

Dr. Hannah M. Stone, of New York, has prepared a comprehensive report on therapeutic contraception based on material from the Clinical Research Department of the Birth Control League of New York City. This report shows the character of the work which is being done by the League, and has been submitted to us as their contribution to our Birth Control Forum.

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FOREWORD

A search for case histories of contraception, which was made in 1923, showed that the library of argument and invective on the subject of birth control was built on an absurdly small amount of medical information. At that time the Committee on Maternal Health did not find over thirty cases, properly accredited and followed up, on which to start clinical studies. The gynecological and obstetrical departments of medical colleges have been reluctant to bestir themselves in accumulating records of cases requiring contraceptive advice for the safeguarding of life and health, and this has made our four year compilation of material a slow process. Therefore, welcome should be extended to this report on a long series of patients treated by a medical woman of known skill. I believe this to be the first considerable and detailed study of the efficacy of contraceptive measures combined with reliable follow up that has ever been made.

This belief is based upon American experience together with the 1924 findings of our former executive secretary, Dr. Gertrude E. Sturges, in Holland, England and France, and those of the writer on a visit in 1926 to fourteen foreign countries. Contrary to popular belief, Holland, with its forty years of experience, has never had actual clinics under medical control with physicians in charge, nor kept records. Some of the clinics in England were well conducted and in charge of clever young medical women, but so far as I could observe, their well planned record blanks failed to show reasonable entries of physical examinations and pelvic findings, and they had no follow up facilities. Chicago has some better records. The birth control movement

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is to be congratulated on a worker possessed of the open mindedness and critical spirit exhibited in the report which follows.

From my observation of Dr. Stone's work, I am inclined to credit this report of her own cases at its face value. The small percentage of failures is surprising. The figures have been checked by Dr.. Louise Stevens Bryant, executive secretary of the committee, and I have inspected at the clinic a considerable number of original case records taken at random. This report constitutes a pioneer contribution.

As a practical comment on a study built largely on vaginal pessaries, one cannot fail to draw attention to a handicap which should be removed. Mensingas cannot be bought here, and the Federal Law forbids their importation. The rubber in the Ramses made in Milwaukee and New York does not retain its elasticity as many months as the German product. The brass spiral spring in all Ramses, foreign or American, is weak for the larger sizes, sixty-five mm. and above, as compared with the coil of Italian watch spring in the Leipzig and London Mensinga. Therefore, adequate tests of mechanical methods could be made if the Custom House did not prevent importation of foreign pessaries, which are specified as necessary for careful and properly supervised scientific investigations. The three exceptions made for the Committee on Maternal Health in order to supply its nine studies in leading out patient departments should be extended to meet the need of institutions of high standing. This claim for material should apply also to any demonstration clinic which is under actual control of a group of physicians of the type which the organized profession would endorse.

ROBERT L. DICKINSON, M.D., FA.C.S.,

Secretary, Committee on Maternal Health. November 21, 1927.

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THERAPEUTIC CONTRACEPTION* By Hannah M. Stone, M.D.

New York

Physicians desiring knowledge of measures for protection of patients whose life or health would be jeopardized by pregnancy have been handicapped by the absence of adequate clinical reports. In order properly to evaluate the results of any contraceptive measure, the method should have been used by a considerable series of patients, and by each for at least six months—preferably for a year. The patients here reported on were all cared for by a single physician during 1925, and results ascertained up to January, 1927. Consequently a period of from twelve to twenty-four months had elapsed in every case treated.

The total number of patients during 1925 was 1,655. In this total are included 198 patients who, upon examination, were found unsuitable for contraceptive instruction. This left 1,457 patients (or 1,469 cases, since 12 were given two different methods during the year) who were actually advised. Many more applied for information, so that, counting all applicants, one out of four did not even get as far as medical examination. No histories were taken for those refused without examination.

Although this is a special service and many patients are referred with a diagnosis from a private physician or clinic, this is verified whenever it appears necessary. Whatever the diagnosis may be, however, each individual is given a general chest and abdominal examination with a blood pressure test, and urine and hemoglobin examinations are often

^{*}From the Clinical Research Department of the American Birth Control League, New York City.

made. Whenever it seems advisable, vaginal smears are taken.

Cases "not advised."—The main reason for withholding contraceptive advice from applicants was the absence of medical indications. The New York State Law permits the physician to give contraceptive information only for "the prevention or cure of disease." Only those applicants could, therefore, be accepted as patients who presented a definite health reason. When no such condition existed, we refused contraceptive information.

Some applicants were found to be pregnant, or possibly pregnant, at the time of their first visit. Others could not be instructed in the use of a contraceptive method because they were menstruating. A few could not be advised because they applied too soon after delivery. In fitting a pessary especially, it is advisable to wait until complete involution has taken place; otherwise, the proper size cannot readily be ascertained.

Many women applied for general sex advice, or for information regarding sterility and related problems, and those advised on sex matters only were not tabulated.

A few were not advised either because they objected to a physical examination or because they thought the method prescribed unsuited to their needs. A few applied for sterilization, and these were directed to various hospitals and institutions.

Inability to learn technic.—It is significant that among 1,457 patients there were only about ten who could not learn the technic of using any of the methods. These few had difficulties either because of some physical defect or because their intelligence was much below the average.

CONTRACEPTIVE METHODS

These were of the following types:

- 1. Jellies.
- 2. Occlusive pessaries, vaginal and cervical.

Therapeutic Contraception

3. Combination of pessaries with jellies.

4. Miscellaneous contraceptives; condoms, in conjunction with jellies; effervescent tablets; suppositories.

Jellies.—Contraceptive jellies consist, generally, of a chemical spermatocide incorporated in a gelatinous base. At the beginning of the year, the only jellies available were those put up by various pharmaceutical concerns. An analysis of the four jellies most commonly employed showed them to have approximately the following composition:

Number

Percent.

I.	Boric acid	5
	Glycerin	. 10.0
	Tragacanth	. q.s.
II.	Boric acid	. 1.0
	Chinosol	. 1.5
	Glycerite of starch	
	Irish moss	. q.s.
III.	Boric acid	. 1.0
	Acetic acid	5
	Glycerite of starch	. a.s.
	ChinosolNot	determined
IV.	Boric acid	
	Glycerite of starch	. q.s.

On account of the proprietary character of these jellies and the uncertainty of their exact composition, it was thought advisable to introduce and utilize one of a definitely known formula.

Lactic acid jelly.—Furthermore, several instances of marked local irritation having been observed following the use of chinosol preparations, experiment with a jelly containing a different chemical ingredient seemed desirable.¹ Lactic acid was selected because it had already been successfully employed as a contraceptive by other investigators, and a jelly

¹Dr. Dickinson has commented on the very high percentage of chinosol in the commercial formulas like I and II as unnecessary, and at times irritating. However, he questions the desirability of omitting chinosol altogether, provided the claim is made good that 0.2 per cent is effective not only for sperm but for the gonococcus and spirochetae as well.

Therapeutic Contraception

(henceforth known as Jelly V) of the following composition prepared:

				ſ	ercent.
v.	Lactic aci	id .			1.0
	Boric acid	1			10.0
	Glycerite	of	starch		q.s.

Lactic acid is the normal constituent of the vaginal secretion, and is an effective spermatocide, in the sense of producing a more or less enduring paralysis of the activity of spermatozoa.² In the percentage contained in the last formula, it approximates the normal lactic acidity of the vagina, only slightly exceeding it, and apparently has no irritating effect. Glycerite of starch was selected as a base. The efficiency of a contraceptive jelly depends upon its physical properties as well as upon its chemical action. Since the substance of the jelly acts as a mechanical hindrance to the progress of the spermatozoa, the consistency of the base is an important factor in the formula. Glycerite of starch forms a semisolid mass, is not irritating in character, and furthermore is believed to possess in itself spermatocidal properties.

Pessaries.—The pessaries employed were of the following types: Three were vaginal diaphragms, known as the Ramses, Mensinga and Matrisalus, and there was one cervical cap, the "Mizpah." These pessaries were prescribed for use either alone or, as was most usual, in conjunction with one or the other of the jellies mentioned.

Miscellaneous.—Condoms with one of the jellies, effervescent tablets, and suppositories were also occasionally prescribed. The suppositories used consisted of an antiseptic jelly containing boric acid, lactic acid and glycerine in a shell of cocoa butter with salicylic acid, quinine and resorcinol. These latter methods were advised particularly where for some reason the pessary could not be employed.

²Sperms immobilized by weak acids can usually be activated by alkaline applications, and the double action repeated several times.

SUMMARY OF METHODS

The methods prescribed in 1,469 cases during the year may be summarized as follows:

1. Contraceptive jellies alone.—These were prescribed in 360 cases, with the following compositions distributed thus:

Jelly	_ <u>I</u>	136
lellv.	- 11	61
Jelly	<u>111</u>	48
lellv	1	6
Jelly	Ŵ	109

2. Occlusive pessaries alone.—These were prescribed in 36 cases, with types distributed as follows:

Ramses type	28
Mensinga type	5
Mizpah type	3

3. *Pessaries with jellies.*—These were prescribed in 1,017 cases with types and compositions in the following combinations :

Ramses type with Jelly I	267
Ramses type with Jelly II	103
Ramses type with Jelly III	12
Ramses type with Jelly V	568
Mensinga type with jelly	44
Matrisalus type with jelly	б
Mizpah type with jelly	17

4. *Miscellaneous methods.*—These were prescribed in 56 cases as follows:

Ramses type pessary with tablets	21
Ramses type pessary with suppositories	8
Mensinga type pessary with tablets	3
Condoms with jelly	13
Effervescent tablets	7
Suppositories	4

CLINICAL PROCEDURE

All the cases reported upon in this paper were examined and advised by the writer, so that uniformity in methods and results may be assumed. Each patient was examined individually, and a contraceptive chosen according to the needs and indications of the particular case. In each instance careful instructions were given the patient on local hygiene and the care of, and manner of employing, the contraceptive.

When a jelly alone was prescribed, the patient was supplied with a glass nozzle which fitted the neck of the collapsible tube containing the jelly. By inserting the nozzle into the vagina and turning a key at the bottom of the tube, a definite amount of jelly, about 4 c. c., would be injected high into the vagina. The patient was directed to make this application prior to coitus.

When a pessary was prescribed it was always carefully fitted. Vaginal diaphragms are obtainable in a number of graded sizes, varying from 40 to 90 mm. in diameter. As the diameter of the vaginal canal is a variable factor, each woman must be fitted individually. The patient was instructed how to apply the diaphragm, and was required to demonstrate her understanding of the technic before leaving.

When a pessary and jelly, the method most commonly prescribed, were advised, the patient was instructed to smear some of the jelly around the rim of the pessary before inserting the latter. If desired, the pessary could be inserted in the evening and remain *in situ* until the next morning. The patient was also advised to douche with plain warm water preceding and following the removal of the pessary.

FOLLOW UP

In order to evaluate the efficiency of any method prescribed it is essential that complete reports be obtained. Accordingly each patient was asked to return at certain intervals, or else to report by mail the results with the method prescribed. A large number of patients failed to report, however, and towards the end of the year it was found necessary to employ a social worker to follow up these cases.

Questionnaires were mailed to all delinquent cases,

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and a large number of reports were obtained in this manner. When no reply was received, the social worker endeavored, whenever possible, to visit the patient at her home in order to ascertain her results and reactions.

Much tact and care must be employed in obtaining reports from patients. The use of contraceptives is a very intimate problem with the woman, and in discussing results she will often consciously or unconsciously suppress certain pertinent facts. Statements from patients must, therefore, at times be carefully evaluated.

The total results of the follow up are shown in Table I, which gives the report on each method prescribed. In Table II, the results are shown in summary form according to the general method used.

"NO REPORT" CASES

In spite of the follow up efforts, no reports have been obtained as yet from 336 of the patients. In 114 of these cases the mail was returned either because the patient had originally, consciously or unconsciously, given the wrong address, or else because the patient had moved in the meantime, leaving no new address behind. In the 222 others no replies were obtained to the questionnaires, and no home visits have been made, chiefly because most of these patients are living in outlying districts or in other states. These "No Report" cases are still being followed up, and more data may possibly be obtained from them later on.

REPORTED CASES

Reports on the contraceptives prescribed were received from 1,133 patients. Many reported in person, either when coming for further materials or for further information and advice; others sent in replies to our questionnaires with more or less complete statements, while a number were visited and their reports obtained in this way.

	CUNITALEFILYE MELTIOUS LAESCALEED IN 1,7707 LIGATOR	THURSDAY Y			Results Reported on Follow-Up	Results Reported on Follow-Up	Follow-Up		
							Success With Use	Vith Use	
МЕТНОР	Total Times Prescribed	No Report	Method Not Used	Doubtful	Failure	Under Six . Months	2:2	e One to Two Years	Over Two Years
Grand Total, All Methods	1,469	336	174	S	35	153	323	393	47
1 Decorios with Telly	1.017	238	115	9	17	105	231	287	18
	950	224	110	9	16	66	224	256	15
Number V. Number II	568 267 103	156 58 7	13269	404-	rv40	1 1 1 1 1 2 2 1 1 2 3 3 1 2 3 3 1 2 3 3 1 2 3 3 1 2 3 3 1 2 3 3 1 2 3 2 3	151 52 19	108 43 4	0%20
Mensinga Type with Ielly	4	6	5	0	1	5	4	21	8
	17	¥	c	c	C	4	~	9	0
Number V Number II Number III		+000	0		010	0-0	0-0	944 944	000
Mizpah Type with Jelly	11	5	5 ÷	0	0		cı -	6 -	
Matrisalus Type with Jelly	٥	~ ;	-		,		10	40	, ⁶
2. Jellies alone	360	82	49	-1	c 1	41	8/	1	32
Number I Number V Number II Number II Number IV	136 109 61 6	33 26 13 13	07 07 07 07 07 07 07 07 07 07 07 07 07 0	00000	V4-0-	15 37 175 175 175	27 26 15 15	31 13 8 2 2	031103 03103
3. Pessaries alone	36	11	v	0	0	S	1	7	1
Ramses type Mensinga type Mizpah type	8 20 m	<u>онн</u>	4-10	600	000	002	0 1 0	401	100
4. Miscellaneous	56	22	5	0	3	ભ	2	29	'n
Ramses type with Tablets Ramses type with Suppositories Mensinga type with Tablets All other	24.382 24.382	0 00%	000m	0000	000%	1001	6104	0000 1000	4400

Therapeutic Contraception

"NOT USED" CASES

Of the total of reported cases, 174 stated that they' were not using the methods prescribed. This constitutes about twelve percent of the total number of patients and fifteen percent of those reporting. This, we believe, is rather a small proportion. Any method which depends upon the personal aptitude of the individual using it, and which requires a definite, even though small, amount of effort on his or her part, will always be avoided by a certain number. Furthermore, many patients came from the most

TABLE II SUMMARY OF GENERAL CONTRACEPTIVE METHODS ADVISED WITH RESULTS REPORTED

	All	Pessaries	Jellies .	Pessaries	Miscel-
	methods	with jelly	alone	alone	laneous
Total prescribed	1,469	1,017	360	36	56
Not reported	174	238	82	11	5
Total reported		779	278	25	51
Method not used		115	49	5	5
Method used		664	229	20	46
Result reported with use: 1. Not a success Doubtful Failure 2. Success, total Under six months Six months to year One to two years Two years and over	35 916 153 323 393	23 6 17 641 105 231 287 18	17 2 15 212 41 78 70 23	0 0 20 5 7 7	3 0 3 43 2 7 29 5

congested districts of the city where even the most elementary privacy is often unobtainable.

The reasons offered by our patients for not employing the method were as follows:

Forty-four patients stated that they, or more frequently their husbands, had no confidence in the particular method, and they were "afraid" to rely upon The methods prescribed must be applied by the it. woman herself, and many husbands have not enough confidence in their wives to depend upon their employment of a new method.

Again, thirteen patients failed to use the method

because they or their husbands objected to it for one reason or another. Some found it too troublesome, some lacked the necessary privacy, while several found the method "uncomfortable."

On account of illness or an intervening surgical operation, or because of a subsequent sterilization, fifteen patients did not employ the methods. A few had decided to conceive, in spite of their physical condition, and they therefore had no need for contraceptives.

Subsequent separation, either on account of the husband's death or illness, or because of domestic difficulties, prevented ten women from using the contraceptive.

Finally, sixty-two patients gave no reason for not employing the method prescribed.

SUCCESSES

In all, 916 patients reported that, for periods varying from one month to over two years, they had used successfully the contraceptive methods. This constitutes over eighty percent of all patients who have reported their results, and deducting from the total reporting those who have not used the methods, we find that the percentage of successful results is over ninety-five. The results in cases where the method was employed for over six months are analyzed later, in Table III.

In this connection it is interesting to find that in certain cases conception ensued as soon as the patient ceased to use the contraceptive. Thirty patients reported that, when they failed to use the method given them, either because they desired a pregnancy or because of some other circumstances, they conceived within the month.

A summary of the successful cases according to the methods used and to the period of time reported on is as follows:

A total of 916 patients reported successful results with the method prescribed.

TABLE III

Result With Methods Adequately Tested as to Time ANALYSIS OF VARIOUS CONTRACEPTIVE METHODS ACCORDING TO RESULTS REPORTED IN CASES ADEQUATELY TESTED

						0449.CONT.	Treserve M and Manufactures Transferrant Transferrant and Taning	honry on	VAND T KADAMA		
							Number			Percent	ent
	Total	Reported used	d used	Test Inadequate		N	Not a Success		Success Doubtful Success six mos. or six mos.	Doubtful or	Success six mos.
Donta IV	Advised	Number	Percent 1	under 6 mos.	Total	Total	Doubtful	Failure	Failure to two yrs. Failure t	Failure	to two yrs.
Grand Total 1,469	1,469	959	65	153	806	43	8	35	763	2	. 36
Total Principal Methods 1,292	1,292	832	65	138	694	37	7	30	657	S	95
1 Ramses with Telly	938	608	65	98	510	21	ŝ	16	489	4	96
Econolis V		343	60	73	270	11	4	-	259	4	96
Formula T	267	182	68	16	166	ŝ	0	ທ	161	3	97
Formula II		83	80	6	74	Υ	н	4	69	9	94
2 Telly alone	354	224	63	40	184	16	20	14	168	6	91
En Juny monotone T		83	61	15	68	7	0	7	61	10	96
Formula V		62	56	17	45	ø	0	4,	39	13	87
Formula II	55	46	62	ωu	43 643	0	00	-10	42 26		80
Formula III		33	69	'n	07	4 '		1 1	3	• •	2.5
Total all other methods	. 177	127	72	15	112	9		'n	100	n	ç

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Of these, 440 had employed the method from one to two years, or longer.

Another group of 323 reported successful use for periods of from six to twelve months.

There were 153 who reported for periods of less than six months. These "short time" reports are either from patients who discontinued the method after using it for several months, not because they found it unsatisfactory, but for a variety of other reasons, or from persons we have been unable to reach with subsequent inquiries. These latter cases are still being followed up.

FAILURES

A total of thirty-five patients reported failure with the method prescribed. Two of these had failed following the use of an effervescent tablet which was given them prior to 1925, leaving a balance of thirtythree failures with the method prescribed during the year. The relation of failures to various methods is as follows:

Jelly I	7
Jelly II	1
Jelly III	2
Jelly IV	1
Jelly V	5
Ramses with Jelly I	3
Ramses with Jelly V	7
Mensinga with Jelly II	1
Effervescent Tablets	2
Other	ĩ

The failures were not immediate; in fact, nearly half came after using the method four months, as shown in the following summary:

Period Before Failure, in	Number	of Failures
Failure, in		
Months	Separate	Cumulative
One	. 5	5
Two	. 4	9
Three	. 8	17
Four	. 5	22

10,000 20,000	Number	of Failures
	Separate 2 3 1 2 1 2	Cumulative 24 27 28 30 31 33 34 35

That a certain number of failures should take place is almost inevitable. Sometimes the failure depends upon the condition of the materials employed. Jellies may harden in an open tube, or they may liquefy if kept under unusual conditions. The rubber of the pessaries, if improperly kept, may weaken or become cracked, or the spring may become stretched or bent. More frequently the failure is due to the carelessness or indifference of the patient. In six of the failures a note was made on the history charts at the first visit that the patients had an "indifferent attitude" towards the method advised and were "unwilling to apply themselves to learn the technic." A certain amount of care must be taken in inserting the pessary, or in injecting the jelly. When this is done carelessly it may not serve as an effective protection.

DOUBTFUL CASES

The reports from eight patients were too indefinite to classify either as successes or failures. They were grouped separately as "doubtful" cases.

ANALYSIS OF ADEQUATELY TESTED METHODS

Because the total figures may be misleading, the details with regard to the methods advised and employed are summarized in Table III, and analyzed with particular reference to those cases in which the methods advised may be considered to have been adequately tested both with respect to the number of cases and the length of time involved. The methods prescribed in 1,469 cases are listed at the left, being subdivided into the two principal methods advised in 1,292, or eighty-eight percent of the cases, and the eleven other methods advised in the remaining 177, or twelve per cent, of the cases. None of these other methods was applied in a sufficient number of cases to warrant a detailed analysis of results.

The first column of figures shows the total cases in which each specified method was advised; the second, the number in which the patient reported that she had used the prescribed method; and the third column shows the percent so reporting. About two thirds of all the cases (from fifty-six to eighty percent) reported that the given method was used. This is a rough measure of its effectiveness in the mind of the patient and of her interest and confidence.

The next column shows the number of cases in which the method was used for a period of less than six months, and which may therefore be considered inadequately tested, though successful thus far.

In all the rest of the cases, numbering 806, the given method had been employed successfully: in 763 for a period of six months to more than two years, 8 had been doubtful in their results, and 35 were failures. The 8 doubtful cases are combined with the 35 failures under the head, "Not a Success," making 43 in all which may be said not to have been a success.

In the last two columns is shown the percent of those here listed as adequately tested which were either a success or not.

To summarize the results shown in Table III in a general way: Of over fourteen hundred patients advised during 1925, reports were received on over eleven hundred, of whom it may be said that only one in twenty-five reported lack of success; one in seven that they had not used the method; and the great majority that they had used the method prescribed with successful results.

The doubtful cases and those reporting failure constitute altogether five percent of those adequately tested. Of the two principal methods, which were advised in about nine out of ten cases, the more successful appears to be the Ramses pessary combined with some form of contraceptive jelly. These altogether show lack of success in four percent, while the other chief method, a jelly used alone, averaged nine percent failures.

If special combinations are considered, the figures seem to indicate that a Ramses with a jelly of Formula I is the most efficacious, with ninety-seven percent successful, and Ramses with Formula V is next, with ninety-six percent a success. As the excess of chinosol in Formula I might make some trouble, it is believed the Ramses with Formula V is, on the whole, the best combination. It is to be noted, however, that where the jelly was used alone the one showing the least proportion of failures was No. II. This has the highest percentage of chinosol, 1.5 percent, and next comes No. III, in which chinosol was present in an undetermined quantity. Jelly V used "alone showed thirteen percent of failures among forty-five cases, with over six months' use.

SUMMARY AND CONCLUSIONS

Because of the fact that the New York State Law allows this care to be given only for the *cure or prevention of disease*, treatment has been restricted to those suffering from disabilities which would render pregnancy or labor especially hazardous. This fact necessitates caution in the selection and administration of therapeutic measures, and these must at the outset appear reasonably safe and efficient.

This report covers a total of 1,655 patients examined in 1925, of whom 1,457 were given contraceptive advice and care, under the direction of one physician. Through January, 1927, reports were secured on 1,133 patients, or over three quarters of the number treated. Of those reporting, eighty-five percent had used the prescribed methods.

In round numbers, nineteen out of twenty women were protected over periods running from six months to two years.

In over eight hundred cases reasonably followed up, and including all the methods that were investigated, the doubtful results and the failures together *averaged five percent*. The two poor showings with medicated jelly alone ran to ten and thirteen percent.

Vaginal occlusive pessaries combined with medicated jellies proved the most efficacious, with ninetysix percent of protection conferred on more than five hundred patients.

CLINICAL RESEARCH DEPARTMENT AMERICAN BIRTH CONTROL LEAGUE, INC. 46 WEST FIFTEENTH STREET NEW YORK, N. Y. •