

Drug Utilization Pattern of Oral Contraceptive Pills in Tertiary Care Hospital

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ABSTRACT

Oral contraceptive pills used to prevent pregnancy. It contains hormones that block the release of eggs from the ovaries. Most oral contraceptives include estrogen and progestin. It is one of the most commonly used methods of birth control by women worldwide. They are also used as non-contraceptives in the treatment of polycystic ovary syndrome, dysmenorrhoea, menorrhagia and hirsutism. The study was about drug utilization which provides an insight to prescriber regarding various usage of diseases, benefits and side effects. **AIM & OBJECTIVES** To assess the utilization pattern with benefits and side effects of OCP's used in tertiary care hospital.

METHODOLOGY The study was a prospective observational study conducted for a period of 6 months in the Obstetrics and Gynaecology department of Karpagam faculty of medical sciences and research. The study data was collected from out patients prescription in a specially designed data collection form and questionnaires: demographic data, symptoms menstrual history and present menstrual status, past medical and medication history, drug-related informations (dose, frequency and duration). A total no of 50 patients included in this study, in which details were used for investigating the utilization pattern of oral contraceptive pills, benefits and side effects of oral contraceptive pills. RESULTS Data were collected from 50 patients who were prescribed with oral contraceptive pills to regulate menstrual cycle, polycystic ovarian disease and endometriosis in the department of obstetrics and gynaecology. According to age distribution, the patients were evaluated 25 patients (50%) belonged to 10-30

years, 9 patients (18%) belonged to 31-40 years, 16 patients (32%) belonged to 41-55 years. Based on disease distribution, 27patients (54%) diagnosed with polycystic ovarian disease (PCOD), 6patients were (12%) belonged to Regulate menstrual cycle and 17patients were (34%) diagnosed with Endometriosis. Benefits of patients while using OCP's, 41 patients (82%) was responded as satisfied with treatment. 9 patients (18%) was responded as not satisfied with the treatment. Side effects encountered with OCP's,were as weight gain (30 [60%]) hair loss (29 [42%]) and light spotting (21[42%]) migraine (16 [32%]) breast tenderness (13 [26%]) nausea (9 [18%]) CONCLUSION The present study revealed an importance of utilization pattern of OCP's. Our study shows that women who has positive attitude towards OCP's use tend to utilize them more appropriately. Combined pills of progestin and estrogen were satisfied while compared to progestin only pills. It would be crucial for future researchers to investigate the utilization pattern and side effects of OCP's among usage in women.

KEY WORDS: Oral contraceptive pills, Drug utilization, Side effects.

I. INTRODUCTION DRUG UTILIZATION

Drug utilization research was defined by WHO in 1977 as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences. (*Bergman U et al.*)

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ORAL CONTRACEPTIVE PILLS

The Oral Contraceptive Pill (OCPs) were approved by the U.S. Food and Drug Administration (FDA) in 1960. A pill is used to prevent pregnancy. It contains hormones that block the release of eggs from the ovaries. Most oral contraceptives include estrogen and progestin. It is one of the most commonly used methods of birth control by women world wide. They are also used as a non-contraceptives in the treatment of polycystic ovary syndrome, dysmenorrhea, menorrhagia and hirsutism .(*Jacqueline A Maybin*, *et.al.*)

AVAILABLE DOSAGE FORMS

The medications are available in various forms, such as pills, injections (into a muscle), topical (skin) patches, and slow release systems (vaginal rings, skin implants, and contraceptive - infused intrauterine devices.) (*Speroff L, et.al.*)

HOW DOES OCPS WORK

1. By blocking ovulation (release of an egg from the ovaries), thus preventing pregnancy.

2. By altering mucus in the cervix, which makes it hard for sperm to travel further.

By changing the endometrium (lining of the uterus) so that it cannot support a fertilized egg.
 By altering the fallopian tubes (the tubes through which eggs move from the ovaries to the

uterus) so that they cannot effectively move eggs towards the uterus.

(Selda demircan, et.al.)

EPIDEMIOLOGY

Oral contraceptive pill is the most popular form of contraception: 11.6 million US women in 2002.Nineteen percent of women ages 15-44 (CDCS National center for Health Statistics).Combined oral contraceptive pills are the most common of reversible birth control in developing countries over 100 million women worldwide. Current contraceptive use increased with age, from 37.2% among women aged (15-19) 73.7% among women aged (40-49). (*Finer LB, et al.*)

COMBINED ORAL CONTRACEPTIVE GENERATIONS

I PROGESTIN DERIVATIVES :

1. First Generation

• Norethindrone { 2.5 mg – 10 mg }

• Norethynodrel { Derivative of Norethindrone }

2.Second Generation :

- Norgestrel (0.5mg)
- Levonorgestrel (0.15mg)
- 3. Third Generation :
- Desogestrel (0.15mg)
- Norgestimate (0.25mg)
- Gestodene (0.075 mg)

II ESTROGEN DERIVATIVES :

- Mestranol (50mcg)
- Ethinyl Estradiol (20- 50mcg)

INDICATIONS OF OCP

To Prevent Pregnancy, To Regulate the menstrual cycle, Endometriosis, Polycystic ovary syndrome (PCOS),To reduce Amenorrhea, Menorrhagia, dysmenorrhea, Dysfunctional uterine bleeding and Pre menstrual dysphoric disorder. (Ayesha yasmeen, et.al.)

MECHANISM OF ACTION:

The inhibition of follicular development ovulation and as consequence corpus luteum formation. It is also involve in the alteration of the cervical mucus that inhibit sperm penetration. Progestogen negative feedback works at the hypothalamus to decrease the pulse frequency of the Gonadotropin releasing hormone. This in turn, will reduce the secretion of follicle stimulating hormone and decreases the secretion of luteinizing hormone. (*Cooper DB, et.al.*)

ADVERSE EFFECTS OF OCPs :

Nausea, vomiting, headache, bloating, breast tenderness, swelling of the feet, weight gain, venous thrombo embolism. Neurological adverse effects with OCPs are migraine, depression, psychosis & cerebral infarction. (*Angeline T, et.al.*)

II. METHODS AND MATERIALS

Study Site

The study was conducted in Obstetrics and Gynaecology Department of Karpagam Faculty of Medical Sciences and Research.

Study Design

Prospective study design was conducted in Obstetrics and Gynaecology department at tertiary care hospital.

Sample Size

Our study sample size was calculated using cochran's formula and population size were 50.



The given Cochran's formula

$$SampleSize = \frac{\frac{z^2 \cdot p(1-p)}{e^2}}{1 + \frac{z^2 \cdot p(1-p)}{e^2 N}}$$

Study Period

The prospective study was conducted for a period of 6 months in Obstetrics and Gynaecology department at Karpagam Hospital.

Study Permission

The permission to use prescriptions and asking questionarries to the patient for research purpose was granted by Medical Superintendent and Head of the Department of Obstetrics and Gynaecology, Karpagam Hospital. The protocol was submitted to Institutional Human Ethical Committee IHEC/247/KCOP/06/2022 reviewed and approval, the study was approved and conducted according to declaration of Helsinki. (Annexure-3)

Study Criteria

Inclusion Criteria

- ✤ Age (15-55Years old)
- Gender : Female
- Outpatient medical or case records
- Prescription with oral contraceptive pills
- **Exclusion Criteria**

- z : z-score p : Population proportion e : Margin of Error
- N : Population size

History of melanoma or breast, uterine or ovarian cancer

- Pregnant and lactating women data
- Psychiatric ill patients
- Hepatic and renal impairment

Source of Data

Data will be collected using a well-designed patient data collection form on a daily basis from patient's prescription.

The following data were retrieved from the prescription and the patient's medical records: demographic data (Age, BMI, Marital Status, Education/Occupation, Menstrual History), 'known' or 'newly diagnosed, drug-related information's (dose, frequency, and duration) and medical history.

Statistical Analysis

The data was subjected to descriptive statistical analysis using Microsoft Excel. Microsoft word and excel have been used to generate piechart and tables.

DESCRIPTIVE PARAMETER	N (VALID PERCENT %)
Age in years (n=50)	
10 - 30 yrs	25 (50%)
31- 40 yrs	9 (18%)
41- 55 yrs	16 (32%)
BMI	
Under weight	3 (6%)
Normal	22 (44%)
Overweight	17 (34%)
Obesity	8 (16%)
Education	
Illiterate	3 (6%)

III. RESULTS Demographic characteristics of women using oral contraceptive pills



Primary school	8 (16%)
High school	20 (40%)
Graduate	19 (38%)
Occupation	
Occupation	
Student	4 (8%)
Professional	5 (10%)
Home maker	35(70%)
Buissness	6 (12%)
Marital status	
Married	37 (74%)
Unmarried	13 (26%)
Age of menarche	
10-12 yrs	5 (10%)
13- 15 yrs	45 (90%)
	1

Table.1 Demographic characteristics of women using oral contraceptive pill

A total of 50 participants met the inclusion criteria, were as prescribed oral contraceptive pills. The age distribution of patients were calculated in table.1, In the age group of 10-30 years were (50%) of 25 patients, In the age group of 31-40 years were (18%) of 9 patients, In the age group of 41-55 years were (32%) of 16 patients shown in figure.2.



Figure.2 Age distribution

Body mass index of patients were as illustrated. 3patients (6%) belonged to underweight, 22 patients (44%) belonged to normal, 17patients (34.1%) belonged to overweight, 8patients (16%) belonged to obesity shown in figure.3.



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Figure.3 Body mass index

In our study, we set and evaluate the menarche and 45 patients were attained at the age of 13-15 years, which belongs to 90% only 10% of

5 patients attained the menarche at the age of 10-12 years. Among 50 patients, 37 patients (74%) were married, 13 patients (26%) were as unmarried.

Utilization pattern of oral contraceptive pills

PILL UIILIZATION PATTERN	N (VALID PERCENT%)
PURPOSE OF USE (n= 50)	
PCOD	27 (54%)
Regulate menstrual cycle	6 (12%)
Endometriosis	17 (34%)
TYPES OF OCP's	
Combined progestin and estrogen	23 (46%)
Estrogen	1 (2%)
Progestin	26 (52%)
DURATION OF OCP	
7 Days	6 (12%)
1 Months	33 (66 %)
2 Months	7 (14 %)
3 Months	4 (8%)
REASON FOR STOPPING PILLS	
Side effects	36 (72%)
Ineffectiveness	12 (24%)
Difficulty of use	1 (2%)
Others	1 (2%)

Table.2 Utilization pattern of oral contraceptive pills

The utilization pattern of OCP's were as described in table.2. Pill utilization pattern showed a positive trend. Indeed more women used pills for non-contraceptives more than 75% of women received doctor consultation & prescriptions were as 27 patients (54%) used for polycystic ovarian disease (PCOD), 6 patients (12%) used to Regulate menstrual cycle and 17 patients (34%) used for Endometriosis shown in figure.4



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Figure.4 Usage of drug

Among 50 patients, 23 patients (46%) were as prescribed with combined progestin and estrogen, 26 patients (52%) belonged to progestin. Approximately half of the women 33 patients (66%) were as prescribed for 1 month shown in figure.5



Figure.5 Types of OCP's

However, 36 patients (72%) were experienced the side effects, 12 patients (24%) stopped the medication due to ineffectiveness. Regarding missed pills 34patients (68%) doesn't missed the pill, were as 16 patients (32%) missed the pill shown in figure.6





Benefits of Oral Contraceptive pills

Benefits of oral contraceptive pills were illustrated in figure 7 & 8, Among 50 patients,41 patients (82%) was responded as satisfied with treatment. 9 patients (18%) was responded as not satisfied with the treatment. Benefits were demonstrated based on the duration of oral contraceptive pills use and also patient wait for withdrawal bleeding to start the new pack, it depends upon the patient using OCPs at exact time everyday. for withdrawal Among 50 patients, 34patients (68%) were belonged to wait for the withdrawal bleeding, 16 patients (32%) who doesn't wait bleeding.



Figure.7 Wait for withdrawal bleeding

Figure 8 described about the OCP's duration were categorized into 7 days therapy, 1 month, 2 month, and 3 month use, out of these category, majority (66%) 33 patients used for 1

month followed by (14%) 7 patients used for 2 months, 12%, 8% used OCP's 7 days therapy, 2 months therapy respectively.



Figure. 8 Duration of OCP pills

Side effects encountered by women using oral contraceptives

PARAMETERS	N (VALID PERCENT %)
Nausea	9 (18%)
Migraine	16 (32%)
Hair Loss	29 (58%)
Breast tenderness	13 (26%)



-	Weight gain	30 (60%)
	Light spotting	21 (42%)

Table.3 side effects encountered by women using oral contraceptive pills



Figure.9 side effects of oral contraceptive pills

SIDE EFFECTS	15- 30 Years (N=25)	30- 55 Years (N=25)
Weight gain	16 (64%)	14 (56%)
Hair loss	14 (56%)	15 (60%)
Nausea	4 (16%)	6 (24%)
Migraine	5 (20%)	9 (36%)

 Table.4 Side effects profile as per different age groups

More than two thirds of women reported that having at least one side effects. The most commonly encountered side effects were weight gain (30 [60%]) hair loss (29 [42%]) and light spotting (21[42%]) migraine (16 [32%]) breast tenderness (13 [26%]) nausea (9 [18%]) shown in table.3, The occurrence of side effects and duration of oral contraceptive pills consumption. Within two age groups (15-30 years and 30-55 years) 15-30 years shows that increase the weight gain (16 [64%]) 30-55 years shows that increase hair loss, nausea, and migraine shown in table.4.

IV. DISCUSSION

Our study focused to assess the utilization pattern of oral contraceptive pills in tertiary care hospital. This study is deliberated to evaluate about the Oral contraceptives (OCP's) utilization pattern among females of a wide range (15-55 years)

In our study we have done rigorous comprehensive and face to face interview and then it was documented with reliable and using validated questionnaires.

Our study women showed a good pattern of OCP's utilization. The majority of them are using OCP's for treating the disease condition by receiving prescription from physicians. Women have positive attitudes regarding oral contraceptive pills benefits and their efficacy. Certain women suffered from side effects like (weight gain, nausea, hair loss, migraine) so this play the major reason for women to stop the oral contraceptive pills. Collectively the positive attitude towards use was highly correlated with the usage patterns.



Out of 50 patients, Hair loss 16(32%) and weight gain 30(60%). But **Ayesha Yasmeen et al** study reveals that the side effects among Saudi women which complies with the results of migraine (35.5%) and weight gain (28.7%).

The **Sanaa k. Baradweel et al** study reveals that among the 1571 patients and side effects were reported in 75.1% of participated women. Headache (41.2%), mood swings (35.5%), weight gain (28.7%) and the occurrence of side effects was the main reason for OCPs discontinuation.

This study also says that among 50 patients, 36(72%) patients were as answered for side effects as a reason for OCPs discontinuation, 12(24%) patients were as responded for ineffectiveness as a reason for stopping pills.

The **Vijayan sharmila et al** reported that OCPs induced hemichorea in an adolescent female within the age group of (15-25years) polycystic ovarian disease. which developed within a week of starting OCPs in an adolescent girl with PCOD. In our study reveals that out of 50 patients, 33(66%) patients, were as received OCPs for polycystic ovarian disease as one months in the age group of (15-28years). The occurrence of side effects as differentiated within two age groups (15-30 years and 30-55 years) 15-30 years shows that increase the weight gain 16 (64%), 30-55 years shows that increase hair loss, nausea, and migraine

According to **Selda Demircan sezer et al** study reveals that among the 418 patients, (45.2%) believed that the pills cause weight gain (7.9%) and (13.4%) lead to infertility and (28.7%) migraine as shows increased in combined oral contraceptive pills. This study also says that COCPs as shown increased side effects as 23(46%) patients, as weight gain and 18(36%) patients, as hair loss when compared to estrogen and progestin pills.

Unfortunately most of the studies were designed to investigate attitude towards contraceptives. Limited number of studies has been designed to study about the utilization patterns and side effects of oral contraceptive pills. This study was designed to know about the knowledge and utilization of oral contraceptive pills. And therefore to promote education programs that could preferentially enhance OCP's utilization. No studies have ever described about the utilization pattern and side effects of South Indian population regarding rational pill use and pattern of utilization. Therefore the aim of our study was to describe different aspects of pill utilization including usage pattern, benefits and side effects.

Our findings imply that more education program about OCP's use .Although more than half of participated women reported that side effects of OCP's were the reason for stopping pills that reduce efficacy of the drug.

LIMITATION

1. The study conducted over a time period of 6 months, so cannot collect large number of sample size.

2. The study has less sample size, the variability are not statistically proven significantly

V. CONCLUSION

The present study revealed an importance of utilization pattern towards OCP's . Our study shows that women who has positive attitude towards OCP's use tend to utilize them more appropriately. Combined pills of progestin and estrogen is satisfied while compared to progestin only pills. In our study out of 50 patients, 41 patients were responded that they are satisfied with the treatment and also combined pills were experienced most of the side effects than the progestin only pills. It would be crucial for future researchers to investigate the utilization pattern and side effects of OCP's among usage in women. Moreover studying the effect of various educational programs on the appropriate utilization of OCP'

FUTURE DIRECTIONS

The future prospective seen to further enhance the availed outcomes of this study are as follows:

> The study can be carried out with a larger sample size to determine the wide range of non contraceptives use of oral contraceptive pills.

> There is a need of prospective multicentered study in large population of women to validate the major causes of polycystic ovarian disease and endometriosis.

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