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## Market Survey of Abortifacients to Explore Unethical Issues

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### ABSTRACT:

The aim of the study was to explore unethical issues of abortifacients used in the market of Rajkot city in Gujarat. A prospective market survey study involving retailers, wholesalers and doctors (M.D.-Gynec) were selected in Rajkot city located in different areas. They were explained about the objective of the study and given a validated questionnaire. The questionnaire included the questions regarding most commonly used allopathic and ayurvedic abortifacients (abortion pills), % sale of allopathic verses ayurvedic drugs, % sale of drugs on prescription, degree of doctors prescribe the abortion medicines, age factor of patients, sale data in respect of month, most commonly side effects seen in patients due to usage of self medicated abortion pills, number of self medicated patients comes for treatment per month etc. This study highlights commonly used self medicated abortifacient drugs in the patient with marital status and age which gives many types of serious side effects. As per doctors opinion that ayurvedic abortion pills are not effective in the process of abortion. While in market survey ayurvedic abortion pills are more used than the allopathic abortion pills by patients. Hence detailed and scientifically designed research on ayurvedic abortifacients for its effectiveness in the abortion process and to discover the seriousness of side effects occurred on the usage of self medicated abortifacients by general public to save the public health is highly required.

**KEY WORDS :** Abortifacients, self medication, Misoprost-200 tablet, Menstrojek Forte capsule, Rajkot.

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### INTRODUCTION:

Now a days due to change in life style of young generation, misuse of Emergency Contraceptive Pills and Abortion pills are a one of the major problems of the society. In present time various advertisements are comes in media to secure the illegal sexual relationship from the pregnancy. Various newer medicines are available with very high dose of drug stated above in respect of 10 times more quantity of drug than the earlier preparations. Now a days "i-pill" manufactured by M/s Cipla Ltd and "UNWANTED-72" manufactured by M/s Unicure (India) Pvt. Ltd are the highest selling brands as a emergency contraceptive pills in the market used frequently by the young generation without any knowledge and adverse reaction-side effects of the drugs. These both brands having "Levonorgestrol IP.....1.5 mg" which is 10 times more than the earlier pills like Mala-D and Choice pills having formulations approved in the Schedule 'K' of the Drugs & Cosmetics Act and Rules there Under.<sup>[1]</sup> In respect of cost factor earlier pills like choice having 28 pills packet at a Rs 10/- price. While newly branded drugs like "i-pill" having one pill packet at a Rs 100/- price and "UNWANTED-72" having one pill packet at a Rs 80/- price. These all are non schedule formulations not requiring any prescription of the doctor and no government price control. Hence manufacturing company of this type of drugs is freely advertising their products in media to misguide the young populations.

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At present Government of India make a strict vigilance on the Abortion procedure under the Medical Termination of Pregnancy Act 2002 & Rules 2003 there under. Only Government approved MTP centers do the abortion activity.<sup>[2]</sup>

Various allopathic Abortion Pills containing schedule formulations requiring doctor prescription like “MT Pill Kit”, “Unwanted Kit” having Mifepristone & Misoprostol as an active ingredients used frequently buy without prescription for abortion by young generation to terminate the pregnancy after illegal sexual relationship. “MT Pill Kit”, “Unwanted Kit” like formulations having a MRP Rs.499/- which is supplied to retailers by a manufacturing company on a subsidize rate like a Rs 60/- to 65/- only. Hence for selling of this type of product no marketing is required the manufacturers and on other side due big profit most of the retailers are pushing this product easily in the market resulting easy availability of the product for the self medication. All allopathic drugs label contains following type of warning are printed as per the Government rules and regulations.<sup>[3]</sup>

Schedule ‘H’ drug: Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only.

Warning: Product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003.

Warning: Misoprostol is contraindicated in pregnant woman and also in those women who are going to be pregnant in short period of time.

Many other ayurvedic capsule preparations are also available in the market which is widely used in the urban and rural area for abortion purpose. All ayurvedic preparation containing following type of warning is printed on the label.<sup>[4]</sup>

Dosage: As prescribed by the physician.

Warning: Not to be given during pregnancy.

In spite of this most of the allopathic and ayurvedic abortion pills are to be used without any consultation of doctors. Various types of side effects were seen after self medicated use of abortion pills which is shown earlier.

Government has banned the formulation contains fixed dose combination of crude ergot preparation and fixed dose combination of oestrogen and progestin for some extent in past.<sup>[5][6]</sup>

Government of India plans for new norms for the advertisement of emergency contraceptive pills due to rate of misuse of product is very high in India.<sup>[7]</sup> A public Interest Litigation was filed by the Hyderabad resident Shri C.S.Ranga Rajan against Drug Controller General of India (DCGI) in the Andhra Pradesh High Court for seeking ban on marketing of contraceptive pills. Andhra Pradesh High Court issues notice to DCGI on emergency contraceptive pills issue. DCGI replies for it but no fruitful out comes seen till date for the restriction of advertisement and restriction of sale by a law.<sup>[8]</sup>

Termination of pregnancy has been practiced since the time immemorial. Most widely used methods for terminating pregnancy in first trimester are surgical, primarily suction evacuation. An estimated 26 million pregnancies are terminated legally throughout the world, and 20 million are terminated illegally, with more than 78,000 deaths. In India alone 10-12 million abortions take place annually, resulting in 15-20 thousand maternal deaths, mainly due to illegal abortions.<sup>[9]</sup> Non availability of trained medical help and the unwarranted secrecy surrounding the unwanted pregnancy often force women to go for illegal abortion which may be fatal at times.<sup>[10]</sup>

Due to above observations it is seen that in today’s market present scenario shows that most of the ayurvedic and allopathic abortifacient drugs are used by way of self medication without any consultation of doctors. Hence it is necessary to check the usage trends of abortion pills in the market to reduce the self medication of abortion pills for the betterment of public health.

In general survey of the doctors (M.D.-Gynecologist) it is seen that they are not confident about the result of ayurvedic abortion pills. Whether its works in a limited times or not? Generally most of the retailers are sell an ayurvedic abortifacient drug at first time. If a required result was not obtained then they are go for allopathic abortifacient pills secondly. This is very serious practice to play with human life. Hence it is decided that medicated abortion which is generally effective between 24 to 60 days of gestation.<sup>[11][12]</sup> In this short time period today’s most commonly used ayurvedic abortifacient pills are really effective or not? Otherwise it makes a very dangerous condition in the life of pregnant woman.

It is generally observed that woman who takes an abortion pills for abortion by way of self medication having very serious types of side effects than a woman who take an abortion pills for abortion under guidance and direct supervision of doctors.<sup>[13][14][15][16]</sup> This situation is occurred due to lake of knowledge about the health situation and abortifacient drugs. Hence it is decided to do clinical study on the self medicated women verses doctor treated woman for abortion in respect of side effects.

Due to above observations it is seen that Government interested in birth control, Public interested in illegal abortion and Businessman interested in big profit, a worst condition is developed in the present scenario. Hence it is necessary to study on the misuse of various type of abortion inducing pills which is directly affect the women health in future days of life by market survey study involving chemist (retailers and wholesalers) and Gynecologist of the Rajkot city of the Gujarat state is selected for this study.

### **Material and Methods**

#### **Design:-**

A prospective market survey study involving retailers, wholesalers and doctors (M.D.-Gynec) of Rajkot city were carried out in the month of May-June 2012.

#### **Subjects:-**

Ten retailers, three wholesalers and five doctors (M.D.-Gynec) of the Rajkot city were selected for the test case study on the self medicated abortifacients.

#### **Methods:-**

The retailers, wholesalers and doctors were explained the objective of the study and given a validated questionnaire.

#### **Outcome Measures:-**

The questionnaire included questions like which three allopathic abortion pills are highest selling brand in the market, which three ayurvedic abortion pills are highest selling brand in the market, % sale of allopathic verses ayurvedic abortion pills, how many customers repeatedly demands this type of medicines, how many % allopathic drugs to be sold in the prescription of doctors, qualification of doctors who wrote a prescription of allopathic abortion pills, gender % of customers, % marital status of customers, % age break up of female customers, month wise sale data of abortion pills from wholesalers, age fraction of patients comes for the treatment due to self medication of abortion pills, % marital status of patients, most commonly used three brands

of allopathic abortion pills in self medicated patients, most common side effects seen due to self medication, ratio of self medicated patients verses doctor treated patients, number of self medicated patients comes for treatment per month, number of patients cases for serious type of side effects, opinion of doctors for the effectiveness of ayurvedic abortion pills etc.

### **RESULTS :-**

From bellow observations it is concluded that

1. Allopathic drug Misoprost-200 tablet, MTP kit, Unwanted kit and Ayurvedic drug Menstrojek Fort Capsule, Em.P.Forte capsule, Ruta Forte capsule are the top most selling brand in Rajkot city market for self medicated abortion.
2. Ayurvedic drugs are more used than the allopathic drugs in self medicated abortions.
3. 90% young generation is selected emergency contraceptive pills than abortion pills.
4. More than 50% allopathic drugs to be sold without prescription of doctors.
5. All ayurvedic drugs are to be sold without any prescription and consultation of ayurvedic doctors.
6. More than 60% customers purchased abortifacient drugs are male.
7. Misoprost-200 tablet is a most leading salable brand confirmed by the sales data of wholesalers.
8. Nearly 75% self medicated abortifacient drugs consumed by ladies age between 20 to 30 years.
9. Due to misusage of self medicated abortifacient drugs, most commonly side effects seen in patients like a severe bleeding retained products, abdominal muscle cramping, diarrhea, nausea, vomiting, vaginal infection, dizziness, headache etc.
10. Numbers of self medicated abortion patients are higher than the doctor treated medically terminated pregnancy (MTP) patients.
11. As per doctors (M.D.-Gynec) opinion that ayurvedic abortifacients are not effective in the process of abortion.

**Tabel 1.Data collected from the 10 retailers of the Rajkot city.**

Sr no	Top selling brnds (Allo.)	Top selling brnds (Ayu.)	% sale Allo./ayu	% of repeat patient	% sale on prescription	Qualification of Doctor	% Gender ratio Male/Female	% of Unmarried/Married	% Age break up
1	1.Mifegest Kit Unwanted Kit 3.MT pill	1.Menstrojek Forte 2.Em.p.Forte cap. 3.DyFot Cap.	80%/20%	10%	10%	M.D.-100%	95%/5%	20%/80%	20-30=80% 30-40=20%
2	1.MT Pill 2.Misoprost 200 3.MTP kit	1.Menstrojek Forte 2.RutaForte cap. 3.Em.P.Forte Cap.	30%/70%	10%	10%	M.D.-30% B.H.M.S.-40% D.H.M.S.-30%	70%/30%	10%/90%	20-30=80% 30-40=20%
3	1.Misoprost 200 2. Unwanted Kit 3.MT pill	1.Menstrojek Forte 2.Em.p.Forte cap. 3.Ruta Forte Cap.	60%/40%	5%	70%	B.H.M.S.-50% D.H.M.S.-50%	50%/50%	10%/90%	20-30=80% 30-40=20%
4	1.Unwanted Kit 2. Misoprost 200 3.Cytolog tablet	1.Ruta Forte cap. 2.Menstrojek Forte 3.menstro Cap.	20%/80%	5%	80%	M.D.-100%	30%/70%	20%/80%	20-30=80% 30-40=20%
5	1.Misoprost 200 2. MTP Kit 3.Unwanted Kit	1.Gyano cap. 2.Menstrojek Forte 3.Hurry Cap.	40%/60%	10%	15%	M.D.-100%	75%/25%	10%/90%	20-30=50% 30-40=50%
6	1.MTP Kit 2. MT Pill 3.Misoprost 200	1.Em.P.Forte cap. 2.Menstrojek Forte 3.Ruta Forte Cap.	60%/40%	2%	50%	M.B.B.S.-20% M.D.-60% B.H.M.S.-10% D.H.M.S.-10%	80%/20%	5%/95%	20-30=70% 30-40=30%
7	1.Cytolog tablet 2. Misoprost 200 3.MTP Kit	1.Menstrojek Forte 2.Nc Norm C.P.cap. 3.	20%/80%	5%	100%	M.D.-100%	80%/20%	0%/100%	20-30=Nil 30-40=100%
8	1.MTP Kit 2. MT Pill 3.Misoprost 200	1.Menstrojek Forte 2.Em.p.Forte cap. 3.Ruta Forte Cap.	60%/40%	5%	90%	M.D.-100%	70%/30%	10%/90%	20-30=70% 30-40=30%
9	1.MTP Kit 2.Misoprost 200 3.Unwanted Kit	1.Menstrojek Forte 2.Ruta Forte cap. 3.Em.P.Forte Cap.	70%/30%	5%	30%	M.D.-100%	50%/50%	10%/90%	20-30=80% 30-40=20%
10	1.Misoprost 200 2. Unwanted Kit 3.MT pill	1.Menstrojek Forte 2.Em.p.Forte cap. 3.Ruta Forte Cap.	30%/70%	10%	50%	M.B.B.S.-50% B.H.M.S.-25% D.H.M.S.-25%	80%/20%	10%/90%	20-30=80% 30-40=20%

**Table 2. Data collected from 3 Wholesalers of Rajkot City**

sr.no.	Name of Brand	4/11	5/11	6/11	7/11	8/11	9/11	10/11	11/11	12/11	1/12	2/12	3/12
1	Misoprost-200 Tablet	74	90	112	163	140	101	107	143	148	130	122	120
2	Misoprost-600 Tablet	75	5	65	16	1	7	15	3	14	21	24	29
3	Unwanted Kit	119	84	99	70	91	91	70	76	91	56	42	63

• Note: sales figure shows quantity in strips/kits.

**Table 3. Data collected from the 5 Doctors (M.D.-Gynec) of the Rajkot city.**

Sr. No .	% Age ratio of patient	% of patients Unmarried/Married	Top brands used by patients	Top most side effects	Self medicated/M TP patient ratio in10	Self medicated patients per month	Serious Side Effects in last 3 years	Are ayurvedic abortifacients effective
1	Below 20=40 20-30=50 30-40=5 More than 40=5	10%/90%	1.Mifegest kit 2.Mifeprin kit 3.MTP kit	1.retained products 2.bleeding 3.abdominal muscle cramping 4.diarrherea 5.nausea 6.vomiting 7.fever/chills	8/10 2/10	15	1.Death=1 2.Ectopic Pregnancy=3 3.Hypotension=4 4.Blood Transfusion=4	No
2	Below 20=10 20-30=40 30-40=15 More than 40=20	10%/90%	1.Mifegest kit 2.Mifeprin kit 3.MTP kit	1.bleeding 2.retained products 3.vaginal infection 4.diarrherea 5.nausea 6.vomiting 7.abdominal muscle cramping	6/10 4/10	8	1.Death=0 2.Ectopic Pregnancy=0 3.Hypotension=0 4.Blood Transfusion=0	No
3	Below 20=10 20-30=80 30-40=8 More than 40=2	25%/75%	1.Mifegest kit 2.Mifeprin kit 3.MTP kit	1.bleeding 2.abdominal muscle cramping 3.fever/chills 4.dizziness 5.nausea 6.vomiting 7.headache	4/10 6/10	10	1.Death=1 2.Ectopic Pregnancy=5 3.Hypotension=10 4.Blood Transfusion=10	No
4	Below 20=20 20-30=40 30-40=30 More than 40=10	10%/90%	1.Mifegest kit 2.Mifeprin kit 3.MTP kit	1.bleeding 2.abdominal muscle cramping 3.diarrherea 4.retained products 5.headache 6.nausea	7/10 5/10	20	1.Death=0 2.Ectopic Pregnancy=2 3.Hypotension=5 4.Blood Transfusion=2	No
5	Below 20=30 20-30=25 30-40=15 More than 40=10	12%/88%	1.Mifegest kit 2.Mifeprin kit 3.MTP kit	1.bleeding 2.abdominal muscle cramping 3.retained products 4.vaginal infection 5.nausea 6.vomiting 7.dizziness	5/10 4/10	30	1.Death=0 2.Ectopic Pregnancy=5 3.Hypotension=5 4.Blood Transfusion=5	No

**Discussion :-**

On above market survey results shows that ayurvedic abortion pills are more used by the general public than the allopathic abortion pills. On other side doctors opinion (M.D.-Gynec) shows that ayurvedic abortion pills are not effective in the process of abortion. It is scientifically proved that all type of abortifacients is effective between 24 to 60 days of gestation. In this short time period today's most commonly used ayurvedic abortifacient pills are really effective or not? Otherwise it makes a very dangerous condition in the life of pregnant woman. Hence it is necessary to carry out laboratory scale study on animals to check the effectiveness of ayurvedic abortifacients in the process of abortion.

It is observed in the above results that various types of side effects is seen by the way of taking self medicated abortifacients. Generally it is observed that woman who takes an abortion pills for abortion by way of self medication having very serious types of side effects than a woman who take an abortion pills for abortion under guidance and direct supervision of doctors. This situation is occurred due to lake of knowledge about the health situation and usage of abortifacient drugs. Hence it is necessary to do clinical study on the self medicated women verses doctor treated woman for abortion in respect of side effects. Outcomes will be very helpful to the public awareness for betterment of human health.

**References :-**

1. Drugs & Cosmetics Act 1940 and Rules there under.
2. Medical Termination of Pregnancy Act 2002 & Rules 2003
3. Label-Carton warning on Unwanted Kit manufactured by M/s Mankind Pharma Limited, New Delhi.
4. Label warning on Menstrojek Forte Capsule manufactured by M/s J.K.Pharmaceuticals, Rajkot.
5. "Fixed dose combinations of crude Ergot preparation except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headache." G.S.R. No. 304 (E) dt.07-06-1991
6. " Fixed dose combination of Oestrogen and Progestin (other than oral contraceptives) containing per tablet Estrogen content of more than 50 mcg (equivalent to Ethinyl Estradiol) and Progestin content of more than 3 mg (equivalent to Norethisterone Acetate) and all fixed dose

combination injectable preparations containing synthetic Oestrogen and Progesterone. G.S.R. No. 863 (E) dt.22-11-1985 (Subs. By Noti. No.743 (E) dt. 10-08-1989)"

7. <http://www.pharmabiz.com>
8. <http://www.drugscontrol.org>
9. Kumar S, Parikh H, Sarkar S, Induction of labour with Misoprostol-prostaglandin E1 analouge. MJAFI 2001; 57(2), 107-9.
10. Spitz IM, Bardin CW, Benton L, Robbins A., Early pregnancy termination with Mifepristone and Misoprostol in the United States. N Eng J Med 1998;338:1241-7.
11. Bartley J, Brown A, Elton R, Baird DT (October 2001). "Double-blind randomized trial of mifepristone in combination with vaginal gemeprost or misoprostol for induction of abortion up to 63 days gestation". Human reproduction (Oxford, England) 16 (10): 2098–
12. Kathy Simmonds, Susan Yanow, *Use of Misoprostol for Self-induced Abortion Around the World*.
13. Thapa SR, Rimal D, Preston J (Sep 2006). "Self induction of abortion with instrumentation". Aust Fam Physician 35 (9): 697–8. PMID 16969439.
14. Sage-Femme Collective, *Natural Liberty: Rediscovering Self-Induced Abortion Methods* (2008).
15. Khokhar, A.; Gulati, N. (2000). "Profile of Induced Abortions in Women from an Urban Slum of Delhi". Indian Journal of Community Medicine (Chandigarh, Republic of India: Indian Association of Preventive & Social Medicine) 25 (4): 177–80. ISSN 1998-3581. OCLC 60622662. <http://medind.nic.in/iaj/t00/i4/iajt00i4p177g.pdf>. Retrieved 2009-07-11.
16. Rod Flower; Humphrey P. Rang; Maureen M. Dale; Ritter, James M. (2007). Rang & Dale's pharmacology. Edinburgh: Churchill Livingstone. ISBN 0-443-06911-5.

