

Long Term Follow Up of Women Using Reversible Contraceptive Methods-Conclusions from Combining Data of 3 Different Audits

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Abstract

Objective: The matter of the choice of the available contraceptive methods has increased in the last few years. Physicians have a wide range of contraceptive methods to choose but in the same time are in a big concern about the appropriate type of contraception they should select for their patient and the effects in woman's health and couple's wellbeing. We present the outcome of 3 different audits in a large population of Northern Greece and we discuss the outcome of their results.

Method: Three different audits studied medical data from 14.880 women, of different ages, which presented to the outpatient family planning clinic of our hospital. They were all interviewed using a standardized questionnaire, from which we got important information about behavior, the use, effects and reactions of contraceptive methods. The only exclusion criterion from the study was the use of the pill for less than three months, removal of IUD in less than three months, failure to attend for follow up and women who had moved away from the geographical area. The data of our analysis were retrospectively selected from the case files of 11.129 women between 15 to 40 years old, who used reversible contraception between the years 1984-2011.

Results: In the first audit, 2120 women participated, users of any type of oral contraceptive pills? They gave information about the satisfaction, the side-effects and the main reasons of discontinuing the use of the pill. In the second audit 9009 women chose different types of Intrauterine Devices (IUD) as a contraceptive method. All of them have been examined in outpatient department and they have been checked for the safety of their IUD in correlation with unexpected pregnancy. Data about outcome, side effects and unexpected pregnancies were recorded.

The third audit refers to the concerns about the use of oral sex steroids in relationship with cervical cancer and pathology in smear test. In the IUD group, we had more often results of inflammatory changes, negative for malignancy, in comparison with the contraceptive pill group. There was not statistically significant difference between the two groups regarding low and high grade squamous intraepithelial lesions (LGSIL/HGSIL).

Conclusions: By studying the results of all these audits, we can get some important information about the behavior, the side-effects and ways of improving the usage of all types of reversible contraception. These results can be used as a baseline from which to monitor trends in the use of contraception in correlation to similar studies.

Keywords: Contraception; Oral contraceptives; Intrauterine device; Cervical neoplasms

Introduction

Since 1959, when the first birth control pill was marketed, contraception has been in continuous development. Many types of pills and differently shaped Intrauterine Devices (IUDS) has been launched, fertility awareness methods have been refined and most recently new ways of administering combined hormonal contraception methods have been created [1].

Since its introduction, oral contraception has evolved to provide, on one hand, a range of products in which the dose of estrogen has been gradually reduced to overcome concerns associated with unwanted side effects and on the other hand, products with new progestins [1,2]. The two main intrauterine devices currently used, are copper and levonorgestrel containing devices (Mirena). These devices are chemically active and they have continuous elution of copper or a progestational agent. Both devices induce a local inflammation inside the uterus, leads to lysosomal activation and other inflammatory reactions which are spermicidal. Finally, the endometrium is transformed into a hostile site for implantation. Both have contraceptive but not abortifacient role [2].

The health care provider has to exam carefully the woman and to council her about the best option for her. He has to be able to compare the possible methods of contraception, to discuss the method failure rate (the failure rate inherent in the method if the patient uses it

correctly 100% of the time) and the typical failure rate (the failure rate seen as the method is actually used by patients, that is, factoring in the mistakes in usage everyone will make from time to time). Although efficacy is important in the choice of contraception, we also need to consider the complications, the availability, the cost and the personal acceptability to woman and her partner.

In this paper we present the outcome of three different audits studied randomly selected women, of different ages, in a large population of Northern Greece and we discuss the outcome of their results. We address the side effects, complications and reason for discontinuing the pill or the Intrauterine Device (IUD). We also provide some interesting data regarding the concerns about the use of oral sex steroids in relationship to the pathology in smear tests.

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Materials and Methods

Three different audits studied medical data from 14.880 women, of different ages, who presented to the outpatient family planning clinic of our hospital. They were all interviewed using a standardized questionnaire, from which we got important information about behavior, the use, effects and reactions of contraceptive methods. The available reversible contraceptive methods used in our department apart from counseling for condoms are COP and IUDs. The only exclusion criterion from the study was the users of the pill for less than three months, removal of IUD in less than three months, failure to attend for follow up and women who had moved away from the geographical area. We have counted as different cases those women who opted to change after 6 months from COP to IUD and vice versa. The data of our analysis were retrospectively selected from the case files of 11.129 women who used reversible contraception between the years 1984-2011. There population studied were all native female Greek women living in the city of Thessaloniki. No other demographic or social criteria were used.

In the first audit participated 2120 women between 15 to 40 years old, users of any type of oral contraceptive pills. They gave information about the satisfaction, the side-effects and the main reasons of discontinuing the use of the pill. Follow up was 6 monthly and for at least two years for the participants. In the second audit 9009 women chose different types of Intrauterine Devices (IUD) as a contraceptive method. All of them have been followed up in outpatient department 6 monthly for at least two years and they have been checked for the safety of their IUD in correlation with unexpected pregnancy. Data about outcome, side effects and unexpected pregnancies were recorded.

The third audit practically combined data from the first two audits. The population contained all 11.129 women presented to the family planning outpatient department from 1985 until 2011. The third audit referred to the concerns about the use of oral sex steroids in relationship with cervical cancer and pathology in smear test. So we have analyzed and compared smear test results. We divided the population in two groups. In group A we placed women who used the IUD (n=9009), and group B those who used the contraceptive pill (n=2120). Statistical analysis was performed by using Graph Pad in Stat *Chi-square* test.

Results

The findings of our retrospective study highlight the complications and side effects to the contraceptive pill users and to those who opted for IUD.

The results in the first audit demonstrate that the main side-effects were middle-cycle bleeding spot 13.5%, headache 3.04%, breast tenderness 2.93%, nausea, menorrhagea and emotional discomfort (Figure 1). Hence healthy women without any personal medical history of thrombosis-blood clots or other health risks in general, showed in very high levels to be safe and satisfied with this method of contraception.

In the second audit regarding the IUD users, 77 women had an undesirable pregnancies from which 4 were ectopics, 937 had problems with their menstrual cycle and 312 complained for lower abdominal discomfort. 868 in total had the IUD removed because of personal reasons. In 749 we removed it because women wished fertility and in the rest due to psychological problems mainly stress, anxiety, depression or because of the side effects mentioned above. In 482 women the coil was expelled and in 10 of them it was lost in the endometrial cavity (Figure 2). 77 had an unwanted pregnancy, from which one was first trimester missed miscarriage, and 4 were tubal ectopics.

According to the third audit analysis of the smear test results 780 women (7%) had a LGSIL/ASCUS and 167 women (1.5%) a HGSIL smear. In group A (IUD group) 622 women (6.9%) had a LGSIL/ASCUS and 128 women (1.46%) HGSIL. In group B (COP group) 158 women (7.45%) had LGSIL/ASCUS and 35 (1.65%) had HGSIL. In group A, we had more often results of inflammatory changes, negative for malignancy, in comparison with group B. There was not statistically significant difference ($p=0.3839$) between the two groups regarding intraepithelial lesions LGSIL and no significant difference regarding the HGSIL ($p=0.4092$).

Discussion

Women's contraceptive choices are often based on advice from healthcare providers or from family, friends even from partners. Effectiveness is usually mentioned as the single most important reason for choosing a contraceptive. Therefore, communicating effectiveness of the various methods to the lay person who needs contraception in a manner that is comprehensible is crucial for informed choice. Women demand to know which factors affect contraceptive effectiveness and those that may limit the usefulness of the method. It appears in

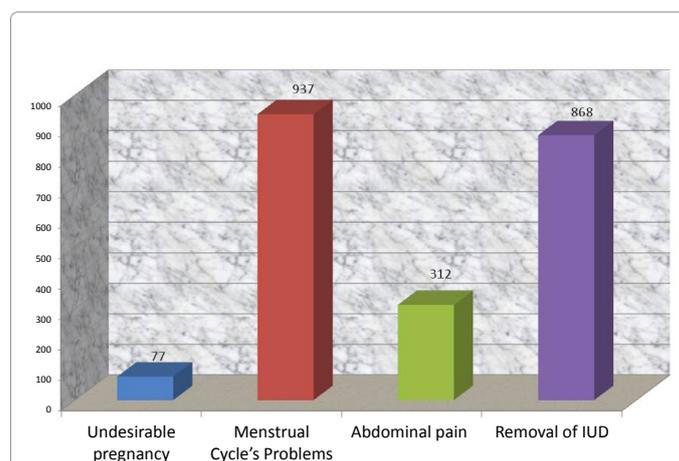


Figure 1: Results of the Usage if Intrauterine Devices During the Period 1983 to 2011.

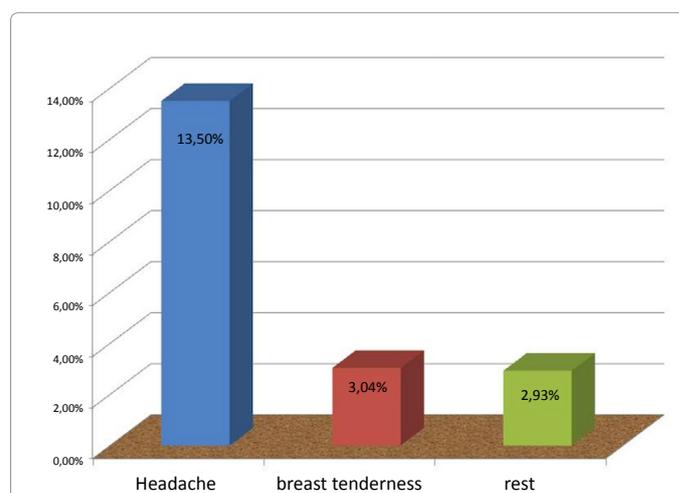


Figure 2: Side effects among users of contraceptive pills.

these interviews, that lack of knowledge about sex and method of contraception, and access to the services of health system, play a major role in unwanted pregnancies. Taking these results in mind, will give the right decision about the choice of contraception method suitable for the woman or the couple [1-3].

The main advantage of our study is that it presents data covering a long period of time, 1984-2001, and a high number of women are included in the analysis. The population studied is in a high way homogenous regarding nationality and geographical origin of living. The weakness is perhaps that we have not subdivided our groups according to social demographic criteria like job, marital status and educational level. According to our first audit, the main side effects for the users of oral contraception were mainly bleeding spot, headache and breast tenderness. However, these side effects do not seem to actually prevent women from the use of contraceptive pills [4,5]. Concerning the side effects of IUDs, the second audit showed that the main issues are undesirable pregnancies, menstrual cycle problems, low abdominal pain and psychological problems. It is crucial to mention, that about 5% of the unwanted pregnancies in IUD users were ectopic, but the percentage in the total population of IUD users, was extremely low. It is also important to underline that about 10% of our study, had the IUD removed because of personal issues. We need to suggest the proper insertion of the IUD inside the endometrial cavity in order to be safe, effective and well tolerated. We can see that women who use copper IUDs have very low rates of dysfunctional carriage. Between them, undesirable pregnancy is low (10%) and out of these pregnancies, ectopic pregnancy is also low (5%) and miscarriage not of important significance (1%) [2,6]. It is a fact that IUD offers greater protection against intrauterine than extrauterine pregnancy, and the relative ratio of extrauterine pregnancy is greater in a woman who uses an IUD than in a woman not using contraception [2,7-9]. A key finding of this audit is that the proper information is given to the women by the medical team, for proper routine examination and self-checking of the position of the IUD. Comparing the complications of the use of IUD and the use of oral contraceptives, we can effort the aspect that the use of the pills is safer than the IUDs. A joint analysis of the previous data, gave us the opportunity to derive our third audit concerning the correlation of cervical alternations in Pap smear in relationship with the contraception method. Our study indicates that it is unlikely that hormonal contraception causes cancer but many other studies showed that there is a protective effect concerning ovarian and endometrial cancer. We have to mention that there are still many conflicting reports concerning the risk of premalignant and malignant changes of

the cervix. Studying the last ones, we can say that the risk of cervical dysplasia and oral contraceptive use, and the risk of cervical cancer increases after five years [10,11]. It is still unclear if these associations have a causal basis because there are many factors who can bias the result, for example HPV virus or the time getting the sample and many others so it is difficult to correlate our result with the incidence of cervical alternations in Pap smear.

Conclusion

By studying the results of all these audits, data can be extracted about the behavior, the side-effects and ways of improving the usage of all types of reversible contraception. These results can be used as a baseline from which to monitor trends in the use of contraception in correlation to similar studies.

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