EVALUATION OF EFFECTIVENESS AND ACCEPTABILITY OF NONOXYNOL VAGINAL CONTRACEPTIVE PESSARY AFTER MTP

by

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SUMMARY

A woman undergoing MTP is strongly motivated to accept contraception. Women desirous of spacing future pregnancies may accept an I.U.C.D. However, women suffering from menorrhagia or those undergoing a second trimester termination are not ideal candidates for a concurrent I.U.C.D. insertion. Nonoxynol vaginal contraceptive pessary offers a suitable alternative for those not accepting I.U.C.D. or other conventional methods.

Introduction

In a review of 3037 patients undergoing MTP by the MTP Committee of FOGSI, it was observed that about 27.5% of women accept concurrent tubectomy and about 33.2% accepted an IUCD. However, many women still go away after an MTP with meagre or no contraceptive advice.

Epidemiological studies all over the world reveal that cultural, moral, religious and personal factors affect the acceptibility of contraception. Education and availability of services often influence the choice of contraceptive methods.

In the past more emphasis has been placed upon safety and effectiveness rather than upon the factors which influence acceptability. Although none of the presently available methods of fertility control are completely safe, effective and reversible, vaginal contraception offers advantages regarding safety and reversibility. It can be promoted without the need of an intermediate health professional, thus filling a lacuna in the national family welfare programme.

Nonoxynol (Nonyl Phenol Ethylene Oxide) is a nonionic surfactant macrogol ether. It is not absorbed from the vaginal mucosa and hence unlikely to exert side effects. Acute, subacute and chronic toxicity studies at the Huntingdon Research Institute, undertaken in animals confirm its safety. Nonoxynol pessaries exert a unique double action (mechanical and chemical)

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on the sperms. The sperms are initially immobilised, later the drug produces its spermicidal effect by acting upon the protective lipid capsule of the sperm leading to fructolysis and loss of sperm motility and sperm lysis. Nonoxynol has been placed in category I by the U.S. Federal Drug Authority and classified as safe, convenient and effective. It has also passed the requirements of the International Planned Parenthood Federation for complete spermicidal effectiveness.

It has been in use in more than 60 countries spanning 5 continents. Thus it constitutes one of the most widely used contraceptive methods acceptable to a wide range of population all over the world.

Material and Methods

Nonoxynol vaginal contraceptive pessaries were evaluated for efficacy and acceptability by contributors of the committee on the basis of the following criteria:

(1) *Extent of dissolution*: The rate of dissolution of Rendall's nonoxynol vaginal pessaries in relation to time was observed in 20 subjects. After deep insertion of the vaginal pessary, the extent to which it dissolved was assessed every 5 minutes for 20 minutes.

(2) *In vitro evaluation of spermicidal efficacy*: This was evaluated on the basis of Modified Sander-Cramer test in 20 subjects. One gm of the pessary was dissolved in 4.0 ml of 0.9% physiological saline, and from 1 ml of this standard solution serial dilutions upto 1/1024 were prepared and placed in a water bath at 37°C. To each tube 0.1 ml of a normal semen sample (count 40-250 million/ml and over 70% motility) of semen was added and the mixture evaluated after 40 seconds for its spermicidal property.

(3) *Clinical effectiveness*: This was evaluated on basis of post-coital tests in 36 subjects.

(4) *Acceptability of vaginal contraceptives*: This was judged on basis of a standard questionnaire in 156 couples.

Results and Discussion

The criteria utilised for critical assessment of nonoxynol vaginal contraceptives are discussed hereafter.

(1) *Dissolution of pessary*: The woman is advised to insert a vaginal pessary deep in the vagina 10-15 minutes prior to intercourse. Adequate amount of the drug disperses within that time and continues to exert its spermicidal action for upto 2 hours. Hence a new pessary must be used prior to every act of coitus.

In 20 subjects, a nonoxynol pessary was inserted and the extent to which it dissolved was observed at 5 minute intervals for the next 20 minutes.

The effects observed are shown in Table I.

TABLE I
Rate of Dissolution of Nonoxynol Pessaries

Extent of pessary dissolved	Time period of observation							
	5 minutes		10 minutes		15 minutes		20 minutes	
	No.	%	No.	%	No.	%	No.	%
1. Upto 25% dissolved	12	60.0	—	—	—	—	—	—
2. Upto 50% dissolved	6	30.0	10	50.0	2	10.0	—	—
3. Upto 75% dissolved	2	10.0	6	30.0	3	15.0	—	—
4. Entire pessary dissolved	—	—	4	20.0	15	75.0	20	100.0

The above observations show that more than 75% of the pessary dissolves in 50% of subjects within 10 minutes and in 90% of the subjects within 15 minutes. In all the subjects the pessary was found fully dissolved within 20 minutes.

(2) *Spermicidal property of nonoxynol pessary—In vitro study*: The spermicidal property of nonoxynol was assessed on the basis of a modified Sander-Cramer test on 20 subjects. The results are shown in Table II.

The above test revealed that the drug exerts marked spermicidal and sperm immobilisation activity upto 1 : 512 dilutions in *in vitro* studies.

(3) *Clinical evaluation of spermicidal activity of nonoxynol on basis of post-coital tests*: The clinical efficacy of the drug was tested in 36 subjects on the basis of post-coital tests. The test was performed between day 10 and day 12 in normally menstruating women who had undergone MTP. They were evaluated within 4 hours of having coitus. The results are shown in Table III.

The post-coital tests confirmed the effectiveness of nonoxynol as a contraceptive agent in a selective group of 36 women who followed the instructions for use correctly. In 94.4% complete spermicidal action was confirmed. One has to make allowance for failures due to improper use.

(4) *Acceptability of nonoxynol pessaries as a contraceptive*: Analysis of 156 standard questionnaire forms for assessment of acceptability of nonoxynol pessaries revealed the following: (Table IV)

The above Table shows that most women find it easy to use, non-irritating and not personally offensive. However, 28 women felt that the act of inserting the pessary 20 minutes prior to coitus anxiety to the wife and annoyance to the husband.

Forty-four women did not prefer it to other contraceptive. Twelve women preferred to have an IUCD after 3 months. Sixteen women were not quite sure about

TABLE II

Assessment of Spermicidal Action

Action of spermatozoa	Serial dilution of Nonoxynol in Phy. saline									
	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024
1. No sperms seen or sperm lysis	20	18	18	12	6	3	—	—	—	—
2. Dead sperms seen	—	2	2	8	14	17	20	20	14	—
3. Sluggishly motile non-progressive sperm	—	—	—	—	—	—	—	—	6	3
4. Motile progressive sperms	—	—	—	—	—	—	—	—	—	17

TABLE III

Post-coital Tests After Use of Nonoxynol Pessary

PCT tests results	Patient distribution	
	No. of cases	% Distribution
1. No sperms seen or sperm lysis	32	88.8
2. Dead sperms seen	2	5.6
3. Sluggishly motile and non-progressive sperms	2	5.6
4. Actively motile and/or progressive sperms	Nil	—

TABLE IV
Acceptability of Nonoxynol Vaginal Pessaries

Question in brief	Answer given	
	Yes	No.
1. Ease of introduction	148	8
2. Local discomfort	Nil	156
3. Vaginal irritation	4	152
4. Offensive vaginal discharge	Nil	156
5. Irritation to husband	3	153
6. Interference with natural coitus	28	128
7. Preferred to other contraceptives	112	44

its effectiveness and hence preferred to go back to condoms or pills, and 16 others wished to undergo a tubectomy at a later convenient date.

Of the 112 women who said they preferred this method to other methods, 19 had used coitus interupts, 15 has tried the rhythm method and in 12 women the husbands had used condoms intermittently. Thirty-four women has used no effective contraceptives earlier. In general the women and their husbands found the pessary acceptable. Hence it is important that this new contraceptive must be included in our armamentarium for population control.

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