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Luteal phase support in IUI: a game-changer for pregnancy outcomes?

İntrauterin inseminasyonda luteal faz desteği: Gebelik sonuçlarını değiştiren bir faktör mü?

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ABSTRACT

Aim: This study aims to evaluate the impact of luteal phase support (LPS) with progesterone on pregnancy and live birth rates in patients undergoing intrauterine insemination (IUI) treatment.

Materials and Methods: A retrospective analysis was conducted on 88 patients who underwent IUI treatment at a tertiary center between 2019 and 2021. Patients were divided into two groups: Group 1 (n=49) received progesterone for luteal phase support, while Group 2 (n=39) did not receive any luteal support. Clinical, demographic, and biochemical parameters, including age, BMI, infertility duration, and ovarian reserve markers, were compared between the two groups. Treatment outcomes such as pregnancy rates, clinical pregnancy, and live birth rates were analyzed.

Results: No significant differences were observed between Group 1 and Group 2 in terms of demographic characteristics (age, BMI, and infertility duration) or biochemical markers (AMH, FSH, estradiol, and progesterone). The pregnancy rate in Group 1 was 14.2%, compared to 12.8% in Group 2 (p=0.640). Live birth rates were also similar between the groups (12.2% in Group 1 vs. 10.2% in Group 2, p=0.510). Treatment parameters, including endometrial thickness and gonadotropin dosage, showed no significant differences.

Conclusion: Progesterone supplementation for luteal phase support did not significantly improve pregnancy or live birth rates in IUI patients. These findings suggest that luteal phase support may not be necessary in routine IUI cycles, particularly when standard ovulation induction protocols are followed. Further research is needed to clarify its role in specific patient populations.

Keywords: Luteal phase support, progesterone, IUI, pregnancy rates, live birth rates

ÖZ

Amaç: Bu çalışmanın amacı, intrauterin inseminasyon (IUI) tedavisi uygulanan hastalarda progesteron ile yapılan luteal faz desteğinin (LFD) gebelik ve canlı doğum oranları üzerindeki etkisini değerlendirmektir.

Gereç ve Yöntemler: 2019 ile 2021 yılları arasında bir üçüncü basamak merkezde IUI tedavisi gören 88 hastanın retrospektif analizi yapılmıştır. Hastalar iki gruba ayrılmıştır: Grup 1 (n=49) luteal faz desteği olarak progesteron almış, Grup 2 (n=39) ise herhangi bir luteal destek almamıştır. Her iki grubun yaş, vücut kitle indeksi (VKİ), infertilite süresi ve over rezerv belirteçleri gibi klinik, demografik ve biyokimyasal parametreleri karşılaştırılmıştır. Tedavi sonuçları olarak gebelik oranları, klinik gebelik ve canlı doğum oranları analiz edilmiştir.

Bulgular: Grup 1 ve Grup 2 arasında demografik özellikler (yaş, VKİ, infertilite süresi) ve biyokimyasal belirteçler (AMH, FSH, östradiol ve progesteron) açısından anlamlı bir fark saptanmamıştır. Grup 1'deki gebelik oranı %14,2 iken, Grup 2'de bu oran %12,8 olarak bulunmuştur (p=0,640). Canlı doğum oranları da benzer şekilde sırasıyla %12,2 ve %10,2 olup istatistiksel olarak anlamlı değildir (p=0,510). Endometrial kalınlık ve gonadotropin dozu gibi tedavi parametrelerinde de anlamlı bir fark gözlenmemiştir.

Sonuç: Sonuç olarak, luteal faz desteği amacıyla uygulanan progesteron takviyesi, IUI hastalarında gebelik veya canlı doğum oranlarını anlamlı şekilde artırmamıştır. Bu bulgular, özellikle standart ovulasyon indüksiyon protokolleri uygulandığında, rutin IUI siklusunda luteal faz desteğinin gerekli olmayabileceğini düşündürmektedir. Luteal faz desteğinin belirli hasta gruplarındaki rolünü netleştirmek için ileri araştırmalara ihtiyaç vardır.

Anahtar Kelimeler: Luteal faz desteği, progesteron, IUI, gebelik oranı, canlı doğum oranı

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INTRODUCTION

Intrauterine insemination (IUI) remains a fundamental option in the treatment of infertility, particularly in cases of unexplained infertility, mild male factor infertility, ovulatory disorders, and cervical factor infertility (1). As a relatively non-invasive and cost-effective alternative to in vitro fertilization (IVF), IUI is often employed as a first-line approach. However, despite its widespread use, clinical pregnancy and live birth rates associated with IUI remain relatively modest, prompting continued investigation into adjunctive strategies that might improve outcomes (2).

Among these strategies, luteal phase support (LPS)—most commonly in the form of exogenous progesterone administration—has received considerable attention. In IVF cycles, the rationale for LPS is well established, as controlled ovarian stimulation often disrupts endogenous luteal function due to supraphysiologic steroid levels and suppression of luteinizing hormone (LH) secretion (1,3). Although the biological rationale for progesterone supplementation in IUI cycles is plausible—given its essential role in enhancing endometrial receptivity, modulating immune responses, and stabilizing the endometrium—its routine use in IUI remains contentious (4). This is particularly true when gonadotropin-based stimulation is employed, under the assumption that endogenous progesterone production may be sufficient to sustain the luteal phase (5).

The literature on this topic presents conflicting findings. While certain meta-analyses and systematic reviews suggest that progesterone supplementation may confer marginal benefits in selected populations, substantial heterogeneity across stimulation protocols, progesterone formulations, dosing regimens, and patient characteristics hampers definitive conclusions (4,6). For instance, a recent study by Dilday et al. (2023) reported no significant benefit of LPS in letrozole-stimulated IUI cycles (7), whereas Xi et al. (2024) observed an improvement in live birth rates with the use of oral progesterone in a similar clinical setting (8). These discrepancies underscore the importance of identifying specific subgroups—such as women with luteal insufficiency or multifollicular response—who might derive the most benefit from luteal support (9).

The present study aims to evaluate the clinical utility of vaginal progesterone for luteal phase support in IUI cycles stimulated using standard gonadotropin-based protocols. Specifically, it investigates whether luteal support is associated with improved clinical pregnancy and live birth outcomes when compared to IUI cycles conducted without any form of progesterone supplementation. By leveraging real-world data from a tertiary infertility center, this study seeks to clarify the role of LPS in routine IUI practice and inform more individualized treatment approaches.

MATERIALS AND METHODS

This retrospective, single-center cohort study was conducted at the Department of Obstetrics and Gynecology, Ankara City Hospital, and included patients who underwent IUI between 2019 and 2021. Ethical approval was granted by the local ethics committee (Approval No: TABED 2-25-1308). Written informed consent had been obtained from all participants prior to their inclusion in the treatment protocol. Relevant clinical, demographic, and treatment-related data were extracted from hospital records and the institutional electronic health database.

A total of 151 women aged 20 to 40 years with a diagnosis of primary infertility who underwent IUI following controlled ovarian stimulation were initially screened. All patients received stimulation via a conventional "step-up" gonadotropin regimen. IUI indications included unexplained infertility, mild male factor infertility, ovulatory disorders, cervical factor infertility, and stage I–II endometriosis.

To reduce confounding variables and ensure data homogeneity, strict exclusion criteria were applied. Patients were excluded if they had chronic systemic illnesses (e.g., diabetes mellitus, hypertension), a history of major abdominal or pelvic surgery, secondary infertility, or BMI > 40 kg/m². Cases using alternative ovulation induction protocols (e.g., human menopausal gonadotropin [HMG], non–step-up protocols) or with incomplete clinical documentation were also excluded.

After application of these criteria, 88 women were deemed eligible for final analysis. The cohort was stratified into two groups based on luteal phase support status:

- Group 1 (n = 49) received vaginal micronized progesterone for luteal support.
- Group 2 (n = 39) underwent IUI without any luteal phase supplementation.

Treatment Protocol

Ovulation induction was performed via the use of recombinant FSH in all patients. The treatment was individualized on the basis of follicular size and the patient's response. Ovulation was triggered with human chorionic gonadotropin (hCG) when the follicular diameter exceeded 16 mm (folliculometry was performed by an experienced gynecologist and radiologist).

For luteal phase support, vaginal progesterone was initiated immediately after the IUI procedure. Patients in the progesterone group were treated with either of the following:

8% progesterone gel (90 mg/day) was administered vaginally to 32 patients.

Vaginal progesterone (400 mg) was administered twice daily starting from day 2 post-IUI in 17 patients.

Progesterone support was continued until the 10th week of pregnancy. The nonprogesterone group (n=39) did not receive any luteal phase support after IUI. Pregnancy outcomes and live birth rates were compared between the two groups.

Outcome assessment

β-hCG levels were assessed 15 days after the IUI procedure. For patients with positive pregnancy tests, β-hCG and progesterone levels were monitored until the 10th week of pregnancy, with progesterone support continuing during this period. For patients with negative pregnancy tests, treatment was discontinued. Pregnancy rates, clinical pregnancy rates (defined by the detection of intrauterine pregnancy via ultrasonography), and live birth rates were compared between the two groups.

Statistical analysis

All the data were analyzed via SPSS 25.0 (Statistical Package for the Social Sciences, IBM Corporation). Categorical data were analyzed via the chi-square test, whereas continuous data were compared via independent group t tests. A p value of <0.05 was considered to indicate statistical significance. Demographic data (age, basal FSH, body mass index, infertility duration, etc.) were compared between the two groups, and the results are presented in tabular form.

RESULTS

In this retrospective study, 88 patients were divided into two groups: those who received luteal phase support (Group 1, n=49) and those who did not (Group 2, n=39). Demographic, clinical, and biochemical parameters were compared between the groups to assess potential differences in outcomes. The demographic characteristics, including age, BMI, and infertility duration, were not significantly different between the two groups. The mean age in Group 1 was 27.0 ± 6.2 years, whereas that in Group 2 was 28.7±4.3 years (p=0.150), indicating a comparable age distribution. Similarly, BMI values (Group 1: 25.4 ± 3.2 kg/m² vs. Group 2: 25.9±3.5 kg/m², p=0.380) and infertility duration (Group 1: 1.6±1.3 years vs. Group 2: 1.9±1.5 years, p=0.315) were comparable (Table 1).

In terms of biochemical parameters, basal AMH levels were slightly greater in Group 1 (2.8 ± 1.2 ng/mL) than in Group 2 (2.3 ± 1.0 ng/mL), but this difference was not statistically significant (p=0.410). Basal FSH levels, which are often indicative of ovarian reserve, were similar between the groups (p=0.375), as were basal estradiol levels (p=0.290), progesterone levels on day 21 (p=0.260), and the antral follicle count (p=0.755) (Table 1).

Treatment parameters

Similarly, no significant differences were observed in treatment parameters such as endometrial thickness, the number of follicles greater than 16 mm, gonadotropin dose, or gonadotropin duration. The endometrial thickness, which is a critical predictor of implantation success, was similar between Group 1 (8.6 ± 1.2 mm) and Group 2 (8.4 ± 1.1 mm), with a p value of 0.420. The number of follicles larger than 16 mm was slightly greater in Group 1 (1.4 ± 0.1) than in Group 2 (1.2 ± 0.2), although this difference was not statistically significant (p=0.340). Additionally, the total Gn dose used in Group 1 (882.55 ± 82.9 IU) was greater than that used in Group 2 (741.21 ± 88.6 IU), but this difference did not reach statistical significance (p=0.360). Similarly, the duration of gonadotropin stimulation was comparable between the two groups (p=0.440) (Table 2).

Table 1. Comparison of Demographic and Biochemical Parameters between Group 1 and Group 2

Parameter	Group 1 (n=49) Mean ± SD	Group 2 (n=39) Mean ± SD	p value
Age (years)	27.0 ± 6.2	28.7 ± 4.3	0.150
BMI (kg/m²)	25.4 ± 3.2	25.9 ± 3.5	0.380
Infertility Duration (years)	1.6 ± 1.3	1.9 ± 1.5	0.315
Basal AMH (ng/mL)	2.8 ± 1.2	2.3 ± 1.0	0.410
Basal FSH (mIU/mL)	6.1 ± 2.3	6.7 ± 2.1	0.375
Basal Estradiol (E2) (pg/mL)	47.5 ± 16.2	43.0 ± 14.8	0.290
Day 21 Progesterone (ng/mL)	13.0 ± 4.5	11.5 ± 3.8	0.260
Antral Follicle Count (AFC)	10.8 ± 3.4	10.0 ± 3.1	0.755

BMI: Body Mass Index, **AMH**: Anti-Müllerian Hormone, **FSH**: Follicle-Stimulating Hormone, **E2**: Estradiol, **AFC**: Antral Follicle Count, **SD**: Standard Deviation, **ng/mL**: Nanograms per milliliter, **mIU/mL**: Milli-international units per milliliter, **pg/mL**: Picograms per milliliter

Table 2. Comparison of Treatment Parameters between Group 1 and Group 2

Parameter	Group 1 (n=49) Mean ± SD	Group 2 (n=39) Mean ± SD	p value
Endometrial Thickness (mm)	8.6 ± 1.2	8.4 ± 1.1	0.420
Number of Follicles >16 mm	1.4 ± 0.1	1.2 ± 0.2	0.340
Gonadotropin Dose (IU)	882.55 ± 82.9	741.21 ± 88.6	0.360
Gonadotropin Duration (days)	11.2 ± 2.2	10.9 ± 2.3	0.440

SD: Standard Deviation, **mm**: Millimeters, **IU**: International Units, **>**: Greater Than

Table 3. Comparison of Pregnancy and Live Birth Rates between Groups 1 and 2

Outcome	Group 1 (n=49)	Group 2 (n=39)	p value
Pregnancy Rate (%)	7 (14.2%)	5 (12.8%)	0.640
Live Birth Rate (%)	6 (12.2%)	4 (10.2%)	0.510

Pregnancy and Live Birth Rates

The pregnancy and live birth rates were also similar between the two groups, with no statistically significant differences observed. Group 1 had a pregnancy rate of 14.2%, whereas Group 2 had a rate of 12.8% (p=0.640). Similarly, the live birth rates were 12.2% in Group 1 and 10.2% in Group 2 (p=0.510) (Table 3).

DISCUSSION

LPS has long been considered essential in IVF protocols, largely due to the disruption of endogenous hormonal balance following controlled ovarian stimulation. In contrast, its role in IUI cycles remains less clear. In our study, the use of vaginal progesterone for LPS in gonadotropin-stimulated IUI cycles did not lead to significant improvements in clinical pregnancy or live birth rates. This finding aligns with a growing body of evidence suggesting that routine LPS in non-IVF settings may offer limited clinical benefit.

Hill et al. (2017), in a well-conducted meta-analysis, similarly found that progesterone supplementation after ovulation induction in IUI cycles had no meaningful effect on pregnancy rates, though they acknowledged potential benefits in select subgroups (6). Supporting this, Salang et al. (2022) reported only marginal gains in pregnancy outcomes with LPS in both IUI and natural conception settings, with no reduction in miscarriage rates (2). These findings echo our results, which were drawn from a clinically and demographically balanced cohort—reducing the likelihood that observed outcomes were confounded by baseline differences such as age, BMI, ovarian reserve, or endometrial thickness.

One reason for the inconsistent literature may lie in the variability of LPS protocols across studies—differences in progesterone type, route of administration, dosage, and patient selection can all influence outcomes. While Ciampaglia and Cognigni (2015) argued that vaginal progesterone offers better physiological absorption (3), our findings—and those of Tokgöz et al. (2020), who saw no improvement in patients with multifollicular development—suggest that such advantages may not translate into clinical benefit (9). Conversely, Xi et al. (2024) reported improved live birth rates with oral progesterone in letrozole-stimulated cycles (8), a result not replicated in similar trials such as that of Dilday et al. (2023) (7). These discrepancies underscore the complexity of LPS and the need for a more personalized approach.

The issue of optimal progesterone dosing also remains unresolved. Biberoglu et al. (2016) compared low- and high-dose vaginal progesterone (300 mg vs. 600 mg) and found no significant difference in outcomes, highlighting concerns around overtreatment and cost-effectiveness (5). Broader reviews, such as that by Miralpeix et al. (2014), suggest that the utility of LPS may be restricted to specific subpopulations, particularly those with hormonal or endometrial vulnerabilities (4).

Recent studies published in the past two years have provided new insights into the role of LPS in IUI cycles. Simopoulou et al. (2025) emphasized the growing importance of metabolomic analysis in assisted reproductive technologies, highlighting that LPS should be considered within the framework of personalized treatment protocols (10). In a study involving women with endometriosis, Gainder et al. (2024) demonstrated that luteal support with dydrogesterone following laparoscopy improved pregnancy rates

in subsequent IUI treatments (11). Furthermore, Agarwal et al. (2025) reported that the addition of piroxicam to conventional progesterone support significantly enhanced IUI success rates (12). In light of these findings, although our study found no significant benefit of routine LPS across all patients, it suggests that certain subgroups may derive clinical advantages from targeted luteal support strategies.

In recent years, several randomized controlled trials have continued to evaluate the efficacy of luteal phase support in IUI cycles. A prospective RCT conducted by Keskin and Aytac (2020) reported no statistically significant difference in pregnancy rates between patients who received vaginal progesterone and those who did not, following gonadotropin-stimulated IUI (13). Similarly, a study by Ebrahimi et al. (2010) involving couples with unexplained infertility found that luteal phase support did not significantly improve pregnancy outcomes (14). In contrast, Rashidi et al. (2014), in a double-blind, placebo-controlled trial, observed that luteal support with progesterone was associated with higher pregnancy rates specifically in women over 30 years of age (15). These findings highlight the importance of patient selection and support a more individualized approach to luteal phase support, rather than its routine application in all IUI cycles.

A major strength of our study is its internal consistency: all participants underwent ovulation induction using the same step-up gonadotropin protocol, within a single tertiary care center. This uniformity strengthens the validity of our comparisons and enhances the interpretability of our results. Moreover, the clinical and demographic similarities between the LPS and non-LPS groups reduce the risk of confounding and reinforce the reliability of our findings.

That said, several limitations should be acknowledged. As a retrospective study, our analysis is subject to inherent selection and information biases. The relatively modest sample size may also have limited our ability to detect subtle but clinically relevant differences. Additionally, we did not stratify patients based on luteal phase sufficiency, which may have obscured potential subgroup benefits. The lack of serum progesterone monitoring is another important limitation, as interindividual variation in absorption and metabolism may have affected treatment efficacy.

Moving forward, prospective, randomized, multicenter trials are needed to more definitively clarify the role of LPS in IUI. Such studies should include predefined subgroup analyses—for example, among women with luteal insufficiency, low ovarian reserve, or advanced age—to identify those most likely to benefit. Comparative investigations of progesterone formulations (vaginal, oral, intramuscular), doses, and administration timing, ideally coupled with pharmacokinetic profiling and biomarker analysis, may help establish evidence-based, individualized protocols.

CONCLUSION

The results of the present study indicate that administering vaginal progesterone for luteal phase support does not yield a statistically significant enhancement in pregnancy or live birth rates among women undergoing intrauterine insemination with conventional ovulation induction protocols. These findings are consistent with previous research suggesting that routine luteal phase support in IUI cycles may not be universally required. Instead, adopting a more tailored approach that considers individual patient characteristics and clinical risk factors may offer greater benefit. To substantiate these observations and inform clinical decision-making, further large-scale, prospective, and randomized controlled trials are essential.

Ethical Approval: Ethics committee approval was obtained from the ethics committee unit of the Ankara Bilkent City Hospital (TABED 2-25-1308). The study commenced after obtaining the relevant ethical committee approval, and consent was obtained from the relevant clinics.

Consent to participate: Following ethics committee approval, written informed consent forms were obtained from all participants for their participation in the study.

Consent for publication: There are no circumstances in the study that violate anonymity, and identifying information has been kept confidential. There are no issues regarding its publication.

Availability of data and materials: Patient data is stored indefinitely in the hospital's HICAMP® automation system. It can be shared upon request, provided that patient identity remains confidential.

Competing interests: There are no conflicts of interest among the authors.

Authors' contributions: M.İ.H., M.İ.K collected the patient data. B.T. was responsible for the study design and research protocol. U.Z. and B.T. wrote the manuscript, while Ö.M.T. reviewed the study.

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