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Original Article

Comparison of Letrozole and Clomiphene Citrate Success Rate in Ovulation Induction

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Abstract

Background: Clomiphene citrate has traditionally been the first-line agent for ovulation induction; however, increasing evidence suggests that letrozole may offer superior efficacy with a more favorable endometrial profile. Comparative data examining treatment response across demographic and socioeconomic variables remain limited, especially within South Asian populations.

Objective: To compare the efficacy of letrozole and clomiphene citrate for ovulation induction in subfertile women with ovulatory dysfunction presenting to a tertiary care hospital in Khyber Pakhtunkhwa, Pakistan.

Methodology: This pilot randomized controlled trial was conducted from January to July 2024 in the Department of Gynecology and Obstetrics at Saidu Group of Teaching Hospital, Swat. A total of 64 subfertile women aged 18–30 years with anovulatory infertility were randomized in equal numbers to receive either letrozole 5 mg/day or clomiphene citrate 100 mg/day for five consecutive days, initiated between cycle days 3 and 5. Ovulation was monitored over three cycles using transvaginal ultrasonography, with biochemical confirmation using mid-luteal serum progesterone where applicable. The primary outcome was ovulation induction success.

Results: Baseline demographic and clinical characteristics were comparable between groups. Ovulation was achieved in 65.6% of women receiving letrozole compared with 37.5% of those receiving clomiphene citrate, representing a statistically significant difference ($p = 0.024$). Exploratory subgroup analyses suggested higher efficacy of letrozole among women with higher body mass index and selected socioeconomic subgroups.

Conclusion: In this pilot randomized controlled trial, letrozole demonstrated significantly higher ovulation induction efficacy compared with clomiphene citrate in subfertile women with ovulatory dysfunction. These findings support the growing evidence favoring letrozole as a first-line ovulation induction agent, while underscoring the need for larger multicenter trials evaluating pregnancy and live birth outcomes.

Keywords: Clomiphene citrate, Letrozole, Ovulation induction, Polycystic ovarian syndrome, Subfertility.

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Introduction

Subfertility is a prevalent reproductive health problem worldwide and is defined as the inability to conceive after 12 months of regular, unprotected sexual intercourse [1]. It is a multifactorial condition arising from anatomical, hormonal, metabolic, and unexplained causes, with ovulatory dysfunction accounting for a substantial proportion of female-related subfertility [2,3]. Among women of reproductive age, polycystic ovary syndrome (PCOS) remains the most common endocrine disorder associated with chronic anovulation and infertility [3,4].

Ovulation induction is a cornerstone of subfertility management in women with ovulatory dysfunction and aims to restore regular follicular development and ovulation through pharmacologic modulation of the hypothalamic–pituitary–ovarian axis [5–7]. Successful induction of ovulation significantly improves the likelihood of conception by correcting hormonal dysregulation and facilitating timely oocyte release [7].

Clomiphene citrate has been used as the first-line pharmacological agent for ovulation induction for several decades due to its affordability, ease of administration, and established efficacy [7-12]. As a selective estrogen receptor modulator, clomiphene acts by blocking hypothalamic estrogen receptors, thereby removing negative feedback inhibition and promoting gonadotropin release [12]. Despite its widespread use, clomiphene citrate is associated with several limitations, including anti-estrogenic effects on the endometrium and cervical mucus, prolonged half-life, and the development of clomiphene resistance in a subset of patients [13,14].

Letrozole, a third-generation aromatase inhibitor, has emerged as an alternative ovulation induction agent with a distinct mechanism of action [8–10]. By inhibiting peripheral estrogen synthesis, letrozole reduces circulating estrogen levels, leading to increased pituitary secretion of follicle-stimulating hormone and subsequent follicular development [9]. Its shorter half-life and lack of sustained estrogen receptor blockade may result in a more favorable endometrial environment and reduced risk of multiple follicular development compared with clomiphene citrate [11]. Letrozole does not exert direct anti-estrogenic effects on the endometrium; any mechanistic explanations should be interpreted in the context of existing evidence.

Several studies have reported higher ovulation and pregnancy rates with letrozole compared to clomiphene citrate, particularly in women with PCOS and clomiphene resistance [15–21]. A study by Ashfaq et al. demonstrated ovulation induction rates of 67.6% with letrozole versus 32.4% with clomiphene citrate [15], while other regional and international trials have consistently reported similar trends [16–20]. However, reported efficacy varies across populations, potentially influenced by differences in demographic, metabolic, and socioeconomic factors.

Despite the growing body of evidence favoring letrozole, there remains a paucity of locally generated data from Khyber Pakhtunkhwa, a region with distinct demographic characteristics, healthcare access challenges, and sociocultural determinants of reproductive health. Understanding treatment response within this population is essential for optimizing ovulation induction strategies and improving subfertility outcomes. Therefore, the present study aimed to compare the efficacy of letrozole and clomiphene citrate for ovulation induction in subfertile women with ovulatory dysfunction, while also exploring the influence of selected demographic and socioeconomic variables on treatment response.

Methodology

Trial Design

This study was designed as a single-center, parallel-group, randomized controlled trial conducted to compare the efficacy of letrozole and clomiphene citrate for ovulation induction in women with ovulatory dysfunction. The trial was conducted in the Department of Gynecology and Obstetrics, Saidu Group of Teaching Hospital, Swat, Pakistan, over a six-month period from January to July 2024. Given the absence of prior local data to inform robust sample size estimation, the trial was conceived as a pilot randomized controlled study aimed at generating preliminary efficacy estimates and exploring demographic modifiers of treatment response.

Participants

A total of 64 subfertile women aged 18–30 years were enrolled consecutively after meeting predefined eligibility criteria. Subfertility was defined as failure to conceive after at least 12 months of regular unprotected intercourse. Eligible participants had evidence of ovulatory dysfunction, characterized by oligomenorrhea (fewer than six menstrual cycles per year) and biochemical hyperandrogenism, defined as serum testosterone levels exceeding 0.65 ng/mL. Women were excluded if they had hyperprolactinemia (serum prolactin >400 mIU/L), thyroid dysfunction, tubal pathology, other known causes of infertility, or prior exposure to ovulation-induction medications. All participants completed the study protocol and follow-up.

Interventions

Participants were randomly allocated in a 1:1 ratio to receive either letrozole or clomiphene citrate. Women assigned to the letrozole group received 5 mg orally once daily, while those in the clomiphene citrate group received 100 mg orally once daily. In both groups, treatment was administered for five consecutive days, initiated between day 3 and day 5 of the menstrual cycle. Ovulation induction was monitored over three consecutive cycles. Transvaginal ultrasonography was performed serially each cycle to assess follicular development and ovulation.

Outcomes

The primary outcome was ovulation induction success, defined by ultrasonographic evidence of ovulation. Ovulation was considered to have occurred when a dominant follicle measuring at least 20 mm was visualized around mid-cycle, followed by documented follicular rupture or a subsequent reduction in follicle size on follow-up scans.

Biochemical confirmation using mid-luteal serum progesterone levels was performed alongside ultrasonography when feasible. Secondary outcomes included exploratory analyses of treatment efficacy across demographic and clinical subgroups, including age, body mass index, residential status, socioeconomic status, educational level, and duration of subfertility. Pregnancy and live-birth outcomes were not assessed in this pilot trial.

Sample Size

No formal a priori sample size calculation was performed due to the exploratory nature of the study and lack of locally derived effect size estimates. A total of 64 participants (32 per group) were enrolled based on feasibility considerations. A post-hoc power analysis using the observed ovulation rates demonstrated an absolute difference of 28.1% between treatment groups, corresponding to a moderate-to-large effect size (Cohen's h = 0.58) and an estimated statistical power of approximately 75–80% at a two-sided alpha level of 0.05. These findings support the adequacy of the sample size for detecting clinically meaningful differences in ovulation induction efficacy.

Randomization

Randomization was performed using a computer-generated random sequence to ensure equal allocation between the two treatment arms. Allocation concealment was maintained through the use of sealed, opaque, sequentially numbered envelopes prepared independently prior to participant enrollment. Envelopes were opened only after participants had provided informed consent and completed baseline assessments.

Blinding

Due to the nature of the pharmacological interventions, blinding of participants and treating clinicians was not feasible. However, to minimize assessment bias, ultrasonographic evaluation of follicular development and ovulation was performed by an independent radiologist who was blinded to treatment allocation.

Ethics

Ethical approval for the study was obtained from the institutional ethics review committee of Saidu Group of Teaching Hospital. All participants provided written informed consent after receiving a detailed explanation of the study objectives, procedures, potential benefits, and risks. The study was conducted in accordance with the principles of the Declaration of Helsinki and local ethical guidelines.

Statistical Methods

Data were analyzed using SPSS version 26. Continuous variables, including age, body mass index, and duration of subfertility, were summarized as means with standard deviations, while categorical variables were presented as frequencies and percentages. The primary comparison of ovulation induction efficacy between the letrozole and clomiphene citrate groups was performed using the chi-square test.

Subgroup analyses were conducted to explore associations between treatment response and demographic variables using chi-square or Fisher's exact tests, as appropriate. A p-value of less than 0.05 was considered statistically significant. All subgroup analyses were exploratory and were not adjusted for multiple comparisons.

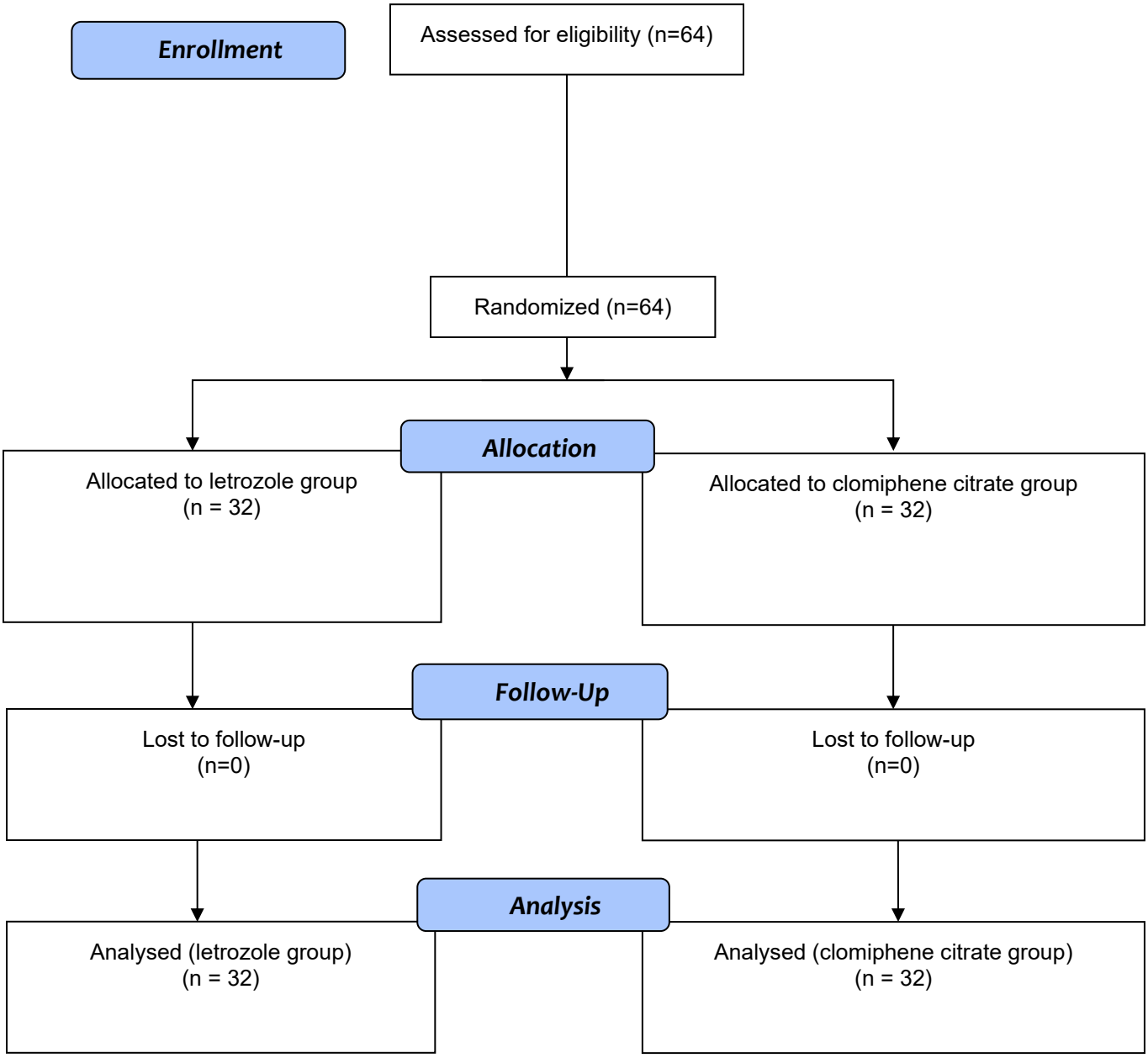


Figure 1. CONSORT flow diagram showing participant recruitment, randomization, allocation, follow-up, and analysis.

Results

Recruitment

A total of 64 eligible subfertile women with ovulatory dysfunction were recruited consecutively from the Department of Gynecology and Obstetrics at Saidu Group of Teaching Hospital between January and July 2024. All eligible women who met the inclusion criteria and provided informed consent were enrolled and randomized. No participants declined participation after eligibility assessment, and no withdrawals or losses to follow-up were recorded during the three-month intervention and monitoring period (Figure 01).

Baseline Data

Baseline demographic and clinical characteristics were comparable between the two treatment groups (Table 1). The mean age of participants was 25.91 ± 2.81 years in the letrozole group and 25.91 ± 2.69 years in the clomiphene citrate group. Mean body mass index values were also similar (24.83 ± 1.53 kg/m² vs. 24.88 ± 1.52 kg/m², respectively). Residential distribution was identical in both groups, with equal proportions of rural and urban participants. Educational attainment and socioeconomic status were evenly balanced across treatment arms, indicating successful randomization and minimal baseline imbalance in key demographic variables (Table 01).

Numbers Analyzed

All 64 randomized participants completed the study protocol and were included in the final analysis. Thirty-two women were analyzed in the letrozole group and thirty-two in the clomiphene citrate group. Analysis was performed on a complete-case basis, as there were no missing outcome data and no protocol deviations requiring exclusion from analysis (Table 02).

Outcomes and Estimation

The primary outcome successful ovulation induction was achieved in 21 participants (65.6%) in the letrozole group compared with 12 participants (37.5%) in the clomiphene citrate group (Table 2). This difference was statistically significant (p = 0.024), demonstrating superior ovulation induction efficacy with letrozole. Conversely, failure to achieve ovulation occurred in 11 women (34.4%) receiving letrozole and 20 women (62.5%) receiving clomiphene citrate. The observed absolute difference in ovulation rates between groups was 28.1%, favoring letrozole.

Ancillary Analyses

Exploratory subgroup analyses were conducted to assess the association between demographic variables and treatment efficacy (Table 3). Among women with a body mass index greater than 25 kg/m², letrozole demonstrated significantly higher ovulation rates compared with clomiphene citrate (66.7% vs. 20.0%, p = 0.027). Urban residents receiving letrozole also showed significantly higher efficacy compared with those receiving clomiphene citrate (75.0% vs. 31.3%, p = 0.034). Educational level appeared to modify treatment response, with women having secondary education exhibiting higher ovulation rates with letrozole than with clomiphene citrate (90.0% vs. 33.3%, p = 0.037). Higher efficacy with letrozole was additionally observed among women of higher socioeconomic status (90.0% vs. 30.0%, p = 0.022). Differences observed across other subgroups, including duration of subfertility and lower BMI categories, did not reach statistical significance. All ancillary analyses were exploratory and were not adjusted for multiple comparisons (Table 03).

Harms

No serious adverse events were reported in either treatment group during the study period. Participants tolerated both letrozole and clomiphene citrate well, and no treatment discontinuations occurred due to medication-related side effects. Minor adverse effects were not systematically recorded, and safety outcomes were not a predefined endpoint of this pilot trial.

Table 1: Demographics of the patients

Demographics	Group A (n = 32)	Group B (n = 32)
Age (years), Mean ± SD	25.91 ± 2.81	25.91 ± 2.69
BMI (kg/m²), Mean ± SD	24.83 ± 1.53	24.88 ± 1.52
Rural, n (%)	16 (50.0%)	16 (50.0%)
Urban, n (%)	16 (50.0%)	16 (50.0%)
Uneducated, n (%)	8 (25.0%)	8 (25.0%)
Primary education, n (%)	9 (28.1%)	9 (28.1%)
Secondary education, n (%)	10 (31.3%)	9 (28.1%)
Higher education, n (%)	5 (15.6%)	6 (18.8%)

Table 2: Comparison of efficacy between the two groups

Efficacy	Group A (n = 32) n (%)	Group B (n = 32) n (%)	P value
Yes	21 (65.6%)	12 (37.5%)	0.024
No	11 (34.4%)	20 (62.5%)	
Total	32 (100%)	32 (100%)	

Table 3: Association of efficacy with demographic variables

Variable	Category	Group	Yes n (%)	No n (%)	P value
BMI (kg/m²)	**≤25**	**A**	11 (64.7%)	6 (35.3%)	0.486
		B	9 (52.9%)	8 (47.1%)	
	>25	**A**	10 (66.7%)	5 (33.3%)	0.027*
		B	3 (20.0%)	12 (80.0%)	
Residential	**Rural**	**A**	9 (56.3%)	7 (43.8%)	0.479
		B	7 (43.8%)	9 (56.3%)	
	Urban	**A**	12 (75.0%)	4 (25.0%)	0.034*
		B	5 (31.3%)	11 (68.8%)	
Education	**Uneducated**	**A**	4 (50.0%)	4 (50.0%)	0.606*
		B	2 (25.0%)	6 (75.0%)	
	Primary	**A**	8 (88.9%)	1 (11.1%)	0.293*
		B	5 (55.6%)	4 (44.4%)	
	Secondary	**A**	9 (90.0%)	1 (10.0%)	0.037*
		B	3 (33.3%)	6 (66.7%)	
	Higher	**A**	0 (0.0%)	5 (100%)	0.521*
		B	2 (33.3%)	4 (66.7%)	
Socioeconomic	**Poor**	**A**	4 (36.4%)	7 (63.6%)	0.632*
		B	2 (18.2%)	9 (81.8%)	
	Middle	**A**	8 (72.7%)	3 (27.3%)	1.000*
		B	7 (63.6%)	4 (36.4%)	
	Rich	**A**	9 (90.0%)	1 (10.0%)	0.022*
		B	3 (30.0%)	7 (70.0%)	
Subfertility (years)	**≤3**	**A**	16 (84.2%)	3 (15.8%)	0.103*
		B	11 (55.0%)	9 (45.0%)	
	>3	**A**	5 (38.5%)	8 (61.5%)	0.196*
		B	1 (8.3%)	11 (91.7%)	

*** Fisher's Exact Test**

Discussion

The present pilot randomized controlled trial demonstrated a significantly higher ovulation induction rate with letrozole compared to clomiphene citrate in subfertile women with ovulatory dysfunction. Ovulation was achieved in 65.6% of participants receiving letrozole, compared with 37.5% in the clomiphene citrate group, indicating a clear efficacy advantage for letrozole. These findings are consistent with a growing body of evidence suggesting superior ovulation induction outcomes with letrozole, particularly among women with PCOS-related anovulation [15–21].

The observed efficacy of letrozole in this study aligns closely with previously published regional and international trials. Ashfaq et al. reported ovulation induction rates of 67.6% with letrozole compared with 32.4% for clomiphene citrate [15], while Shafiq et al. and Khakwani et al. similarly documented significantly higher ovulation rates favoring letrozole [19,20]. Although absolute ovulation rates vary across studies, likely reflecting differences in patient characteristics, diagnostic criteria, and monitoring protocols, the consistent pattern of letrozole superiority across diverse populations strengthens the validity of the present findings.

The comparable baseline demographic characteristics between treatment groups indicate that the observed difference in ovulation rates is unlikely to be attributable to confounding by age, body mass index, residential status, or socioeconomic background. The mean age and BMI of participants in this study were similar to those reported in other South Asian studies evaluating ovulation induction therapies [16–18], suggesting that the study population is representative of women commonly presenting for subfertility treatment in this region.

Exploratory subgroup analyses suggested that letrozole may offer particular benefit in women with higher body mass index, urban residence, and higher socioeconomic or educational status. The significantly higher ovulation rates observed in women with BMI >25 kg/m² treated with letrozole are consistent with reports that aromatase inhibition may be less affected by adipose-derived estrogen metabolism than clomiphene citrate [18,19]. However, these subgroup findings should be interpreted cautiously, as the study was not powered to detect interaction effects and multiple comparisons were not adjusted.

The pharmacological characteristics of letrozole may partially explain its superior performance. Unlike clomiphene citrate, which has a prolonged half-life and exerts sustained estrogen receptor blockade, letrozole has a shorter half-life and does not produce prolonged anti-estrogenic effects on target tissues [11,13]. This may result in more physiologic follicular recruitment and a more favorable intrauterine environment, although mechanistic interpretations should remain grounded in existing evidence.

While pregnancy and live birth outcomes were not assessed in this study, ovulation induction remains a clinically meaningful intermediate endpoint in the management of anovulatory subfertility [5–7]. The present findings therefore contribute valuable local evidence supporting the use of letrozole as an effective ovulation induction agent in women with ovulatory dysfunction in Khyber Pakhtunkhwa.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, the relatively small sample size reflects the pilot nature of the trial and limits the statistical power to detect smaller differences, particularly in subgroup analyses. Second, pregnancy and live birth outcomes were not evaluated, precluding conclusions regarding ultimate reproductive success. Third, although biochemical confirmation of ovulation using serum progesterone was performed where feasible, ovulation assessment relied primarily on transvaginal ultrasonography. Additionally, minor adverse effects were not systematically recorded, limiting the ability to compare safety profiles between treatment groups. Finally, the study population largely reflects women with hyperandrogenic, PCOS-like anovulatory infertility, which may limit generalizability to other causes of ovulatory dysfunction.

Conclusion

This pilot randomized controlled trial demonstrates that letrozole is significantly more effective than clomiphene citrate for ovulation induction in subfertile women with ovulatory dysfunction. The superiority of letrozole was consistent across the overall study population and appeared particularly pronounced in selected demographic subgroups. These findings support the growing evidence favoring letrozole as a first-line ovulation induction agent in women with anovulation, including those with PCOS. However, larger multicenter trials incorporating pregnancy and live birth outcomes are warranted to confirm these results and inform definitive clinical practice guidelines.

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Authors' Contributions:

All authors meet the ICMJE criteria for authorship.

Author 1: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 2: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 3: Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 4: Analysis and interpretation of data, critical revision, final approval, agreed to be accountable for all the work.
Author 5: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.

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