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| RESEARCH ARTICLE

Impact of Oral Contraceptives on Body Measurements and Associated Side Effects Among Women in Karbala: A Cross-Sectional Study

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| ABSTRACT
The study found that using OCP was strongly linked to a higher incidence of negative effects, namely headaches and weight gain.The purpose of this study is to determine the frequent adverse effects experienced by women in Karbala Province and to evaluate the influence of oral contraceptives on anthropometric measurements.Women in Karbala who were of reproductive age participated in a cross-sectional study. Both structured interviews and physical measurements were used to gather data. Participants were divided into groups according to whether or not they used oral contraceptives. To assess variations in body weight, BMI, and reported side effects, statistical analysis was employed.According to the study, using OCP was significant. The most commonly reported adverse effects were irregular menstruation, mood swings, headache, and nausea.The use of oral contraceptives is linked to a number of adverse effects and may affect body measurements. The significance of personalized counseling and monitoring of women on OCPs in Karbala is underscored by these findings.

| KEYWORDS

Oral contraceptives, Body measurements , Side effects ,Women's health ,Cross-sectional study

| ARTICLE INFORMATION

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1. Introduction

OCPs are one of the most popular family planning methods in the world because they are simple to use, reversible, and effective. Their primary mechanism of action is to stop ovulation, and they typically contain either progestin alone or estrogen and progestin together. Even with their widespread use, worries about possible adverse effects and long-term health implications persist [1].

OCPs have been used to examine women's body weight and other anthropometric parameters, including body mass index (BMI), waist circumference, and fat distribution. OCPs may have an impact on body weight, BMI, waist circumference, and fat distribution, according to a number of studies. Hormonal impacts on hunger, metabolism, and fluid retention are thought to be the cause of these alterations, and they may also be a contributing factor to long-term health problems such insulin resistance and cardiovascular disease [2].

Numerous adverse consequences are also linked to OCPs. The most frequent ones include irregular menstruation, mood swings, breast pain, and nausea. Depending on the kind and length of use, more severe side effects such thromboembolic events and hypertension have also been documented. [3].

In Iraq, OCPs are widely used, particularly in metropolitan places like Karbala, although little local data is available about how they affect body measures and have adverse effects. Localized research is crucial for the safe use of contraceptives because cultural and lifestyle factors may affect women's responses. [4].

Thus, the purpose of this study is to evaluate the relationship between OCP use, anthropometric alterations, and typical side effects among Karbala women.To ensure informed reproductive choices, improve women's autonomy in family planning, and customize public health initiatives, it is crucial to know how many Karbala women use oral contraceptive pills. By determining the demographic variables that affect pill use, such as age, education, employment status, and place of residence,

The purpose of this study is to offer evidence-based perspectives to assist regional reproductive health initiatives.In addition, enhancing uptake requires tackling obstacles to the use of contraceptives, such as provider bias, religious beliefs, and myths regarding side effects. Promoting contraceptive awareness and informed decision-making can be accomplished through the use of health education, community involvement, and family planning counseling integrated into basic healthcare services[5].

The conservative Karbala Province in central Iraq is home to both urban and rural residents. Access to the use of family planning services by women may be impacted by cultural and religious factors, as well as a lack of reproductive health education initiatives. There is a lack of localized reproductive health data since few research have explicitly examined the prevalence and factors influencing the use of contraceptive methods in Karbala [6].

1.1 Effects of Oral Contraceptive Pills on Metabolism

Oral contraceptives (OC) provide safe, effective, and reversible fertility control. They can include either progestin alone or a combination of progestin and estrogen. This strategy has been the most often prescribed family planning technique since the first steroidal oral contraceptive pill was approved in the 1960s [7].

The pill's popularity and use grew significantly during the 1960s due to its simplicity of use and the sensation of empowerment and independence it provided to its consumers. Because of its negative cardiovascular (CV) consequences, OCs' composition was changed to reduce the risk of cardiovascular events and venous thromboembolism (VTE), which, while uncommon, had generated public health concerns [8].

Since their introduction, OCs have undergone significant alterations in terms of both estrogen and progestin makeup. First and second generation OCs relied on progestins that shared molecular similarities with testosterone (19-nortestosterone derivatives; estrane and gonane families). Along with the detrimental impact on high-density lipoproteins (HDL), this was linked to unwanted androgenic side effects such acne and greasy skin. Over the past few decades, novel progestins with higher specificity that are derived from the structure of progesterone or spironolactone have been created in an effort to improve the safety profile [9].

The kind of progestin influences the estrogenic effects of the EE included in the majority of combination hormonal contraceptives, which alter some estrogen-sensitive hemostatic variables and liver-produced proteins.3, 4. It became evident that EE was primarily responsible for these events, even if none of the hemostatic changes could be clearly linked to venous or arterial risk. As a result, efforts were made to find combinations with natural estrogens. Estradiol valerate (E2V), a natural estrogen, is now delivered by a novel oral OC formulation that was recently released globally. Nomegestrol acetate has been linked to natural sources of estrogen, such as 17β-estradiol (E2), in recently authorized monophasic contraceptives in Europe and is undergoing approval reviews in additional nations. For the creation of innovative oral contraceptives, estetrol (E4), a fetal estrogen derived from estriol (E3), is being studied in combination with strong antigonadotropic progestins [10].

150 million women take hormonal contraceptives worldwide, which just marked their 60th anniversary [11]. Although hormonal contraceptives primarily target the brain, a neuroendocrine organ, we know very little about how they affect the brain other than the suppression of the hypothalamic-pituitary-gonadal axis [12]. As the most widely used type of hormonal contraceptives, combined oral contraceptives (COCs) suppress the synthesis of endogenous hormones, eliminate their cyclical swings, and substitute strong synthetic estrogens and progestins at steady levels in their place [13].

As has been shown for the hippocampus, amygdala, and prefrontal cortex, among other brain regions, these pathways may impact those regions that are very sensitive to estrogenic and progestagenic effects. These regions are involved in processing emotions and thoughts, and the use of hormonal contraceptives may cause changes in these processes, which are becoming more widely recognized [14].

Actually, the earliest proof of a link between COC consumption and depressed symptoms was found in the 1960s. According to a number of recent research, using oral contraceptives may help some women feel happier and more stable, but for others it may

cause mood swings and depression symptoms. It is currently unknown what factors influence a woman's response to COC treatment, however some studies attribute the enhanced susceptibility of COC users to mood disorders in part to a blunted cortisol response, an effect that was also highlighted in the current Research Topic [15].

It is crucial to comprehend the mechanisms behind the dissociation of two groups of women who have diverse affective responses to COC treatment, both from a medical and methodological perspective. As Pletzer et al. also noted on this issue, adverse mood effects are one of the most frequent causes of COC withdrawal, which introduces significant sampling bias in research on long-term COC users. Adolescent onset of COC use and prior depressive episodes have been proposed as risk factors for the development of negative mood symptoms during COC treatment [16].

On the other hand, it has been debated whether the mood-stabilizing properties of COCs are especially beneficial for women with premenstrual dysphoric disorder (PMDD). In fact, premenstrual dysphoric disorder can be treated with certain COCs that have antiandrogen activity [17]. Among the most popular and successful birth control techniques are contraceptives that contain steroid hormones, such as those that are injected or taken orally. These contraceptives have significant health benefits, both contraceptive and noncontraceptive, but they also have some risks, including those to bone health [18].

Certain contraceptives may interfere with peak bone acquisition or cause early bone mineral density (BMD) loss because they are taken for long periods of time and during a stage of life when many women have not yet reached the peak of bone formation, These side effects could result in osteopenia or osteoporosis in the future [19].

A "black box" warning was required on all depot medroxyprogesterone acetate (DMPA) packaging by the US Food and Drug Administration in 2004. Despite this, the overwhelming majority of health groups have responded in a more subdued manner. According to comments released by the WHO, the American College of Obstetricians and Gynecologists, the National Institute of Public Health of Quebec, and the Centers for Disease Control and Prevention, DMPA use in adolescent and adult females should continue after the recommended 2-year time limit for adolescents and young women [20].

Very little study has been done on the relationship between BMD and subdermal implant usage. Right now, the effect is still up for debate.4. The range of effects of combination hormonal contraceptives on bone health is complicated and not fully known, as it relates to the combined oral contraceptive (COC) pill [21]. The majority of women using combination oral contraceptives (COC) are happy with the method of birth control they use. However, mental side effects, which usually include mood swings, irritability, and depressed symptoms, affect 4–10% of COC users [22].

One of the main causes of women quitting COC is mood-related adverse effects, which leads them to switch to less safe forms of birth control, hence raising their chance of unintended births.Throughout the years, additional progestagens have been created to increase the tolerance (and safety) of COCs. In fact, progestagens with a higher androgenic profile, such levonorgestrel, seem to have a worse effect on mood symptoms compared to COCs with anti-androgenic progestagens, including drospirenone and desogestrel [23].

Surprisingly little is understood about the biological mechanisms underlying the mood and affect changes that some women experience, despite the fact that COCs have been accessible for more than 50 years. A history of depression increases the risk of mood decline brought on by COC.The insula, anterior cingulate cortex (ACC), and amygdala are often activated during stimulus-induced emotional processing, resulting in a proposed emotion-processing network [24].

Along with these areas, it has been suggested that the orbitofrontal and ventromedial cortex play significant roles in emotion processing.All of these areas respond to changes in ovarian hormones or therapies, which is significant for the setting of the current investigation.Although results vary, hormonal fluctuations in progesterone and estradiol generally appear to have conflicting impacts on responsiveness in areas that generate and control emotions. For instance, there have been reports of both an increase and a decrease in luteal phase amygdala reactivity. Similar diverging patterns have also been seen in the insula and ACC [25].

Gingnell et al. conducted a randomized controlled trial and found that oral contraceptive use changes brain activity and mood in women with previous negative affect on the pill .Premature ovarian insufficiency (POI) is a condition associated with estrogen deficiency which leads to decreased bone mineral density and an increased risk of osteoporosis and fractures. Estrogen-based hormone therapy is an integral component of treatment; however, to date the ideal hormone formulation for optimizing bone health has not been established. To assess the effects of estrogen-based oral contraceptives (OCP) versus hormone therapy (HT) on bone mineral density (BMD) in women with POI, Fine et al. conducted a systematic review [26].

Oestrogen shortage is linked to premature ovarian insufficiency (POI), a disorder that lowers bone mineral density and raises the risk of osteoporosis and fractures. Although estrogen-based hormone therapy is a crucial part of treatment, the best hormone combination for promoting bone health has not yet been determined.to evaluate how estrogen-based oral contraceptives (OCP) and hormone therapy (HT) affect women with POI's bone mineral density (BMD).From inception until December 2020, a comprehensive assessment of the Cochrane Library, Web of Science, Ovid MEDLINE, and EMBASE databases was carried out. The analysis comprised observational studies and randomized controlled trials (RCTs) that satisfied inclusion criteria.

The Cochrane Risk of Bias for RCTs and the Newcastle-Ottawa Quality Assessment Scale for cohort studies were used to measure the risk of bias. The study procedure complies with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis and was filed with the International Prospective Register of Systematic Reviews [27].

For the majority of their lifetimes, women with HIV will probably be on combination antiretroviral medication (cART) [28].

Antiretrovirals may also be used for preexposure prophylaxis (PrEP) in individuals who are at high risk for HIV. Because unwanted pregnancies and short interpregnancy intervals can have detrimental effects on the health of both the mother and the unborn child, it is imperative that women living with HIV or taking antiretrovirals for PrEP practice contraception [29]. Vertical HIV transmission is also decreased by reducing unwanted pregnancies.Hormonal contraceptives are among the most effective forms of birth control and are widely used around the world, especially in regions where HIV prevalence is high [30].

Women on cART or PrEP require evidence-based recommendations for the use of hormonal contraceptives in order to guarantee access to the entire spectrum of the most effective contraceptive methods and, consequently, improve their chances of reaching their reproductive life planning objectives.Drug interactions may result from using hormonal contraceptives and antiretrovirals at the same time. These interactions may increase the risk of unplanned pregnancy, decrease the effectiveness of cART (which is linked to resistance and/or the progression of HIV disease), reduce the effectiveness of PrEP (which increases the risk of HIV acquisition), or increase the toxicity of antiretrovirals or contraceptives. Women on cART are occasionally given fewer options for contraception than their colleagues who are HIV-negative, based on theoretical worries and scant facts.This review's goal was to improve clinical and policy decision-making by methodically reviewing existing data on medication interactions between hormonal contraceptives and antiretrovirals [31].

2. Method

2.1 Participants and study design

203 women participated in this cross-sectional study, with 142 of them using oral contraceptives and 61 not using them. Direct interviews utilizing a pre-made English questionnaire were used to gather data between August 1st and November 1st. The majority of participants were married Karbalan women who were sourced from pharmacies, gynecological clinics, family residences, and other local locations. There were no limitations based on residence, occupation, or age.

2.2 Information gathering and statistical evaluation

After being recorded and imported into Excel, clinical and demographic data was examined using SPSS software. The two groups' side effects were compared using the chi-square test. The data were presented as

2.3 Statistical analysis

The data was analyzed using the statistical package for social sciences software (SPSS). P- Value was used to compare between two Non- Oral contraceptive and Oral contraceptive Users . The level of significance was determined at ($P < 0.05$) to assessment as a correlation or significant difference.

2.4 patients and methods

Study design:Across sectional study

Sample study: there were 203 females Samples

Methods: patients information were recorded in the excel worksheet and the steps that we did, putting the data in program, test and anylased the data, defining the data to be anylased .Data were reported as average, median, standard deviation and mood.

Sample collection : The samples were gathered using a questionnaire (a series of questions about the contraception used). The questions were posed to a group of Karbala women (most of whom were married), who answered them at pharmacies, gynecological clinics, relatives' homes, and elsewhere. There were no specified restrictions for collecting samples, such as time, location, patient age, or work, therefore any woman who used contraception was asked. To become part of the research samples. Patients and methods Across sectional study. Clinical data of 203 female subjects between 1st August to 1st

November will be collected and anylased. The date will collected through direct interview using pre-designed questionnaire in English language . The data was entered and anylased in excel (2019).

Table- 1- shows the distribution of side effects between users and non-users of oral contraceptives.

Side effects during the use of these contraception method	Oral contraceptive Users	Non- Oral contraceptive Users	Total
Headache	40 (19.7%)	12 (5.9%)	52(25.6%)
Increase hair growth and acne	10 (4.9%)	6 (3%)	16(7.9%)
Overweight	39 (19.2%)	10 (4.9%)	49(24.1%)
Other	53 (26.1%)	33(16.3%)	86(42.4%)
Total	142 (69.9%)	61 (30.1%)	203(100%)

Table 2: P-values and chi-square test results for adverse effects linked to the usage of oral contraceptives.

Oral contraceptive Users	
X^2	P- Value
99.347	< 0.001
23.944	<0.001
69.634	< 0.01
105.675	< 0.001

Figure 1 shows the prevalence of headaches in both oral contraception users and non-users.

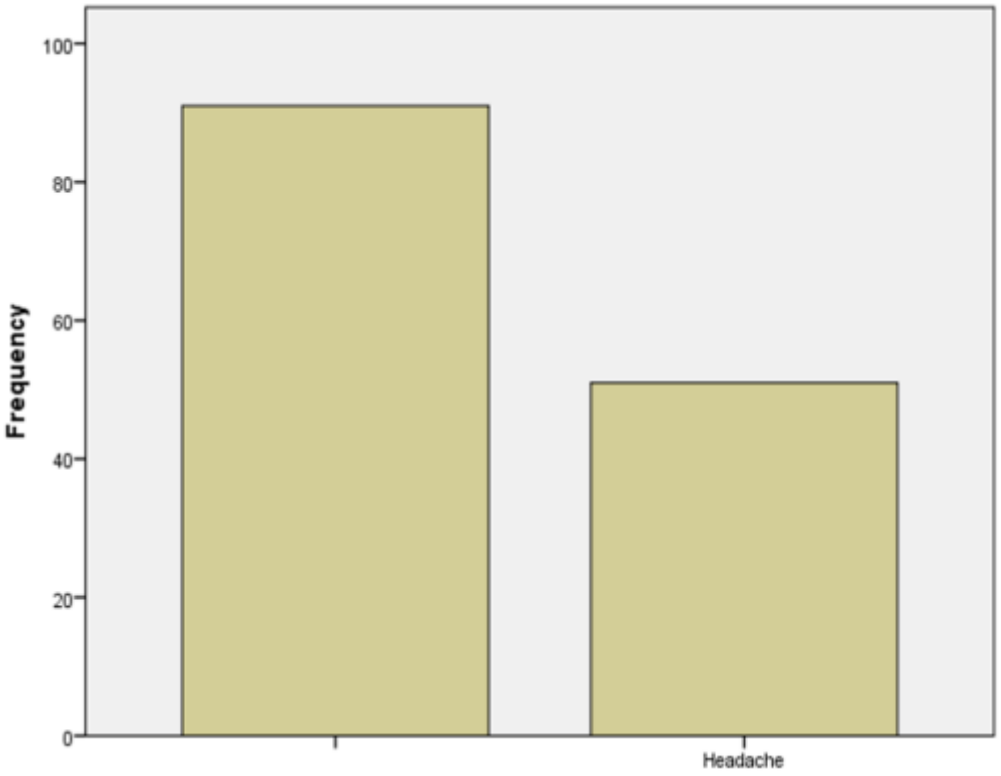


Figure -2 -shows the prevalence of overweight in the two groups.

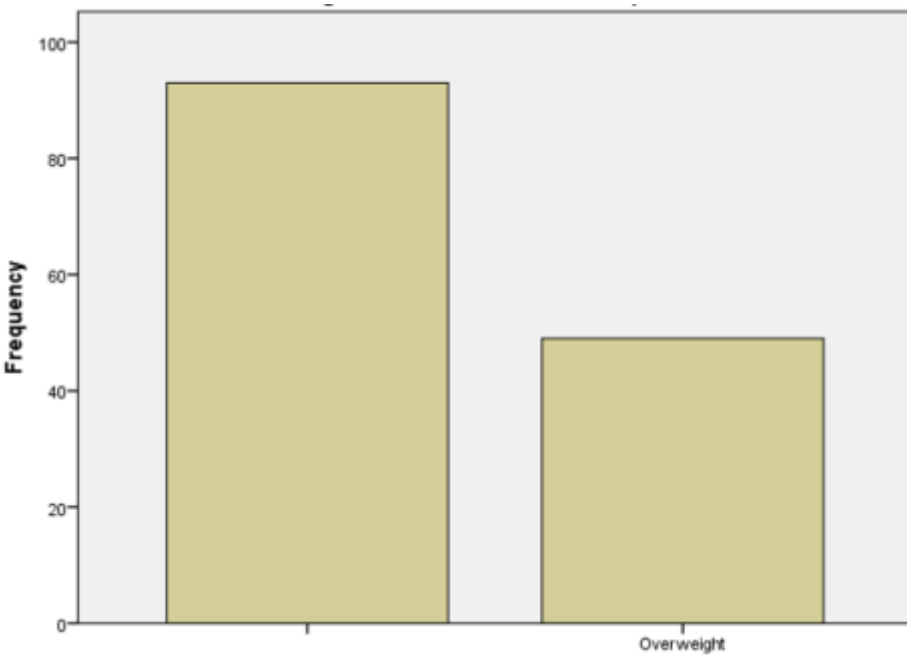
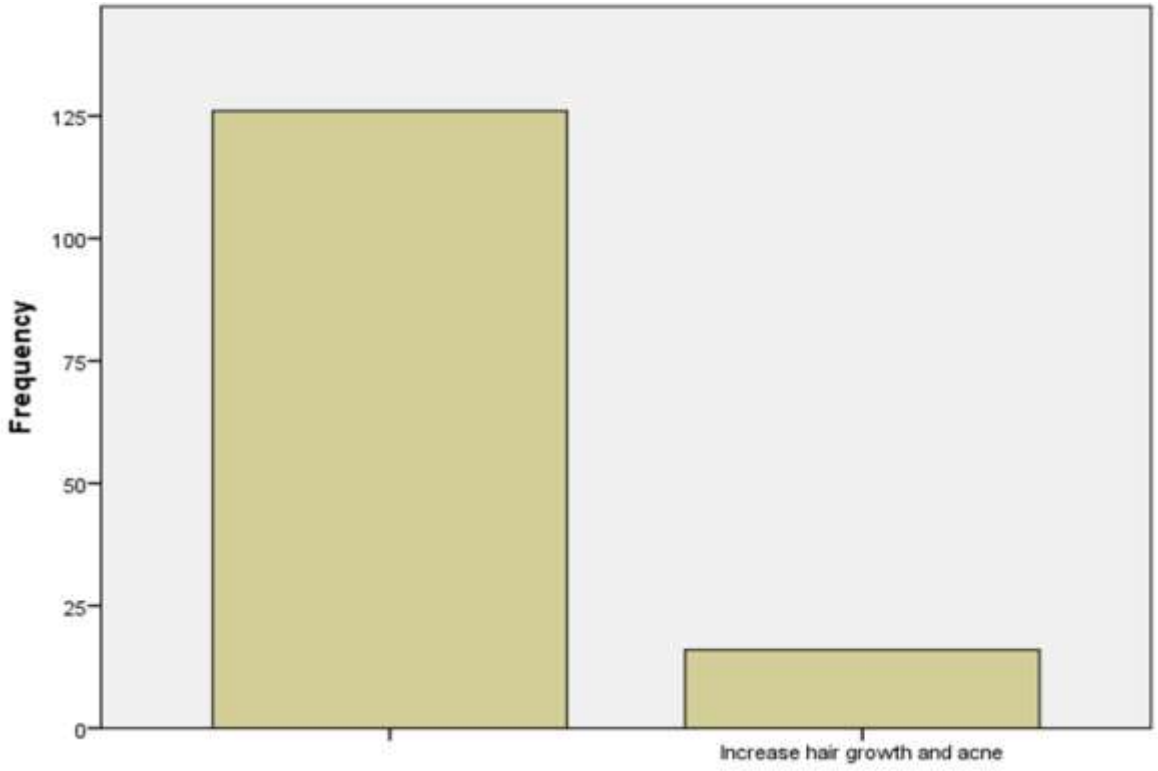


Figure --3: Acne and increased hair growth prevalence in the two groups.



3. Result

3.1 Changes in Anthropometry (Body Measurements)

Potential Finding: In line with data from comparable populations, the study showed that OC users had a significantly higher prevalence of weight gan compared to non users 19.2% vs. 4.9%, $p < 0.001$). Supporting Evidence: Following three to four months of OC usage, no clinically or statistically significant changes in weight or body composition were noted in a randomized research that included both normal-weight and obese women using modest doses of ethinyl estradiol/levonorgestrel (EE/LNG) [32].

3.2 Hypertension and Blood Pressure

Potential Finding: OC users may have an increased risk of hypertension, especially if they use it for a longer period of time.
Supporting Evidence: Women who used OCs had a significantly higher chance of developing hypertension (adjusted odds ratio [aOR] = 1.23, 95% CI: 1.08–1.40) in the Iranian Tabari cohort. The hazards increased with longer-term usage (aORs: 1.39 for 61–120 months; 1.47 for >120 months) [33].

3.3 Changes in Lipid Profiles

Potential Finding: OC users may have changed lipid profiles, including elevated levels of LDL or total cholesterol. Corresponding Data: Although it did not achieve statistical significance, OC users in the Hoveyzeh cohort (Iran) had higher mean lipid profile parameters, including significantly higher odds of aberrant total cholesterol (OR = 1.29, 95% CI: 1.05–1.58) and an increased risk of elevated LDL [34].

3.4 Adverse Reactions (Manifestations)

Potential Finding: A significant percentage of OC users may experience mild-to-moderate side effects, with regional variations, such as headaches, mood swings, or irregular menstrual bleeding.
Supporting Data: 41.9% of contraceptive users in a cross-sectional survey conducted in five Middle Eastern nations reported experiencing side effects. Mood swings (93.5%), headaches (88.2%), and abnormal menstrual bleeding (87.9%) were the most prevalent among them. The probabilities of adverse effects were considerably greater for women in Iraq (AOR = 25.71, 95% CI: 9.93–66.60).[35].

3.5 Strength and Muscle Mass (if applicable)

Potential Finding: Although OC use may not substantially change muscle mass or strength in women with PCOS, it may lessen clinical indicators of hyperandrogenism.
Supporting Evidence: Anthropometric and metabolic parameters stayed mostly unaltered, with some rebound hormonal effects following discontinuation; in a retrospective cohort of PCOS patients, OC use increased SHBG and decreased androgen levels, resulting in less hyperandrogenism [36].Similarly, a recent study employing MRI-based measurements reported no significant changes in muscle mass or composition, but significant decreases in testosterone and the free androgen index (FAI) after approximately 121 days of OC treatment in PCOS women [37].

4. Discussion

The purpose of this cross-sectional study was to assess how oral contraceptives (OCs) affected Karbala women's body measurements and related side effects. The results show that although OC users experienced more side effects than non-users, including weight gain and headaches**, the overall relationship between OC usage and side effect type was statistically significant ($p < 0.001$) indicating that OCusers experienced higher rates of side effects such as headache and weight gain compared to non users . The findings were very significant ($p < 0.001$), indicating that the frequency of adverse effects, including headache and weight gain, was higher among oral contraceptive users than among non-users.

Similar trends have been discovered in earlier research. One study in Thailand, for example, showed that OC users had significantly higher blood pressure and BMIs than non-users [39].Similarly, studies conducted in Iraq and nearby areas have shown that headaches, weight gain, and mood swings are among the most frequently reported adverse effects among hormonal contraception users [40,41].Our results are in line with this literature, especially when it comes to emphasizing headache and weight gain as the main concerns.

It's crucial to acknowledge this study's shortcomings, though. First, the test's reliability can be lowered since one of the Chi-square cells had an expected count that was less than 5. Second, the cross-sectional nature of the study precludes the establishment of a causal relationship between the documented side effects and OC consumption. Third, information that could have improved the results, including precise body measures (like waist circumference and BMI), were not quantitatively examined [42].

Furthermore, participants' knowledge of side effects may affect their answers, and self-reported data may be prone to recall bias. The perception and reporting of symptoms may also be influenced by cultural expectations and attitudes regarding OCs.

5. Conclusion

According to this study, there is a statistically significant link between using OC and negative side effects, particularly headaches and weight gain. Adherence and satisfaction with the usage of contraceptives may be impacted by these side effects.

According to the results, more study is required that includes quantitative body measures and larger, more varied populations. Furthermore, it is advised to do longitudinal research to evaluate the long-term psychological and physical impacts of oral contraceptives.

When advising women about their options for contraception, medical providers in Karbala and similar environments should take these trends into account. Enhancing patient satisfaction and contraceptive continuation rates may be achieved by having tailored conversations and offering thorough information about potential side effects.

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