is a more nuanced understanding of its role within broader reproductive care plans.

However, there are a few important considerations for future research. While the study provides valuable insights into the use of progesterone, it also has some limitations. For instance, the study does not delve into the long-term effects of progesterone usage, particularly among women who are in menopause or post-menopause. Further research could explore how extended use of progesterone impacts overall health, bone density, or cardiovascular risk, as these are important considerations for women in these stages. Additionally, it would be valuable to include a comparison group of patients who are not using progesterone to better understand its relative effectiveness compared to other treatments.

While these results are promising, it's important to acknowledge that the study primarily focused on short-term outcomes. Future research should investigate the long-term effects of progesterone use, especially for women in menopause and post-menopause, to ensure there are no significant long-term risks or adverse effects. Additionally,

The findings suggest that progesterone is an effective treatment option, especially for women in reproductive stages, though its benefits extend to those in menopause and post-menopause as well. However, while the results are promising, further research is necessary to assess the long-term effects of progesterone, particularly in older women, and to compare its effectiveness with other treatment options. Overall, this study underscores progesterone's valuable role in enhancing reproductive health and quality of life for many women.

This study underscores the multifaceted role of progesterone in addressing a variety of reproductive health issues, from menstrual irregularities to fertility challenges. The majority of patients in the study particularly those dealing with conditions like endometriosis, PCOS, and irregular menstrual cycles reported positive outcomes, suggesting that progesterone can be an effective therapeutic option for these common reproductive concerns. Additionally, the improvement in pregnancy rates among those using progesterone highlights its potential in supporting fertility and assisting women in achieving successful pregnancies.

The adherence to the prescribed treatment regimen, with most patients taking progesterone orally once a day and reporting no missed doses, is an important finding. This high adherence rate not only indicates the ease of use and convenience of the medication but also supports the notion that patients are seeing enough benefit to remain committed to their treatment plans. The positive feedback regarding symptom relief, particularly reduced menstrual pain and bleeding, further adds to the evidence that progesterone provides tangible improvements in quality of life for women suffering from reproductive health issues.

comparing progesterone's effectiveness to other hormonal therapies or alternative treatments would provide a more comprehensive understanding of its place in treatment regimens.

Ultimately, this study highlights the significant therapeutic potential of progesterone in managing reproductive health conditions, improving fertility outcomes, and providing symptom relief for a variety of issues. The findings suggest that progesterone could be a valuable treatment for many women, but further research is needed to refine our understanding of its long-term impacts and optimal usage.

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