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Original Article

A study of Prescription of Potentially Teratogenic Medications to the females of Reproductive age group (14-45 years) in Surendranagar

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ABSTRACT

Aim :- The study was conducted to identify the potentially teratogenic medications most frequently prescribed to women of reproductive age group (14-45 years), the specialty of the physicians who prescribes such medications and estimation of contraceptive counseling prescribed to these females of reproductive age group exposed to potentially teratogenic drugs. **Method: -** The data about prescriptions of potentially teratogenic medication and provision of contraceptive counseling was collected in a sample of 400 visits by women of reproductive age group to twenty enrolled doctors in Surendranagar district of Gujarat during August- September, 2006. It was analyzed by SPSS Version (11.5) software by calculating Means and Standard deviation for continuous variable and percentage for categorical variables. **Result :-** This study demonstrated 23% (92 out of 400) of study subjects were prescribed potentially teratogenic drugs (group D and X). Antibiotics were highly prescribed (17 out of 30) among prescribed potentially teratogenic drugs, Surgeons and psychiatrist prescribed potentially teratogenic drugs more frequently than other specialty of doctors. 32 Out of 92 study subjects prescribed potentially teratogenic drugs were advised contraceptive counseling. **Conclusion: -** Doctors' awareness about risk associated with teratogenic drug (group D and X) and importance of contraceptive counseling advice seems low. Group-D drug is prescribed more frequently than group-X among studied prescription.

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1. Introduction

Teratogens are toxic influences on the conceptus which either kill the embryo or produce congenital malformation (structural abnormalities) or derange the different level of biological organization to result in biochemical, physiological or behavioral defects, the drugs with teratogenic potential are called potentially teratogenic drugs [1]. All measures permanent or

temporary designed to prevent pregnancy due to coital act is called contraception [2,3]. The potential of many drugs to cause perinatal harm is well established. This type of effects seen vary and include spontaneous abortion, still births and congenital malformation at birth and conditions detected only months or years after births [4]. Teratogens are of three types e.g. environmental, dietary and medications. As for some conditions equally effective medications that are not teratogenic don't exist, and use of potentially teratogenic drugs is sometimes necessary in treating women of reproductive age group [4]. It has been estimated that about 80 percent women have used either prescribed or over the counter drugs [5]. Most medications given in the pregnancy are for the benefit of the mother and the fetus is unintended recipient. Drugs taken by the pregnant women may pass to the fetus via the placenta and may have pharmacological effect on the fetus [6].

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Prior studies have found that women and their partners are concerned that use of a medications during pregnancy may result in birth defect [7-9]. One of the most common reason women contacts a teratogenic counseling hotline is concern about use of a medications early in pregnancy [10]. Because some women choose to terminate pregnancy exposed to teratogens, even when the absolute risk of defect is low; inadvertent exposure of pregnant women to teratogens may cause hardship even when it does not result in birth of a disabled child [11]. According to US Food and Drug Administration (FDA) drug classification system (1979), drugs in class A are those medications for which there is no evidence of fetal harm in studies of humans; drugs in class B are those for which animal studies have not demonstrated fetal risk; class C demonstrated drugs for which adequate studies are not available; class D are drugs for which there is evidence of fetal risk and require cautions during pregnancy; class X are drugs those are contraindicated in women who are or may become pregnant [11].

India has higher infant mortality rate [63 per 1000 in a year] [12]. Hospital based studies showed that 2.5% of new born have a birth defects and figure may rise up to 4% if the children are followed for 5 years and it ranks as third most common cause of perinatal mortality [13,14]. The exact cause of birth defect is generally unknown, although teratogenic potential is known to underlie some birth defects.

In affluent countries bulk of information is readily available but in developing countries like India there is dearth of knowledge on these types of teratogens.

This study was held to estimate most frequently prescribed potentially teratogenic drugs, specialty of doctors who commonly prescribe such type of medications to the females of reproductive age group (14-45 years) and Estimation of contraceptive counseling provided to the subjects while being prescribed such medications.

2. Materials and Methods

A cross sectional study conducted at Surendranagar, Gujarat during August 1, 2006 to September 30, 2006. The study subjects defined as females of reproductive age group (14-45 yrs.) visiting the doctors attached to Private clinics, Trust hospitals, Government hospitals and Teaching hospitals for their own health. 400 patients were enrolled through Convenience sampling method from 20 doctors (5 from each category). After taking the informed consent (either from patient or her attendant) we have interviewed through pretested semi-structured Proforma to collect the data of potentially teratogenic medications. Descriptive statistical analysis was done through SPSS (Version 11.5) software by calculating means and Standard Deviation for continuous variable and percentages for categorical variables.

3. Results

Of the 400 study subjects, 92 (23%) were prescribed potentially teratogenic drugs (Table- I), in these subjects about 30 potentially teratogenic drugs were prescribed and antibiotic group was claiming the pie square, followed by anticonvulsants and anxiolytics (Table-II). The minimum and maximum age of the respondents was 15 years and 44 years respectively. Majority (93%) of the subjects were living with their husband .At the time of

data collection only 9% study subjects were pregnant (Table-III).Eighty percentage of prescribers were highly qualified and from them study enrolled the subjects. The attachment of the prescribers was equally distributed in four categories of hospitals (Table-IV).Of the 400 study subjects 42% were already using contraceptives, while prescribers provide contraceptive counseling to only 12% of them (Table-V).60.86% of study subjects were prescribed potentially teratogenic drugs by Surgeons, Gynecologist and Psychiatrist (Table-VI).

Descriptive Analysis

Table-I: Descriptive statistics of potentially teratogenic drugs.Prescribed by doctors to the study subjects

Class of drug ^{a)}	Number (n=400)	%
Class-A	48	12.00
Class-B	276	69.00
Class-D	92	23.00
Class-X	00	00.00

a) Class of drugs according to the US Food and Drug Administration (FDA).

Class-A: Drug for which no evidence of fetal harm in studies of human.

Class-B: Drug for which adequate studies are not available.

Class-D: Drug for which there is evidence of fetal risk.

Class-X: Drug which are contraindicated in pregnancy.

Table-II: Different types of potentially teratogenic drugs prescribed to study subjects

Type of drugs	Number ^{a)}	% ^{a)}
Anxiolytics	08	34.78
Antibiotics	17	73.91
Anticonvulsants	05	21.73
Others ^{b)}	00	00.00

a) Number and percentage may not equal to 92 and 400 respectively because some doctors prescribed more than one drugs to study subjects

b) All drugs of groups of D and X expect anxiolytics, antibiotics and anticonvulsants

Table III: - characteristics of the Respondents

Variable	Number (n=400)	% ^{a)}
Age (yrs.)	29.6±7.09	
Marital status		
Married	372	93
Unmarried	28	07
Pregnancy status		
Pregnant	36	09
Non Pregnant	364	91
Living with husband		
Yes	372	93
No	28	07

Table IV:- Details of prescribers (Teratogenic drugs)

Variable	Number (n=20)	%
Specialty	04	20
MBBS		
Other doctors		
(Highly qualified specialist)	16	80
Attachment of doctors (Hospitals)		
Government	05	25
Trust	05	25
Teaching	05	25
Private	05	25

Table V:- Details of contraceptive counseling and status

Variable	Number	%
Contraceptive counseling		
Yes	48	12.00
No	352	88.00
Current use of contraceptive Method.		
Yes	168	42.00
No	232	58.00
Type of contraceptive method (n=168) ^{a)}		
Barrier	16	09.52
Intrauterine device	84	50.00
Hormonal	20	11.90
Sterilization	48	28.57
Type of contraceptive advised (n=48) ^{b)}		
Barrier	32	66.66
Intrauterine device	08	16.66
Hormonal	04	08.33
Sterilization	04	08.33

- a) The number and percentage are of study subjects currently using contraceptive method.
 b) The number and percentage are of study subjects advised contraception.

5. Discussion

From available standard data prescribers seem to provide contraceptive counseling to very few of women receiving potentially teratogenic drugs. This study reports overall 12% contraceptive counseling has been done on such women is consistent with other study [11]. This study also reports that 23 percent reproductive age group female were prescribed potentially teratogenic drugs is consistent with study by Schwartz EB, et al 2005.

Although anticonvulsants are associated with structural deformities, in this study these are less prescribed drug group. Results show there is significant differences in advice of contraceptive counseling to the study subject prescribed and not prescribed potentially teratogenic drugs (chi-square test). But still it left more than 50% of women to be exposed to potentially teratogenic drugs without any contraceptive counseling.

Limitation:-As we don't have complete information on dose and duration of prescribed teratogenic drugs; although we have a question for it in our Proforma but we are unable to collect information on these, partly because of inappropriate information written in prescription by doctors and some patients may visit next time to the doctor. It is a cross sectional study so we are unable to predict cause and affect relationships. In Indian culture now it is not so uncommon for unmarried females to be with child before marriage. Unmarried women were kept in the study because some females may require drugs for longer duration for their illnesses, which may have carry over effects, during this period they may get married and be with child. Information of women's desire to conceive was not available. Study did not determine whether prescribed potentially teratogenic drugs were new or long time prescription (already prescribed) and whether study subjects received contraceptive counseling in her previous visit. Women with chronic illnesses who have frequent contact with physician and who are following up with a doctor they have seen before may be more likely to have received contraceptive counseling in previous visit.

Table-VI: Doctors prescribing potentially teratogenic drugs and contraceptive counseling to study subjects

Variable	Total study subjects (n=100)	Number of study subjects prescribed potentially Teratogenic drugs n=92 (%a)	Contraceptive counseling n=32
Specialty			
Physician (MBBS)	92	16 (17.39)	04
Physician (MD)	76	12 (15.78)	00
Surgeon (MS)	60	16 (26.66)	08
Gynecologist (MD/DGO)	92	20 (21.73)	16
ENT Surgeon (MS)	32	08 (25.00)	00
Psychiatrist (MD)	48		
Category of doctors ^{b)}		20 (19.23)	04
Category-I	80	20 (25.00)	04
Category-II	100	20 (20.00)	04
Category-III	112	28 (25.00)	16
Category-IV	108	24 (22.22)	08

a) No. in the brackets () show the % of study subjects prescribed potentially teratogenic Drugs.

b) Category of doctors according to their attachment
 Category-I : Private hospitals
 Category-II: Trust hospitals
 Category-III: Government hospitals
 Category-IV: Teaching hospitals

6. Conclusion

Study shows that doctors have inappropriate awareness about teratogenic medication and contraceptive counseling. Very low proportions of study subjects who were prescribed potentially teratogenic drugs were advised contraceptive counseling.

Antibiotics were most frequently prescribed among potentially teratogenic drugs.

Surgeons prescribed most frequently potentially teratogenic drugs.

Suggestions:-On the basis of study result and conclusions it is strongly suggested to increase the awareness among doctors about potentially teratogenic drugs through seminars workshops and continuing medical education (CME). Knowledge and consciousness about potentially teratogenic drugs and contraception should be increased among general population through health education. More research and clear guidelines for use of potentially teratogenic drugs and to find out their better alternatives are required.

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