

## PREFERENCES OF WOMEN FOR USE OF INTRA VAGINAL MEDICATIONS

ARATI JOGLEKAR, C. T. RHODES, MICHELE DANISH.

DEPARTMENT OF PHARMACEUTICS, UNIVERSITY OF RHODE  
ISLAND, KINGSTON, R. I. 02881.

### INTRODUCTION :-

Pharmaceutical dosage forms introduced specifically into the vagina are surprising few in number. They are, usually, only used for the treatment of specific gynecological diseases. The potential of the vaginal route of drug delivery appears to have been explored only to a limited extent. In 1988, the German pharmaceutical industry registered 10853 drugs out of which only 98 were for vaginal applications. There is a sound understanding of the principles of rectal drug delivery. Many comprehensive studies dealing with local or systemic action of active substances from rectal therapy have been published ( 1, 2, 3 ). However, scientific knowledge about the possibilities of local or systemic therapy using the vaginal route is relatively poor. It could be said that the design of many galenical preparations for vaginal applications may be obsolete and this is caused mainly because knowledge about rectal therapy has been unthinkingly transferred to vaginal preparations. It is not realised that this gynecological area has its own, completely different milieu and pharmacological peculiarities.

There are prescription as well as non- prescription (OTC) drugs available for vaginal therapy. The OTC preparations

include vaginal contraceptives, vaginal cleansing and deodorant products, topical antipruritics, anesthetics and lubricants. Nonprescriptive vaginal contraceptives work primarily as spermicides and as mechanical barriers to prevent sperm from entering the cervix and uterine cavity. If used properly, all vaginal spermicides are probably effective. Patient acceptance and compliance determines the actual product effectiveness.

The routine use of some vaginal products such as douches and deodorants, by healthy women is controversial. Few OTC douches are medicinal and the use of douches may delay patients from seeking proper medical treatment. The FDA has classified deodorant sprays as cosmetic rather than 'hygienic' products. Irritation is the most common adverse effect and is caused by overuse and application to previously inflamed surfaces. The usefulness of topical antipruritics and anesthetics in relieving vulvar pruritis is limited and treatment for a serious underlying disorder may be delayed because of inappropriate use of these products. Though the preparations are generally safe, allergic reactions may occur. However, lubricants are useful to treat dyspareunia from excessive dryness and do not appear to have serious side-effects.

These OTC products can provide safe, convenient and effective treatment for a variety of gynecological disorders. Since OTC products may be purchased in various retail settings including grocery stores- infact only 46 % are purchased in pharmacies ( 4 ) - the patient may not come in contact with a health professional to provide guidance in product selection and use. Much of the information the patient receives about OTC products comes from commercial advertisements, which are sometimes misleading, or family members and friends whose knowledge may be incomplete. Present laws do not require manufacturers to list the concentration or quantity of each ingredient in OTC products. Thus this information is not readily available to consumers.

Vaginal infections are bacterial, fungal and viral, various prescribed drugs are available such as antibacterial, antifungal and antiviral agents. Nystatin, imidazole drugs ( econazole and metronidazole ) are commonly used. Various formulations

available for intravaginal therapy include tablets, creams, suppositories, pessaries, foam, solution, ointment, gel and capsules.

It is generally considered that the main function of the vagina relates to conception. The literature contains numerous useful studies of the utility of the intravaginal route for administration of various contraceptives. Thus, Chi and his coworkers have published the results of an international, multi-center trial of the vaginal contraceptive sponge and Neo Sampooon tablets ( 5 ). However, at present the literature appears to be pauce on the subject of the attitudes of females in the United States towards the use of intravaginal drug delivery. The objective of this study was to evaluate the acceptability of this type of product. Clearly however effective the intravaginal route may be if there is substantial prejudice against its use the market for intravaginal products, especially OTC's, would be limited.

#### **METHOD :-**

A questionnaire was designed ( see appendix 1 ) and was administered to 185 women. The respondents consisted of students, staff and faculty of University of Rhode Island, and other Rhode Island residents.

Each participant was approached and asked to complete the questionnaire in the presence of the investigator. Responses were collected from 4 age groups: 18-25 years, 26-35 years, 36-45 years and 45+ years. The questionnaire was designed to divide the respondents as per age groups and as per educational levels. The questionnaire included questions regarding the use of tampons and intravaginal medications, the reservations about using tampons and intravaginal medications, the frequency of prescribing these medications, the tendency of completing the prescribed therapy and willingness to use intravaginal medications if they have not been used previously.

The SAS statistical software package was used to analyze the data. Results were evaluated by non- parametric statistics at the 95 % confidence level ( 6 ).

## RESULTS AND DISCUSSION :-

About 47 % of sample consisted of college educated group, 84 % of women had not undergone hysterectomy, 19 % of sample size was postmenopausal, the average age at which most women had their first period was 12- 14 years.

The survey showed that 82 % of the survey respondents had used tampons. Out of this 78 % used them every month. When asked if they have any reservations about using tampons, 31 % answered 'yes'. The reasons expressed for not wanting to use tampons were many. The most frequent reason was fear of toxic shock syndrome. 42% of women said that they were worried about toxic shock syndrome. 13% of women found it uncomfortable and thought that tampons restrict movements. 7% of women were concerned about chemicals and deodorants used in the tampons. 7% of women thought that tampons do not have adequate absorbancy whereas 7% thought that they absorb natural body fluids excessively. 9% of women were concerned about infections caused by tampons and 4% feared that pieces would come off and would remain inside. 5% of women found it difficult to remove the tampons after use.

In addition to tampons, almost 50 % of women had used intravaginal medications. The majority of positive responses (64%) comes from the age group of 26-35 years and the least (36%) from the age group of 18-25 years. The survey has shown that creams have been prescribed for most of the cases ( 44.57 % ). Next came the suppositories ( Appendix 2 ). It was seen that for first three age groups, 60 % of the time or more, intravaginal medications were prescribed only once in life time. Whereas for age group of 45 + years, they were prescribed for more than six times a year in 50 % of the cases ( Appendix 3 ). Though most of the women did fill their prescriptions, about 22 % of women did not. Of these women who filled their prescriptions, approximately 10 % of women did not complete their prescribed therapy. The main reasons for not completing the therapy were given as lengthy treatment and that use was found to be messy. Women showed their preference for 3 days suppository treatment rather than 7 days cream therapy. Many women expressed the opinion that the use of creams was inconvenient and they are willing to use a suppository product.

Out of women who have not used intravaginal medications 78 % were willing to use them. When women were asked to rate the various criteria concerning the importance to insure proper treatment ( survey question # 16), various results were obtained. These are tabulated in Appendix 4. Most women were concerned with irritation and comfort. Women also stated that ease of administration and side effects are important. They thought that it is equally important to apply the medication directly to the infected area. The least number of women were bothered about portability of the medications. This was true for all four age groups( Appendix 5 ).

Most of the women (60%) who did not want to use the intravaginal medications were reluctant for apparent psychological or sociological reasons. That is they said that they feel awkward, nervous or embarrassed to use intravaginal medications. To some women it sounds scary to use such medications. Many find that use of a tampon every month is enough of intravaginal application. Many women are concerned about irritation, side effects and discomfort caused by these medications. The main complaints about creams were messiness and leaking. In summary, the main two reasons for not wanting to use intravaginal medications were psychological and lack of proper and sufficient information about intravaginal medications and their administration.

Although many reasons given for not wanting to use intravaginal medications, it was surprising to know that there is a substantial percentage of women who have used such medications and who are willing to use such medications ( almost 80% ). Many women expressed the view that they are ready to use these medications if necessary. Many found them as a fast, safe and efficient remedy. They wanted to use these medications as they cut down on drug dose as it is applied directly to the infected area. Though some women thought intravaginal medications are messy and difficult to use, other women found it convenient to use them.

It was thought that there might be a relationship between educational level and opinion about intravaginal medications of women. Statistically significant relationships were found between age of a woman and use of tampon (  $p < 0.05$  ), between level of education and use of tampon (  $p < 0.05$  ). Significant

relationship was also found between educational level and reservations about using tampons. No statistically significant relationships were detected between age of a woman and use of intravaginal medications or between educational level and use of intravaginal medications. No significant relationship was found between educational level and reservations about use of intravaginal medications.

Although this study of 185 women was restricted to women in Rhode Island, we do not believe that the attitudes of women in other parts of the United States are likely to be substantially at variance with the broad trends observed in this study.

## **CONCLUSION :-**

This survey has showed that there is surprisingly large potential market for intravaginal medications in the United States. Many women have been using intravaginal medications and a large percentage of those who have not used these medications are ready to use them. If the women are educated and given proper and more information about intravaginal medications, it would help them in overcoming their concerns about these medications. It would definitely increase the use of these products if they are made less messy and more easy to use. Suppositories obviously have advantage in this respect. Ease of use was the most frequently expressed concern among women willing to use intravaginal medications. This survey provides evidence that the majority of women are willing to use well formulated intravaginal products if adequate information concerning administration and potential adverse effects is provided.

## **REFERENCES :-**

- 1) Pandit J. K., Choudhary P. K., Mishra B., The Eastern Pharmacist, Jan. 1990, pp. 171- 173.
- 2) Losse G., Muller F., Fisher S. et al., Pharmazie, May 1989, 44 : 331- 332.
- 3) Puglisi G., Garagiola U., Curr. Ther. Res., March 1989, 45 : 333- 338.

- 4) Klein Wendy- Schwarty, Hoopes James M., " Patient Assessment and Consultation ", Handbook of Non- Prescription Drugs, 1990, 9<sup>th</sup> Edition, American Pharmaceutical Association, Washington DC.
- 5) Chi I Cheng, et al. Contraception, Nov. 1987, vol. 36, # 5, pp. 499-512.
- 6) "SAS User's Guide : Basics" , "SAS User's Guide : Statistics", 5<sup>th</sup> Edition, SAS Institute Inc., Cary, NC, USA ( 1985 ).

## APPENDIX I

### SURVEY ON THE USE OF INTRAVAGINAL MEDICATION

We are investigating the use of intravaginal medications and womens' preferences for the various types of product available (eg: tablets, creams, medicated tampons). The information obtained in this study will be used in the development of medications for vaginal diseases.

We would be most grateful if you would take a few minutes to complete this questionnaire. The results will be kept fully confidential.

Dr. Michele Danish  
Ms. Arati Joglekar  
Department of Pharmaceutics  
University of Rhode Island

### QUESTIONNAIRE

1. Please specify your age group: 18-25 yrs ☐ 25-35 ☐ 36-45 ☐  
over 45 yrs ☐
2. What is your level of education? Graduated from High School ☐  
College ☐ Postgraduate ☐
3. Have you undergone gynecological surgery eg: hysterectomy?  
Yes ☐ No ☐
4. Are you still having periods? Yes ☐ No ☐
5. Can you indicate about how old you were when you had your first period? \_\_\_\_\_
6. If you are postmenopausal (i.e. you no longer have periods), how many years, approximately, is it since your last period? \_\_\_\_\_
7. Have you used tampons? Yes ☐ No ☐
8. How often have you used tampons? Very rarely ☐ Few times ☐  
Every month ☐

9. Have you any reservations about using tampons? Yes \_\_\_ No \_\_\_  
If yes, please specify.

10. Do you feel tampons restrict movement? Yes \_\_\_ No \_\_\_

11. The purpose of intravaginal medication is to deliver medicine directly to the (area) where it is needed. Have you used any medication intravaginally such as suppositories, creams, tablets?  
Yes \_\_\_ No \_\_\_

If yes, please continue with question 12  
If no, please continue with question 15

12. If yes, please indicate which ones. (one or more items may be checked) Tablets \_\_\_ Suppositories \_\_\_ Creams \_\_\_ Medicated tampons \_\_\_

13a. How often has your doctor prescribed intravaginal medication for you? Once \_\_\_ Once a year \_\_\_ less than 6 times a year \_\_\_ Other \_\_\_

b. Have you filled the prescriptions? Yes \_\_\_ No \_\_\_

c. Did you always complete the prescribed therapy? Yes \_\_\_ No \_\_\_  
If no, why not?

14. Have you found it easy, convenient and acceptable to use intravaginal medications? Yes \_\_\_ No \_\_\_

15. If you have not used intravaginal medications would you be willing to use intravaginal medications? Yes \_\_\_ No \_\_\_

16. If you needed medication to treat a vaginal disease what would be important to you to insure proper treatment? (Please rate each of the following from 1 to 3, very important = 3, important = 2, not important = 1. (Each rating number can be used any number of times)

Direct application to infected area \_\_\_ Ease of administration \_\_\_  
Portability \_\_\_ Less side effects \_\_\_ Irritation \_\_\_ Comfortable \_\_\_  
Disposable \_\_\_ Appropriateness of insertion of foreign material  
into vagina \_\_\_

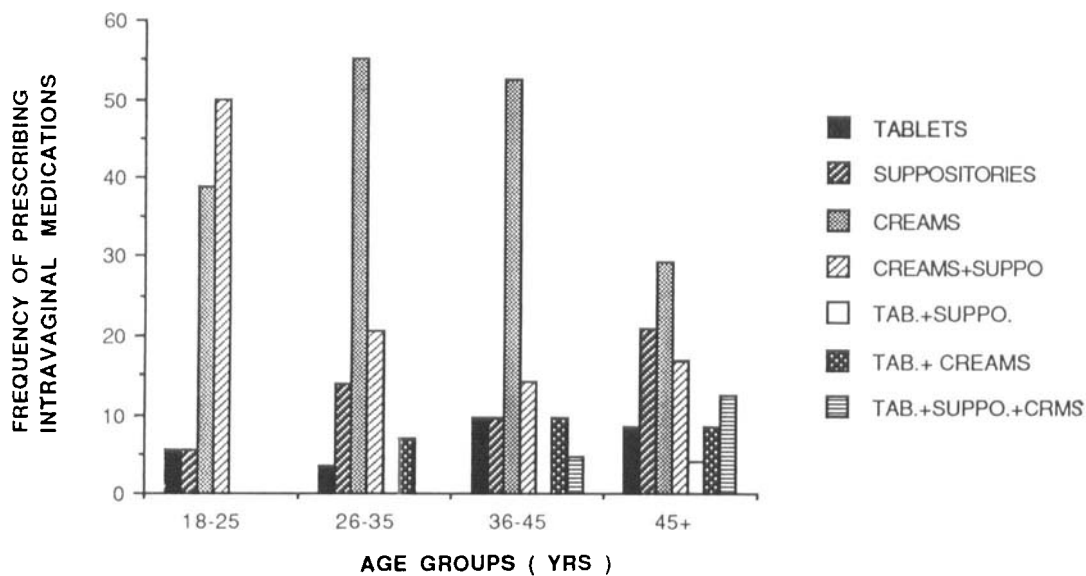
17. Do you have any reasons for not wanting to use intra vaginal medications?

18. Do you have any reasons for wanting to use intra vaginal medications?

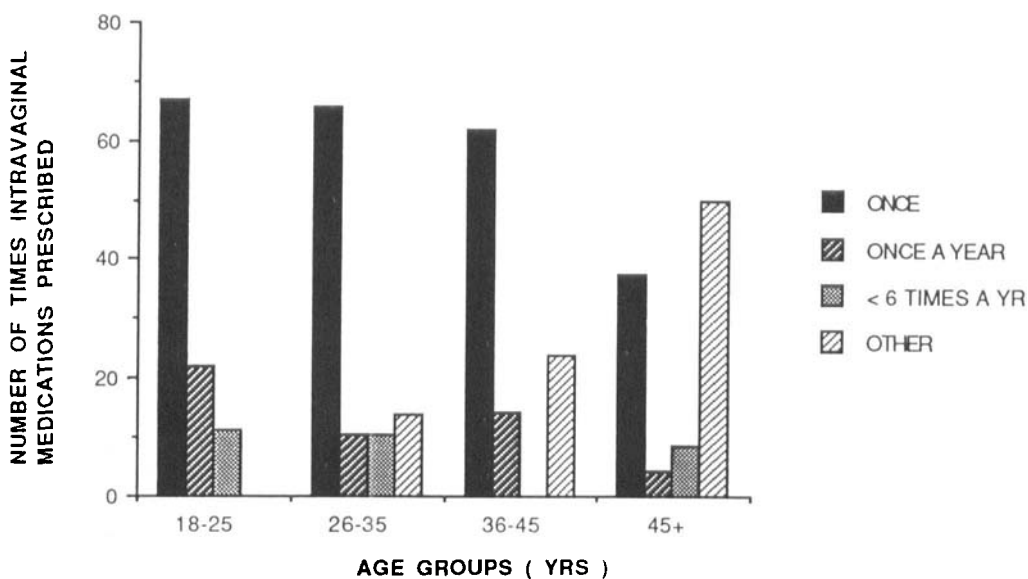
(All information will be confidential. Thank you for your cooperation.)



APPENDIX II  
TYPES OF INTRAVAGINAL MEDICATIONS PRESCRIBED



APPENDIX III  
FREQUENCY OF PRESCRIBING INTRAVAGINAL MEDICATIONS



APPENDIX IV  
RATING BY WOMEN OF VARIOUS CRITERIA REGARDING INTRA VAGINAL DOSAGE FORMS

COND.	AGE GROUPS											
	18-25 YRS			26-35 YRS			36-45 YRS			45+ YRS		
	1	2	3	1	2	3	1	2	3	1	2	3
1	10	32	58	07	20	73	02	19	79	15	19	66
2	04	32	64	07	11	82	02	21	77	06	17	77
3	16	54	30	20	42	38	37	30	33	34	38	28
4	06	10	84	00	22	78	05	09	86	06	28	66
5	04	14	82	00	24	78	02	14	84	04	19	77
6	06	14	78	02	29	67	00	19	81	06	15	79
7	26	36	38	31	40	29	42	35	23	21	38	40
8	06	24	70	16	27	58	16	30	56	13	26	62

( all the values from column 2 to 12 are in % )

condition 1 : direct application to infected area

condition 2 : ease of administration

condition 3 : portability

condition 4 : less side effects

condition 5 : irritation

condition 6 : comfortable

condition 7 : disposable

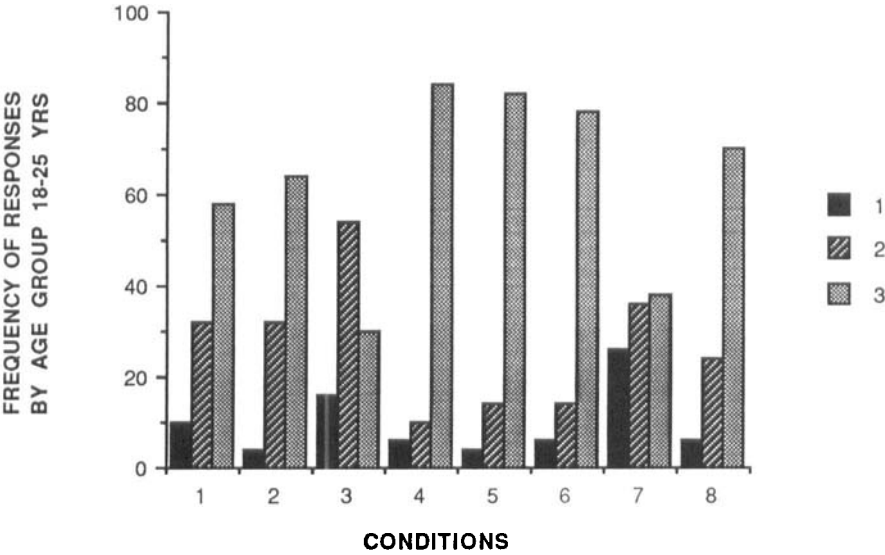
condition 8 : appropriateness of insertion of foreign material into vagina

3 = very important

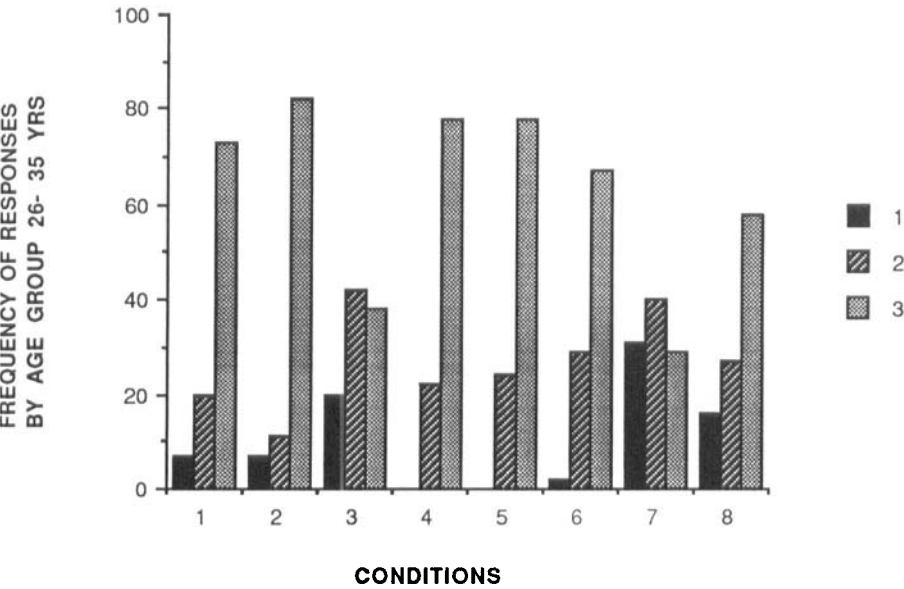
2 = important

1 = not important

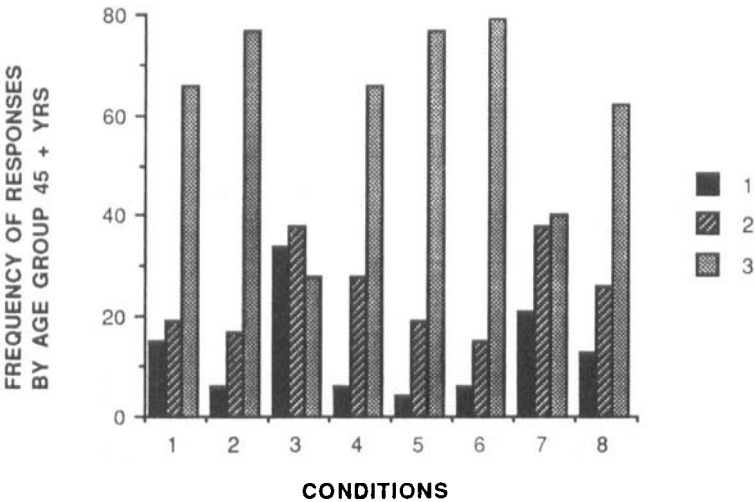
APPENDIX V  
RATING BY WOMEN OF VARIOUS CONDITIONS AS PER AGE GROUP



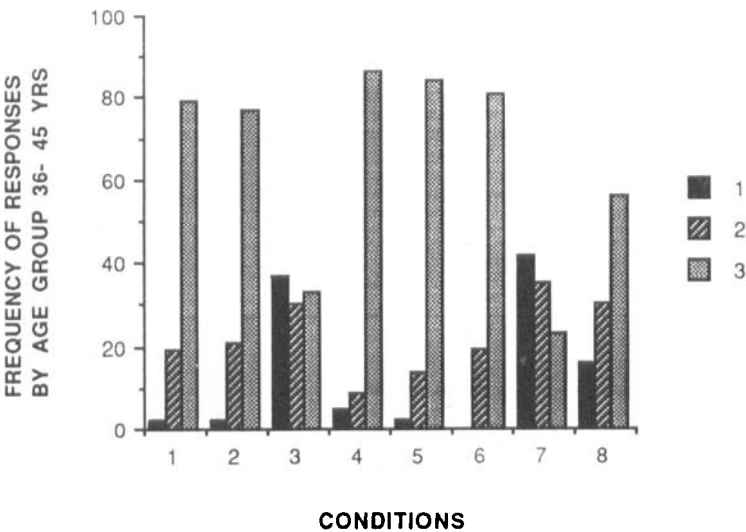
RATING BY WOMEN OF VARIOUS CONDITIONS AS PER AGE GROUP



APPENDIX V  
RATING BY WOMEN OF VARIOUS CONDITIONS AS PER AGE GROUP



RATING BY WOMEN OF VARIOUS CONDITIONS AS PER AGE GROUP



( PLEASE REFER TO APPENDIX IV FOR EXPLANATION OF TERMS )