

Original Article

An empirical study on oral contraceptive pills in Moradabad region

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ABSTRACT

Oral Contraceptive pills (OCPs) are medications taken by mouth for the purpose of birth control. They consist of one or more synthetic female sex hormones (estrogen and progestin or progestin only) that prevent pregnancy by blocking the normal process of ovulation. Centchroman is a nonhormonal oral birth control pill developed that is available in India marketed under the brand Saheli. A market survey was done among the gynecologists and the drug market of Moradabad region on the use of OCPs. Parameters selected were the success rate of OCPs over other contraceptive methods, preferred hormonal combination used by OCP manufacturing units and the preferred active ingredient and brands of emergency OCPs used. It was found that OCPs were the most effective contraceptives than any other method of contraception with very low side effect profile and additional advantage of preventing various types of cancers in women. Pharmaceutical companies prefer cyproterone acetate and ethinylestradiol combination in their combined OCPs as these both hormones together work better in preventing pregnancy. Most of the emergency OCPs contained levonorgestrel as the active ingredient. Among them i-pill (Piramal Life Science) was the most used emergency OCP brand.

1. INTRODUCTION

Oral Contraceptive Pills (OCPs) are medications taken by mouth for the purpose of birth control [1]. Hormonal contraceptives consist of one or more synthetic female sex hormones (estrogen and progestin or progestin only). These sex hormones prevent pregnancy by blocking the normal process of ovulation. They may also alter the lining of the uterus (endometrium) so that it is unable to support a fertilized egg and they change the mucus in the cervix so that it is hard for the sperm to travel hence conception is less likely should ovulation occur. Estrogen and progestin are two female sex hormones. Combinations of estrogen and progestin work by preventing ovulation (the release of eggs from the ovaries) [2,3]. They also change the lining of the uterus (womb) to prevent pregnancy from developing and change the mucus at the cervix (opening of the uterus) to prevent sperm (male reproductive cells) from entering. A pack of OC contains active pills and inactive pills. “Active pills” refer to the pills in

the package that contain hormones. “Inactive” or “placebo” pills are members of the pill package that do not contain any hormone. Their presence in the pack is to help a women stay on schedule taking her pills [4].

By the 1930s, scientists had isolated and determined the structure of the steroid hormones and found that high doses of androgens, estrogens or progesterone inhibited ovulation. The first oral-contraceptive formulations marketed in the United States, in 1960 and 1961, contained 2 to 5 times as much estrogen and 5 to 10 times as much progestin as the oral contraceptives now in use. Since introduced in May of 1960, these pills have provided reliable contraception for millions of woman throughout the world [5].

OCPs are classified as combination pills and mini-pills. Combination pills contain two hormones, progestin and estrogen, while the “mini-pills” contain only progestin. Generally, combination birth control pills are slightly more effective than

progestin-only birth control pills. These pills contain the female hormones estrogen and progestin [6]. Estrogen is usually in the form of ethinyl estradiol while the progestin may be in different forms such as Levonorgestrel, Desogestrel, Norgestimate, gestodene. Combined pills are available in 2 different packs, the 21-day pack and the 28-day pack. The 28-day pack contains both the hormones in the first 21 pills and the last 7 pills have no hormones and are referred to as the spacer pills. In some packs, these spacer tablets contain iron. The pills are to be consumed daily at the same time. The common brands available in the US market are Levlite, Alesse, Mircette and LoEstrin while those in the Indian market are Mala D, Ovral, Marvelon – 21, Crisanta, Ovarel-L and Femilon etc. Minipills contain only a low dose of progesterone. They are not as effective as a combined pill. An example of a minipill is Ovrette. Morning after pill are also mini-pills used after sexual intercourse to prevent pregnancy. It contains a progestin either as 1 or 2 tablets. It is available in brands such as unwanted -72, i-sure, i-can, i-pill etc. Centchroman is a nonhormonal oral birth control pill developed and available in India. It does not have the side effects of hormonal contraceptives such as Saheli [7,8].

OCPs were developed to prevent ovulation by suppressing the release of gonadotropins. Combined hormonal contraceptives, including COCPs, inhibit follicular development and prevent ovulation as a primary mechanism of action. Progestogen negative feedback decreases the pulse frequency of gonadotropin-releasing hormone (GnRH) release by the hypothalamus, which decreases the secretion of follicle-stimulating hormone (FSH) and greatly decreases the secretion of luteinizing hormone (LH) by the anterior pituitary. Decreased levels of FSH inhibit follicular development, preventing an increase in estradiol levels. Progesterone negative feedback and the lack of estrogen positive feedback on LH secretion prevent a mid-cycle LH surge. Inhibition of follicular development and the absence of a LH surge prevent ovulation. Estrogen was originally included in oral contraceptives for better cycle control (to stabilize the endometrium and thereby reduce the incidence of breakthrough bleeding), but was also found to inhibit follicular development and help prevent ovulation. Estrogen negative feedback on the anterior pituitary greatly decreases the secretion of FSH, which inhibits follicular development and helps prevent ovulation. Another primary mechanism of action of all progestogen-containing contraceptives is inhibition of sperm penetration through the cervix into the upper genital tract (uterus and fallopian tubes) by decreasing the water content and increasing the viscosity of the cervical mucus [9].

Besides the convenience of taking the pills once a day, there are many other advantages of OCPs. OCPs have a high level of effectiveness to prevent pregnancy and are easier to use than other contraceptive methods. OCPs decrease a woman's risk for cancers of the ovaries and the uterine lining (called endometrial cancer), fibroadenoma, anemia, ectopic pregnancy and pelvic

inflammatory disease. Taking them also lowers your chances of having benign or non-cancerous breast masses and ovarian cysts. OCPs decrease women's menstrual cramps, pain and reduce menstrual blood loss and a woman's risk for anemia. OCPs help to improve acne and premenstrual dysphoric disorder (PMDD). One pill brand, OrthoTri-cyclen® is FDA approved for the treatment of acne. No serious side effect is reported by its use [10].

2. MARKET SURVEY

Market research on OCPs was an organized effort to gather information about target markets or customers. It is a key factor to maintain competitiveness over competitors and provides important information to identify and analyze the market need, market size and competition. Top most OCPs manufacturing pharmaceutical companies identified are given in Table 1.

This market survey was performed focussing various gynaecologists and medical stores in Moradabad region (Lajpat nagar, Ram Ganga Vihar, Gandhi Nagar, Pilikothi and Buddha Bazar). Some regular OCPs available in Moradabad drug market are given in Table 2.

Table 1. OCPs manufacturing pharmaceutical companies

S.No.	Pharmaceutical Companies	Brand Name of OCP
1.	Bayer Pharma	Diane 35, Mirena, Famodene, Yasmine
2.	Cipla	Ginette-35
3.	Mankind	Unwanted-72
4.	Famy Care	Movelon 21, Femilone, Plan –B One Step, P2
5.	Dr. Reddy	Diwa 35, Velocit
6.	Pfizer	Mahapill
7.	Piramal Life Science	i-pill, i-sure, i-can
8.	SunPharma	Krimson 35, Dronis 20, Mifepriene
9.	Zydus Pharma	Triquilar, Mefiprex

A survey on success rate of OCPs over other contraceptives was done among various gynaecologists in Moradabad region. The doctors visited were:

- Dr. Shobha Chaturvedi (Obstetrics and Gynecology).
- Dr. Sangita Madan (Obstetrics and Gynecology).
- Dr. Anjali Jain (Obstetrics and Gynecology).
- Dr. Neetu Rastogi (Obstetrics and Gynecology).
- Dr. Anjani Gupta (Gynecology).
- Dr. Sunita Goel (Gynecology).

A market survey was also done on the active ingredients preferred for use in formulation of OCPs among ten top most OCP manufacturing units. The active ingredient combinations generally used in monophasic, biphasic and triphasic OCPs are given in Table 3.

Table 2. Active ingredients used in combined OCPs

Active Ingredient Combinations		
Monophasic	Biphasic	Triphasic
Chlormadinone Acetate + Ethinylestradiol	Levonorgestrel + Ethinylestradiol	Levonorgestrel + Ethinylestradiol
Cyproterone Acetate + Ethinylestradiol		Norgestimate + Ethinylestradiol
Desogestrel + Ethinylestradiol		Norethindrone + Ethinylestradiol
Dienogest + Ethinylestradiol		
Drospirenone + Ethinylestradiol		
Gestodene + Ethinylestradiol		
Levonorgestrel + Ethinylestradiol		
Norethindrone + Ethinylestradiol		
Norgestimate + Ethinylestradiol		
Norgestrel + Ethinylestradiol		

A market survey was also done on use of emergency OCPs in the drug market in Moradabad. Emergency OCP mainly contain progesterone only pill.

Table 3. Emergency OCPs with their brand names

S. No.	Brand Name	Company Name	Pack Size	Active Ingredient & Their Dose	Price (Rs.)
1.	i-pill	Piramel Health Care Pvt.Ltd.	1 mini pill	Levonogestrel – 1.5mg	100
2.	i-sure	Piramel Health Care Pvt.Ltd	1 mini pill	Levonogestrel – 1.5 mg	100
3.	Unwanted -72	Mankind	1 mini pill	Levonogestrel – 1.5 mg	80
4.	Velocit	Dr. Reddy	1 mini pill	Levonogestrel – 1.5 mg	80
5.	My Way	Gavis	1 mini pill	Levonogestrel – 1.5 mg	50
6.	Levonelle	Schering	2 pill	Levonogestrel – 1.5 mg	100
7.	Mirena	Bayer Cadila	1 mini pill	Levonogestrel – 1.5mg	80
8.	i-check 72	Hicks	1 mini pill	Levonigesterol – 1.5 mg	100
9.	Mefiprin	Sunpharma Pvt. Ltd.	1mini pill	Mifepristone – 600 mg	80
10.	Plan-B One Step	Famy Care	1 mini pill	Levonogestrel – 1.5 mg	80

3. RESULTS & DISCUSSION

When a survey was done on the success rate of OCPs (Fig. 1) over other contraceptive methods, it was observed by various gynaecologists that OCPs were very effective in controlling pregnancy. With perfect use, cyclic oral contraceptives are highly effective; 0.3% of women have an unwanted pregnancy when taken perfectly for 1 year. Unfortunately, with typical use the rate rises to 8% of women in 1 year of OCP use. The most common risk with OCPs is imperfect use, typically due to “missed pills.” When pills are missed at start of the pack and the days without active pills are extended, the risk of ovulation may increase. Permanent sterilization methods, implants and IUDs have less than one pregnancy per hundred women in a year, but they are associated with the disadvantage of irreversibility or infections. In comparison to them, OCPs may show 6- 12 pregnancy per hundred women in a year that to when the cases are of missed pills. Otherwise their effectiveness is excellent with very few side effects and reversibility. Mechanical and periodical methods are associated with very high failure rates, ie. 18-20 pregnancy per hundred women in a year and 28- 30 pregnancy per hundred women in a year respectively.

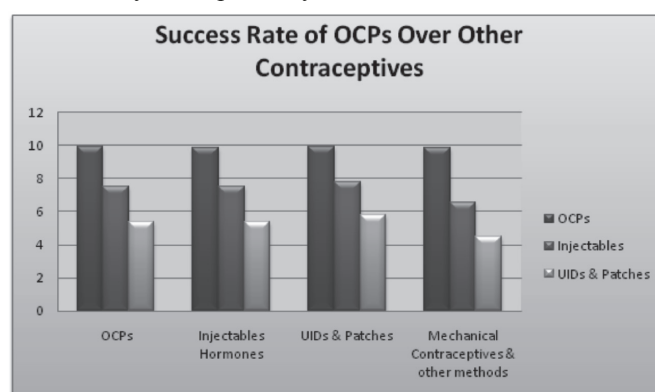


Fig. 1. Success rate of OCPs over other contraceptives

A market survey was also done on the active ingredients preferred for use in formulation of combined OCPs by manufacturing units. The available brands of top most manufacturing units (Table 4) included in the survey are Sunpharma Pvt. Ltd., Bayer Pharma, N.V. Organone, OSS, Cipla, Famy Care and Zydus Healthcare.

Table 4. Combined OCPs with their brand names

S. No.	Brand Name	Company Name	Pack Size	Active Ingredients & their dose	Price (Rs.)
1.	Krimson 35	Sunpharma Pvt. Ltd.	21 Tab	Cyproterone Acetate - 0.035mg Ethinylestradiol - 2 mg	260
2.	Dronis 20	Sunpharma Pvt. Ltd.	24 Tab	Drospirenone – 0.15 mg Ethinylestradiol – 0.03 mg	247
3.	Diane 35	Bayer Pharma	21 Tab	Cyproterone Acetate – 2 mg Ethinylestradiol – 0.035 mg	259
4.	Desogestrel Tab BP Cerazette	N.V. Organone OSS	28 Tab	Desogestrel – 0.15 mg Ethinylestradiol – 0.03 mg	330

5.	Ginette 35	Cipla	21 Tab	Cyproterone Acetate – 2mg Ethinylestradiol – .035 mg	245
6.	Movelon	Famy Care	21 Tab	Desogestrel – 0.15 mg Ethinylestradiol – 0.03 mg	153
7.	Triquilar	Zydus Healthcare	21 Tab	Levonorgestrel – 0.05 mg Ethinylestradiol – 0.03 mg	82
8.	Marvelone 21	Famy Care	21 Tab	Desogestrel – 0.15 mg Ethinylestradiol – 0.03 mg	165
9.	Famodene	Bayer Pharma	21 Tab	Gestodene – 0.075 mg Ethinylestradiol – 0.03 mg	230
10.	Femilon	Famy Care	21 Tb	Desogestrel – 0.15 mg Ethinylestradiol – 0.02 mg	154

The most preferred combination is cyproterone acetate and ethinylestradiol used by about 55% of manufacturing units. Combination of cyproterone acetate and ethinylestradiol is preferred because these two hormones work together to reverse the effects of too much androgen, while at the same time protecting against unwanted pregnancy. The combination of a progestagen (cyproterone) and an oestrogen (ethinylestradiol) in Ginette 35 tablets, provides effective contraception, by blocking ovulation, preventing development of the endometrium so that a fertilised egg would not be able to implant and grow, and preventing the thinning of cervical secretions so that sperm cannot get through. Among the other combinations drospirenone-ethinylestradiol is used by 21% companies, desogestrel-ethinylestradiol used by 9% companies, levonogestrel-ethinylestradiol used by 8% companies and chlormadinone acetate – ethinylestradiol by 7% companies.

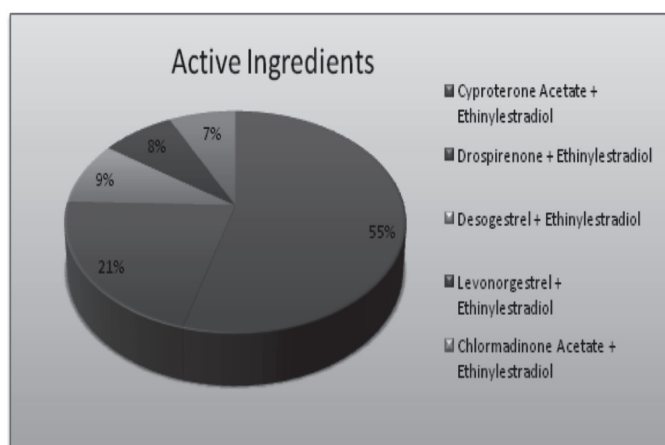


Fig. 2. Preference of active ingredients used to formulate combined OCPs

Progestin-only emergency contraceptive pills reduce risk of pregnancy by about 88%. The different progestins used in OCP are levonorgestrel, desogestrel, norgestimate and gestodene. Among them levonorgestrel is the most preferred one due to its better bio-availability profile. A survey in Moradabad drug

market was done on the brands of emergency OCPs preferred by consumers. Various brands selected for study were i-pill, i-sure, Unwanted -72, Velocit, My Way, Mirena, i-check 72, Mefiprin and Plan-B One Step. As per data provided by medical stores in Moradabad region it was observed that the most preferred brand is i-pill manufactured by Piramal Life Science. Unwanted-72, i-sure, Plan-B one step, My way, i-check 72, Velocit, Levonelle and Mirena are preferred by 17%, 15%, 14%, 11%, 8%, 6%, 5% and 4% respectively. On discussion with doctors and other health care professionals, it was observed that this preference is not associated with any study over the success rates of the drug. As consumers buy them directly from medical stores or on advice by nurses, the brand preference is basically due to the better promotion of drug by pharmaceutical companies. i-pill is marketed with through advertisement on both print media and television which leads to its better consumer awareness, hence making it the preferred brand among other available brands.

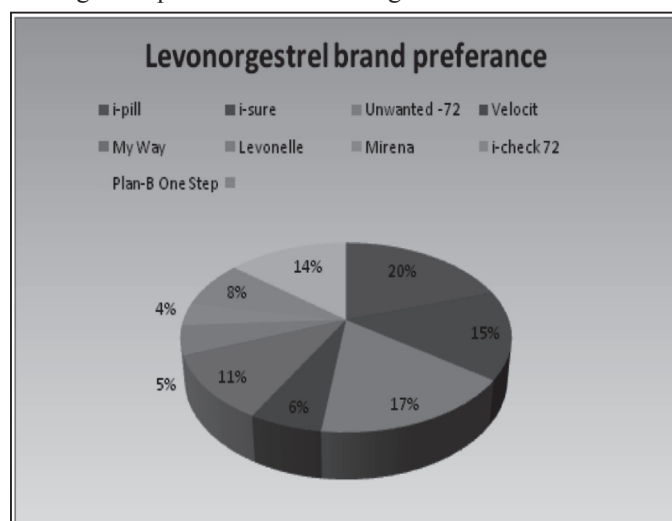


Fig. 3. Emergency OCPs: brand preference

4. CONCLUSION

The above market survey derived some important conclusions about the use of OCPs in Moradabad region. As per gynaecologist's view OCPs were preferred contraceptives over any other method of contraception. This was due to their effectiveness in preventing pregnancy, ease of use, very low side effect profile and additional advantage of preventing various types of cancers in women. Pharmaceutical companies prefer cyproterone acetate and ethinylestradiol combination in their combined OCPs. This is because these two hormones work together to provides effective contraception, by blocking ovulation, preventing development of the endometrium so that a fertilised egg would not be able to implant and grow, and preventing the thinning of cervical secretions so that sperm cannot get through. Emergency OCPs contained progestin that can be used in various forms such as levonorgestrel, desogestrel, norgestimate and gestodene. Among them levonorgestrel is the most preferred one. It was also found that among various brands available as emergency OCPs, i-pill (Piramal Life Science) was the most used brand, probably due to the good advertisement and promotion strategy of the company.

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