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ISSN: 0975-7538

Research Article

Epidemiological studies for oral contraceptive pills prescription pattern, its efficacy and side effects in a South Delhi teaching hospital

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ABSTRACT

The objective of this study is to review the prescription pattern of oral contraceptive pills along with the drug utilization evaluation of oral contraceptives and to monitor their adverse drug reaction. The study was prospective, qualitative and questionnaire based. It was conducted for duration of 4 months, at gynecology OPD at Hakeem Abdul Hameed Centenary (HAHC), Jamia Hamdard, New Delhi, INDIA. Subjects in the form of 90 female participants of age 18-45 years were gathered on the belief of exclusion and inclusion criteria enduring contraceptive for the period of a month. A series of short questions emphasizing on types of oral contraceptives, their uses, and awareness of the health benefits as well as the risks were observed and assessed. Majority of the questions necessitate a tick box (yes/no) answer only. Mala-D was remarkably the most prescribed oral contraceptive and was chiefly utilized for birth control. Out of 90 participants 73% women took their pill at the same and invariable time while 23% missed a pill during the cycle. Intermittent bleeding and nausea were reported by 52% of the subjects and 40% of them experienced common side effects during administration of oral contraceptive. It is witnessed that literacy was not associated with OC use knowledge or compliance. From this prospective study, it is concluded that Mala-D was the most prescribed OC. The results of the current study signifies that the women were relatively cognizant regarding OC use, their benefits along with the risks, ADRs and acquit able steps to be followed for missed pills. The awareness about the significance of OC use in the participants was relatively on the greater side independent of the level of education. The rationale use of the OCs can be further upgradable through concrete counseling of women by health care provider staff. However, these findings are pilot study level observations and further research is worthwhile and can be used for large scale intervention study.

Keywords: Contraception; Family planning; Mala-D; Oral Contraceptives.

INTRODUCTION

Oral contraceptive (OCs) is the most well-known semblance of contraception around the globe since 1960 (Rosenberg *et al.*, 1995). It is the most common and extensively used form of contraception in Africa, Europe and Oceania (Australia, New Zealand and the South Pacific islands) and the most prevalently practiced reversible contraception technique among the American women who are either married or in a union (World contraceptive use, 2011). However, despite their widespread use and acceptability, there are numerous misbeliefs about both the health relevant benefits and health related risks of OC use. Women are sometimes reluctant and abstains themselves from receiving contraceptives because of perceived health

risks and uncertainties.

Pregnancy may become perplex and troublesome for women with co-existing medical complication. In prospering countries maternal death are usually common, with maternal mortality rates in the range of 20 to 100 times (Scott *et al.*, 2006). Contraception reforms certain non-reproductive health outcomes; curtailing the risk of ovarian and endometrial cancer risk in oral contraceptive users is the paramount illustration of such effects. Health benefits of OCs encircles defense against dysmenorrhea, menorrhagia, iron-deficiency anemia; ectopic pregnancy and ovarian cancer (Specific medicine, 2010). Recent studies have illustrated that over 75% of women surveyed are not conscious of the classic OC health benefits (Bryden *et al.*, 2001) richer than those in the United States. Contraceptive use approves women to space pregnancies, which curtails infant mortality. In the past 40 years, family planning have portrayed a key role in boosting the incidence of contraceptive practice from less than 10% to 60% and plunging the fertility in developing nations from six to around three births per woman (Peipert *et al.*, 1993). Curriculum to encourage family planning in develop-

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Received on: 11-11-2016
Revised on: 20-09-2017
Accepted on: 26-09-2017

ing countries initiated in the response to considerable improvements in child survival, which in turn headed toward expeditious population growth. In the Asian continent, the prime reason was to strengthen the possibilities for socioeconomic development by compressing population growth (Cleland *et al.*, 2006) and government took the lead. Success in hoisting the use of contraceptive measures and reducing fertility was stagnant to come but, in 1990 reproductive adjustments were established throughout most of Latin America and Asia, covering some of the world's poorest citizenries like Bangladesh and Nepal, and fertility downturn had begun in sub Saharan Africa.

Contraceptive adeptness is dependent on both the mechanism of action of a method and on the scope to which the method relies on adherence by the user. Combined oral contraceptive (COC) pills and the contraceptive implant both restricts ovulation and their deterioration rates when used perfectly in a flawless manner are very inferior. However, with characteristic use the failure rate of combined pill hovers a around 7%, while such use is outlined by the inconsistent pill taking (poor adherence) (Coale *et al.*, 1958).

The failure ratio of COC pills is 1-3 per 100 women, which compares favorably with all alternative contraceptives other than injectable progesterone and sterilization. An inflated risk of venous thromboembolism (VTE) associated with low dose COCs has been summarized on consistent basis. In 1998, an expert panel of World Health Organization, primarily on the basis of studies embracing the use of "low dose" OCs (30-40 micro gram of ethinyl estradiol), concluded that present users of OCs owes the risk of VTE that is three to six times of non-users. The utmost risk ensued during the first year of usage, and an increased risk persisted until the termination of the contraceptives use (Levels and trends in contraceptive use, 2003). Variety studies have speculated that consistency of contraceptive pill use is distant from optimal. Inside the first year of oral contraceptive use, side effects are paramount contributors to the discontinuation rates. One other study accounted that 19% of a convenient sample of 6676 European women among the assorted age groups of 16 and 30 stated they generally skipped one or more pills per cycle. Factors clustered with reduced compliance included a dearth of firm routine for pill taking, to read and understand written material accompanying the oral contraceptive package, not receiving competent information from a health care provider and emergence of side effects such as bleeding irregularities, nausea and breast tenderness (Steiner *et al.*, 2003).

In a Drug Utilization Evaluation of emergency contraception study, 63% of women were acquiring prescription birth control, 25% of the subjects narrated contraceptive failure. The patients were pursuing emergency contraception due to a gap in usage of regular birth control or failure of the methodology (Piascik *et al.*, 2010).

The present study was designed to probe the behavior and attitude towards the use of OCs, to figure out the level of knowledge, concerning risks and beneficial aspects of OC use and to investigate the elements responsible for its discontinuation which encompasses socio-demographic status, side effects and compliance respectively.

Materials and Methods

Study Site

The study was carried out in the gynecology OPD at Hakeem Abdul Hameed Centenary (HAHC), Jamia Hamdard, New Delhi, INDIA.

Study Duration

The study consisted of a questionnaire survey conducted for a duration of 4 months; January-April, 2012

Participants

The subject sample for this study comprised of 90 women who visited the gynecology OPD & family welfare center Hakeem Abdul Hameed Centenary (HAHC) hospital. The study included the females taking OC for a month, with of age group (18-45) yrs.; mentally challenged patients were debarred from the study.

Procedures

Participants were interviewed after voluntary informed consents were obtained. Interviews were conducted using structured questionnaire (open question method) by one to one conversation.

Study Design

This study was built upon a qualitative and prospective questionnaire inspection in an outpatient setting. The questionnaires were made off different sections. In the initial section, socio-demographic facts and informations were assessed (age, marital status, number of children, former reproductive history, level of education, duration of OC use). The second section underlined background aspects emphasizing on oral contraceptive use, succinct medical history, strides to be followed if a pill was missed during the cycle, the degree of knowledge concerning the pill i.e. Feasible side effect or benefits.

Data collection

Data were collected from respondent OC users at the gynecology OPD & family welfare center. Each person was handed over a questionnaire to transcript their demographic information: age, marital status, level of education. In addition, structured questionnaire was given to assess information regarding knowledge and behavior in OC use. The family welfare center prescribing record was also used to procure data.

Study approval

Study was reviewed and approved by the *Institutional Review Board* (IRB), Hamdard University, New Delhi.

Written informed consent was obtained from the patients well before interviewing them to collect and complete data.

Age distribution of women

The study comprised 90 women prescribed with Mala-D for the purpose of family planning. The general age distribution of women is rendered in the Fig 1.

Level of education

Majority of the women who took part in the study had secondary level of education followed by participants with graduate level of education.

Reasons for OC use

Majority of participants had oral contraceptive with the primary aim of birth control. However, a small ratio of participants received the pill for managing the painful periods or menstrual unevenness.

Distribution of OC

At HAHC, Family Welfare Centre Mala-D was found to be the most prescribed oral contraceptive; the patients were advised and cautioned to take Mala-D from the foremost day of menstrual cycle, 1 tablet each day for 21 consecutive days, followed by 7 days of iron folic acid supplementation. Among the entire population of the participants, only 1% of the was prescribed with Emergency contraceptive pill.

Awareness regarding correct OC use

An unfastened questionnaire was given to women who participated in the project. Reports about the patient compliance are tabulated below.

No. of adverse Effects

Women participating in the study also addressed of adverse effects of Mala-D.

Distribution of ADR's among various age groups

Among 90 participants majority of the participants belongs to the age group 17-24 followed by the age group 25-31.

Classification of ADRs as per NARANJO'S SCALE

Classification of ADRs was performed according to NARANJO'S SCALE

Majority of participants took oral contraceptives primarily for control. The average spacing of children was reported to be 3 years.

DISCUSSION

Oral contraceptives are the most incessantly used modern contraceptive method for their effectiveness with "perfect use". Controlled use of oral contraceptives are tremendously efficacious if used consistent manner and correct approach with a failure rate of 3 in 1000. Typical or ineffective use is associated with unwanted and untimed pregnancies of 8 in 100

pregnancies. The principal cause of contraception failure is missing pills. (Leung et al, 2010) (Black et al, 2010) Women are sometimes circumspect to use OCs due to perceived side effects, overlooking the health benefits that oral contraceptives serves such as regular periods, less painful periods, relief from acne, ovarian and endometrial cancer risk reduction. Some health risks linked with OC also stands like a a climbed risk of development of a thromboembolism, escalated risk of strokes, breast cancer, and cervical cancer. Inferiorly detrimental health risks include weight change, breast tenderness, nausea, skin problems, abdominal bloating and disruption of a woman's bleeding pattern.

In the present study the majority of women attained the age range of 25-31yrs, followed by the age group of 17-24yrs, 32-41yrs and 42-50yrs. The bulk of women (64%) who were prescribed OCs lied in the range of 25-31 yrs. These women were currently married and required oral contraceptive pills majorly for spacing between their children. Following were women in the age group of 17-24yrs, 21% of this group preferred the OC prescription for menstrual regulation and relief from painful periods. In this study all women were current OC users (who have been using OCs prior to the study). Life stage, age, level of education, and personal experience may play an vital role in women's knowledge of contraception. In this study most of women have completed their secondary education (33%), followed by 26% who claimed a graduate degree, 21% of women finished their primary level and 19% had no schooling. One study in Egypt has pictured that women living in rural areas, (Zafar et al, 2006) (Khan et al, 2001) with no education, and who obtained their last cycle of pills from government facilities were more presumable to take their pills in an untrue sequence due to substandard counselling.

The result of interest in the current study was that the women were relatively aware about OC use, their benefits and risks, ADRs, correct action to be taken for missed pills etc. The most prescribed oral contraceptives were Mala-D (99%) in Family Welfare Centre at HAHC hospital. The remaining 1% was EC-pill (emergency contraception). Mala-D is a merged oral contraceptive pill which contains 1 cycle of 28 pills in which 21 are for contraception and 7 pills are of iron supplement. While on the other hand, EC-pills are a 72 hour birth control pill.

In the present study prescribed duration of OC was mostly for 2-3months (89%), followed by 7% of women who were prescribed 1 cycle of OC for a month, 4% of the women were however endorsed OCs for 6 months.

More recently, in a study of 992 women who completed questionnaires after 2 months of OC use, 47% of users blown one or more pills per cycle in addition to 22% missed two or more (Khan et al, 2001) (Colli et al, 1995). In the present study 23% of women missed pill during their cycle, leaving majority of women rational

Age Distribution of Women

■ 17-24 ■ 25-31 ■ 32-41 ■ 42-50



Figure 1: Age distribution of women

Level of Education

■ NIL ■ Primary level ■ secondary education ■ graduate degree

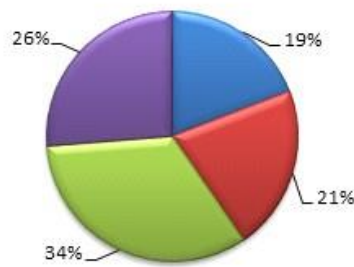


Figure 2: Level of education

Reasons for use of Ocs

■ birth control ■ menstrual cycle ■ painful period



Figure 3: Reasons for OC use

Distribution of OC

■ Mife-D ■ Emergency contraceptive pill

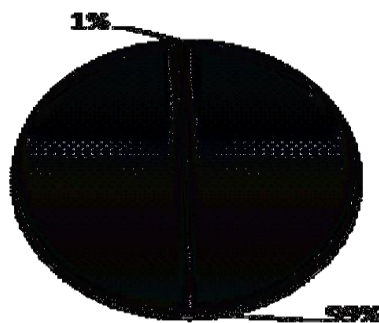


Figure 4: Distribution of OC among study participants

Number of Adverse Effect

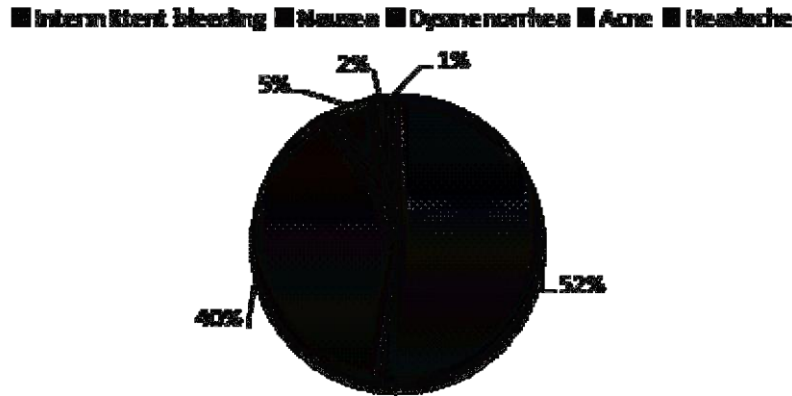


Figure 5: No. of Adverse Effects

Distribution of ADRs among various age group

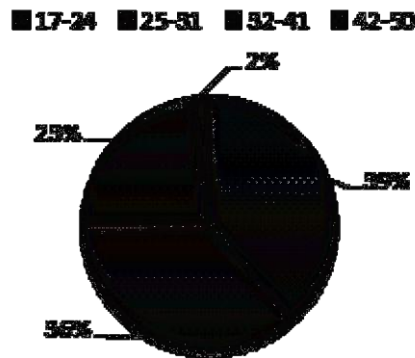


Figure 6: Distribution of ADR's among various age groups

Table 1: Awareness regarding correct OC use

Characteristics of women	No. of women	% of women
Women who missed a pill during their cycle	21	23
Knowledge about what to do with missed pill	75	83
Women who took the OC pill at the same time everyday	66	73
Discontinuation of OC use due to side effects	14	16

Table 2: Classification of ADRs as per NARANJO'S SCALE

Assessment score	No of ADRs	% of ADRs
Possible ADR=1-4	7	8
Probable ADR=5-8	0	0
Definite ADR>9	83	92
Total	90	100

with their regimen (77%).

In regards to step to be chased if a pill was missed during a cycle,83% of women had the intelligence of what steps to follow, and 17% were uncertain about the steps.

Majority (73%) of the women took their pills at the same time everyday and 27% of the women took the pill at fluctuated timings during the day. In the identical way, a retrospective study (Steiner et al, 2003) of 1311 women making initial family-planning visits to urban

health department clinics found that there were only 42% of OC received asserted they took a pill each day and only 20% said they took a pill within 2 hours of the scheduled time each day. The results of many studies indicate that despite increased endeavors to educate women, knowledge of OCs remains a major bothering issue even in a sample of women with steep socio-demographic status. Hence, contraception counseling is exceptionally important for adolescents and young women.

In the present study, a sum of 90 patients recruited and struggled through various adverse events such as irregular bleeding, nausea, acne, headaches. These women were receiving COCs (Mala-D). Number of studies have cited the incidence of side effects or other health complexities as the preeminent reason for the premature discontinuation of OCs (Grimes *et al.*, 2003). Moreover, one-third of undesired pregnancies in South Asian countries are resultant of OCs failure or discontinuation (Ali *et al.*, 1995).

Out of the 90 participants, 16% abandoned oral contraceptive use due to side effects and the rest of 84% complied with the dosage regimen. Due to side effects, 1 lady opted undergo tubectomy as an alternative approach. The experience of side effects is a major patron to the discontinuation of oral contraceptives (Rosenberg *et al.*, 1995). The maximum number of ADRs were grounded in the age group 17-24 yrs. and least in the age group of 42-50. Majority of the ADRs were definite. Entirely in 7 patients, the ADR was possible. The findings of the current study have critically important as well as crucial implications for contraceptive counseling strategy and policies. Appropriate, coherent and comprehensive counseling by a clinical pharmacist is greatly required who can precisely correct the misconceptions and myth regarding the usage of OC, thus can improve and revamp continuation rates, degree of awareness and compliance.

CONCLUSION

From above prospective study, it is concluded that Mala-D was the most prescribed combined oral contraceptive (COC) pill at the gynecology OPD at HAHC hospital. The results of the current study indicate that the women were relatively aware about OC use, their benefits and risks, ADRs and correct steps to be followed for missed pills. The knowledge about the significance of OC use in the participants lied on the higher side regardless of the level of education. The rationale use of the OCs can be further improved in a productive manner through proper and genuine counseling of women by health care provider staff. However, these finding are pilot study level observations and further research is worthwhile and can be used for large scale intervention study.

ACKNOWLEDGMENTS

The authors would like to thank Prof. G. N. Qazi, Vice Chancellor, JamiaHamdard, New Delhi for permission to carry out this research work at Hakeem Abdul Hameed Centenary (HAHC) Hospital, JamiaHamdard, New Delhi.

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