

DISPOSABLE MENSTRUAL REGULATION KITS IN A NON-THROW-AWAY ECONOMY

Judith A. Fortney, PhD¹, D. Vengadasalam, MD²

¹International Fertility Research Program,
Research Triangle Park, North Carolina 27709

²Alexandra Hospital, Singapore (formerly of Kandang Kerbau
Hospital, Singapore)

ABSTRACT

The directions for use that are packaged with plastic menstrual regulation kits state that these kits are designed to be durable for approximately 50 procedures when used as directed. However, in much of the developing world, directions for use are ignored, equipment is not maintained properly and nothing (including disposable medical equipment) is discarded until it is useless. Therefore, it is of interest to know for how many procedures the disposable menstrual regulation kit can safely be used. This paper describes a study conducted in Singapore to determine the durability of three menstrual regulation kits manufactured by different companies and comments on how cleaning and sterilizing affects the durability of these kits.

Accepted for publication February 20, 1980.

Agency for International Development
Library
Room 105 SA-18
Washington, D.C. 20523

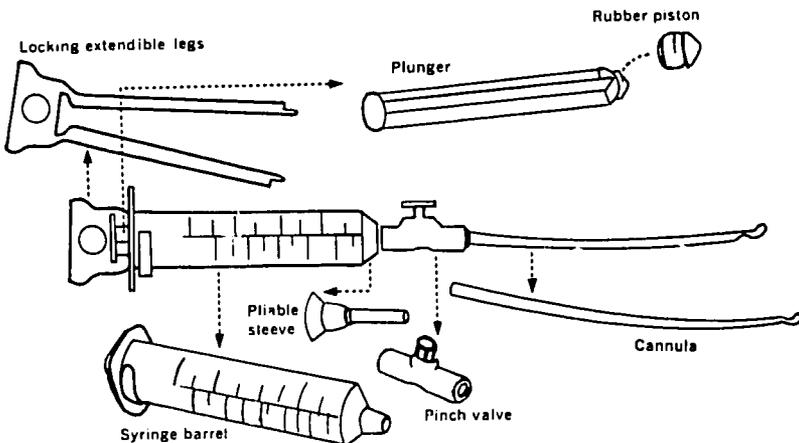
CONTRACEPTION

INTRODUCTION

The flexible plastic cannula developed by Harvey Karman and the adaptation of the plastic hand syringe for uterine evacuation combined to cause a major breakthrough in the provision of family planning services, especially in developing countries. Evacuation of the uterus with this equipment became known as menstrual regulation (or menstrual extraction, menstrual induction, endometrial aspiration, endometrial extraction or interception), a procedure usually used to treat a missed menstrual period, but which can also be used to obtain endometrial biopsies or to treat incomplete abortions.

The concept of menstrual regulation has several advantages for developing countries. The term itself is seen by many as a euphemism that allows the procedure to be performed in countries where abortion is yet legal. Then, because it usually is not possible to determine pregnancy in very early gestation (pregnancy tests are sometimes unreliable at this time and often too expensive for routine use), neither the physician nor the patient need know if the woman undergoing the procedure is pregnant, and this provides both with psychological and legal protection.

The equipment used to perform menstrual regulation offers many advantages to developing countries. The equipment is inexpensive (menstrual regulation kits presently sell for less than \$10) and is hand-operated (Fig. 1), making it usable where electricity is unavailable or unreliable. The equipment also is reusable, and this advantage is the focus of this paper.



SOURCE: The Pathfinder Fund

FIGURE 1: Menstrual regulation equipment

In the early seventies, the International Fertility Research Program (IFRP) initiated a clinical evaluation of the safety and efficacy of the menstrual regulation procedure (1-5). In the course of conducting clinical studies, staff at the IFRP began to notice that some practitioners requested replacement equipment sooner than others, and that some practitioners appeared to be using the equipment for much longer than the manufacturer recommended. One doctor used a cannula for at least 100 procedures and another cleaned, lubricated and reused one syringe over 1000 times. Other users ignored the instructions given by manufacturers for care of the equipment and sterilized the syringe by soaking it in iodine. This caused the rubber tip on the piston to stick inside the barrel so that it could not be withdrawn to provide an adequate vacuum, resulting in some incomplete procedures and a very disconcerted physician.

MATERIALS AND METHODS

Menstrual regulation kits made by three manufacturers* were purchased without informing the manufacturers of the purpose of the study. The kits were evaluated at Kandang Kerbau Hospital in Singapore during 1975 and 1976 to discover how many procedures the kits could safely perform and how different means of sterilizing the equipment had affected durability. This hospital was chosen for the study because of the high volume of cases and the operator's skill in performing this particular procedure. All menstrual regulation procedures were performed by the same operator (DV).

Gamphen and CSO soaps and Chlorhexidine, Cidex and Milton disinfectants were chosen for use because they were readily available at the study location. Gamphen is available throughout Asia; CSO is only locally available. The three disinfectants used are available in much of Asia, although they may be financially beyond the reach of many clinics. The selection of these products is not intended to imply that they are better than products that were not selected.

Each brand of menstrual regulation kit was evaluated under six (3 x 2) different cleaning procedures. The operating physician was instructed to use each kit (one syringe, five 4-mm cannulae, five 5-mm cannulae and five 6 mm-cannulae**) until it was no longer considered safe to use, or for 100 procedures, whichever came first.

*International Projects Assistance Services (IPAS), 123 West Franklin Street, Chapel Hill, NC 27514 USA; Rocket of London Inc., P. O. Box 407, Branford, CT 06405 USA; Burnet Instruments, 700 E 22nd Street, Lawrence, KS 66044 USA

**Additional cannulae were provided where necessary so that brands contained the same number of cannulae.

CONTRACEPTION

The cleaning instructions were consistent with the manufacturer's instructions. After each procedure, it was recommended that the syringe be washed in hot, soapy water then air-dried. It is not necessary to sterilize the syringe since material is only drawn into it and at no time does it touch the woman. The cannulae were to be washed in hot, soapy water then soaked in disinfectant for at least 15 minutes. (In fact, the length of soaking varied with the manufacturer's instructions: cannulae were soaked in Cidex for 20 minutes, in Chlorhexidine for 30 minutes and in Milton for one hour.) The cannula must be bacteriologically sterile as it enters the uterus, but cannot be boiled or autoclaved, as this would cause the plastic to become brittle and crack. A bacteriological swab was taken from the tip of each cannula before every tenth procedure and sent to the laboratory for analysis to check the adequacy of the sterilization procedures under test.

Singapore is no longer a developing country; medical standards are high and medical equipment and suitable disinfectants are readily available. Therefore, the physician conducting the study rejected the equipment as unusable when other physicians with fewer resources may have been content to continue to use it for a while longer. Nevertheless, the relative durability of the different kits would probably remain the same. Used kits were returned to the IFRP for evaluation by a materials engineer after they became unusable.

RESULTS

Eighteen syringes were used in the study (six of each brand), and only two remained usable after 100 procedures (Table I). Both of these were manufactured by IPAS.

TABLE I. Number of times each syringe was used before being discarded.

Disinfectant	BRAND OF KIT USED					
	IPAS		Burnett		Rocket of London	
	SOAP		SOAP		SOAP	
	Gamophen	CSO	Gamophen	CSO	Gamophen	CSO
Chlorhexidine	68	83	73	63	51	34
Milton	59	96	81	89	53	48
Cidex	100 ^a	100 ^a	91	88	59	65
MEAN (kits)	84.3		80.8		51.7	
MEAN (soaps):	Gamophen	70.5				
	CSO	74.0				

^aMaximum number specified in the trial design.

The following results should be viewed in light of the fact that equipment may have been rejected as unusable in Singapore when it might have been judged still usable in other, poorer countries.

The Burnett and IPAS syringes lasted substantially longer than the Rocket* syringes. The least durable of the Burnett and IPAS syringes (63 and 59 procedures, respectively) lasted almost as long as the most durable of the Rocket syringes (65 procedures). The mean number of procedures for the three brands of syringes was 84.3 for the IPAS, 80.8 for the Burnett and 51.7 for the Rocket. It should be pointed out that the mean for the most durable syringes is underestimated since two of the syringes were still operable at 100 procedures and might have been usable for many more procedures. The difference between the Burnett and the IPAS kits is not statistically significant. The difference between the Rocket kit and the other two brands is statistically significant ($p < .001$).

The type of soap used to wash the syringes does not appear to have affected durability significantly. The mean number of procedures was 70.5 for Gamophen and 74.0 for CSO.

The reasons that the syringes (Fig. 2) were judged to be unusable varied from one brand to another. All of the Burnett syringes became unusable when the pinch valve liner became detached from the nozzle of the barrel, resulting in loss of vacuum. The liner began to detach before the series was discontinued; it could be used for four to eight additional procedures after it started to detach.

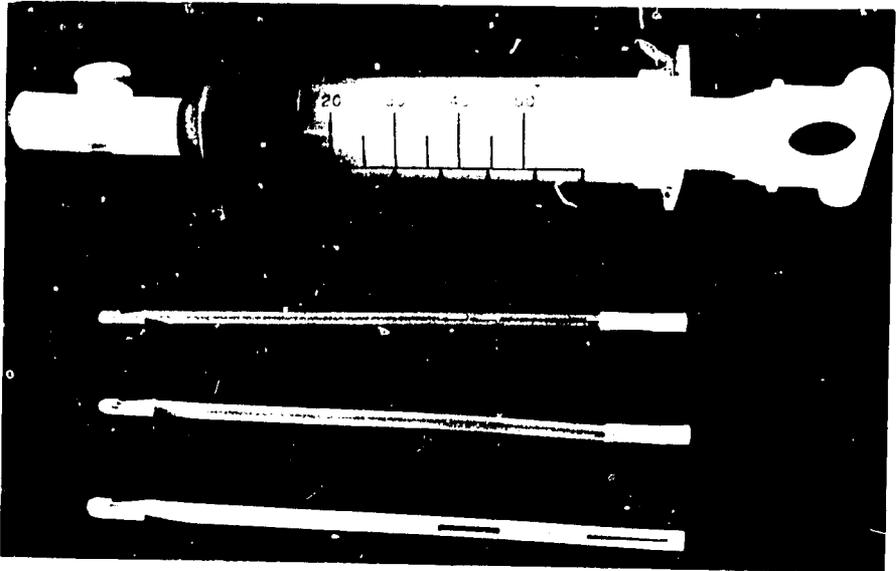


FIGURE 2: Menstrual regulation syringe and cannulae

*The manufacturer's directions with the Rocket kit state that it is intended for one use only.

CONTRACEPTION

The same difficulty occurred in two of the IPAS syringes; as with the Burnett syringes, the operator could perform several procedures after this started to happen. With two other syringes the plunger got stuck inside the barrel. The two remaining syringes were still operative after 100 procedures had been performed.

The Rocket syringes all became inoperable when the adapter between the nozzle and the cannula became loose. The syringe detached from the cannula during the procedure leading to loss of vacuum.

Only the 5-mm cannulae were used with enough frequency to permit analysis. The operating physician was instructed to keep a tally of the number of times each cannula was used.

When the syringe became unusable, the last cannula to be used was frequently still usable. For this reason, the mean number of times each cannula was used was calculated twice; the first calculation excluded the last cannula and the second included it (Table II). The number of cannulae used and the number of times the last cannula was used is, of course, quite dependent upon how long the syringe lasted. For this reason, the number of cannulae used with the Rocket syringes was less (N=14) than the number of cannulae used with the IPAS and the Burnett syringes (17 and 21, respectively). The first of the two means shown is probably the best measure of the durability of the cannulae. As the Table shows,

TABLE II. Number of times each cannula was used.

Disinfectant	BRAND OF KIT USED					
	IPAS		Burnett		Rocket of London	
	SOAP		SOAP		SOAP	
	Gamophen	CSO	Gamophen	CSO	Gamophen	CSO
Chlorhexidine	23	18	25	18	29	25
	22	27	22	30	21	5
	17	30	18	11		
Milton	25	25	28	23	32	18
	28	32	28	17	13	14
		35	23	14		9
			26			
Cidex	25	28	15	21	28	24
	24	30	33	27	25	23
	38	36	32	20		15
			8	15		
MEAN: Excluding last cannula		25.3 (N=11)	23.5 (N=15)	24.1 (N=8)		
Including last cannula		27.2 (N=17)	21.6 (N=21)	20.2 (N=14)		

CONTRACEPTION

there is very little difference in the three brands. The Burnett cannulae averaged 23.5 procedures each, the Rocket cannulae 24.1 procedures, and the IPAS cannulae 25.3 procedures. These differences are not statistically significant.

Table III shows that the different soaps and disinfectants had a negligible effect on the durability of the cannulae.

TABLE III. Mean number of times cannulae are used by type of soap and type of disinfectant used in sterilization.

Disinfectant	SOAP					
	CSO		Gamophen		Total	
	a	b	a	b	a	b
Chlorhexidine	23.6	19.7	23.2	21.3	23.4	20.5
Milton	20.4	21.7	27.2	23.4	23.3	22.5
Cidex	23.8	22.4	25.0	24.2	24.3	23.3
TOTAL	22.6	21.4	25.0	23.0	23.7	22.2

^aThe last cannula (still usable) is excluded.

^bThe last cannula is included.

Table IV shows that the soaps and disinfectants did have a differing degree of success in performing their primary function of sterilizing the cannulae. While there was little difference between the two soaps, the differences between the disinfectants were more marked (but still not statistically significant), and all three performed poorly. Among the cannulae sterilized with Milton, 35.6% had positive bacteriological cultures; positive cultures resulted in 27.2% of cannulae sterilized with Cidex and in 25.0% sterilized with Chlorhexidine.

TABLE IV. Effectiveness of three disinfectants and two soaps in producing sterile cannulae.

Disinfectant	SOAP								
	CSO			Gamophen			Total		
	Swabs Taken	Positive No.	%	Swabs Taken	Positive No.	%	Swabs Taken	Positive No.	%
Chlorhexidine	18	5	27.8	22	5	22.7	40	10	29.3
Milton	23	9	39.1	22	7	31.8	45	16	35.6
Cidex	27	7	25.9	28	8	28.6	55	15	27.2
TOTAL	68	21	30.9	72	20	27.8	140	41	29.3

CONTRACEPTION

The following bacteria were identified: *S. albus*, *S. aureus*, achromobacteria, *E. coli*. Osborne (6) studied the bacterial flora in the genital tract in pre- and postmenopausal women. With the exception of achromobacteria, all of the bacteria found in our study are included in Osborne's list.

It is instructive to compare the results that are presented in this paper with the results of a study conducted by Spence (7) of the cold sterilization of abortion cannulae. Spence's study was conducted in the laboratory and involved no patients; he compared the presence of bacteria in semirigid polyethylene cannulae (size 6) and in the rinse solution after disinfecting the cannulae in each of six disinfectants. The cannulae were soaked for varying periods of time (1, 5, 10 and 20 minutes). (Only one of the disinfectants--Cidex--was also used in our study.) The cannulae had previously been contaminated with *E. coli*, *N. gonorrhoeae*, beta-hemolytic streptococci and *bacteroides fragilis*.

The Spence study found that no bacteria persisted after ten minutes of soaking in Cidex, whereas in our study, 27.2% of the cultures taken after soaking for 20 minutes in Cidex were positive. How can this discrepancy be explained?

Spence notes that "although the cannulae were contaminated with culture media solutions, the degree of this contamination may differ when blood, mucus and tissues from the products of conception are present."

Furthermore, in the Spence study, fresh disinfectants were used, whereas in our study the Cidex was changed every two weeks (the Chlorhexidine was changed weekly, and the Milton daily) regardless of the number of cannulae that had been sterilized in the solution.

It is important to note that no cases of infection were reported in the women in our study despite the fact that a quarter to a third of the cannulae showed positive cultures. It is possible that since all the bacteria found were ones commonly present in the female genital tract, the patient's usual defense mechanism would keep her from becoming infected. Spence and his colleagues suggest that when the defense mechanisms are changed (for example, by inoculating these organisms into a freshly curetted uterine cavity), then more infection may result. Our data suggest that their concern may be unjustified.

An alternative explanation is that when a sterile cannula passes through the cervix, it may transfer whatever bacteria are present in the cervical canal into the uterine cavity; thus one would not necessarily expect a lower rate of uterine infection even with sterile cannulae.

CONCLUSIONS

With proper care and attention, the three menstrual regulation kits tested can be safely used for more procedures than advertised by their manufacturers. In the poverty-level economies that characterize most developing countries, the kits may have been used, probably with complete safety, for many more procedures.

However, menstrual regulation kits do not receive proper care and attention in many clinics. Medical staff generally boil or autoclave operating room equipment and may include the plastic menstrual regulation kits in this procedure, contrary to the manufacturer's instructions. This drastically reduces the useful life span of the equipment. Many clinic staff disregard the recommendation that the syringes should not be sterilized and will soak them in a variety of disinfectants between procedures, sometimes with adverse mechanical results.

The disinfectants that were used in this study are not available to many clinics. For example, the doctor reporting prolonged use of cannulae was using formalin to sterilize them, apparently satisfactorily in terms of durability, but unknown in terms of sterility. The effect of a lack of resources is also seen in the use of disinfectants, which are often used for much longer than they should be, thereby reducing their effectiveness.

It is recommended, therefore, that manufacturers of menstrual regulation kits recognize that practitioners in the developing world will use their kits long past the number of uses recommended in the accompanying literature. Steps should be taken to ensure that the parts most likely to wear out can be easily replaced, or procedures should be adopted to minimize that wear. Several companies, for example, have begun to include a small tube of silicone jelly in their kits to prevent the plunger from sticking inside the barrel, thus prolonging the life of the syringes.

ACKNOWLEDGMENT

Partial support for this work was provided by the International Fertility Research Program with funds from the Agency for International Development.

CONTRACEPTION

REFERENCES

1. Brenner, W.E., Edelman, D.A., Davis, G.L.R. and Kessel, E. Suction curettage for "Menstrual Regulation." *Adv Plann Parent*, 9:15-25 (1974).
2. Vengadasalam, D., Lean, T.H. and Edelman, D.A. Menstrual Regulation--Review of 496 Cases at Kandang Kerbau Hospital, Singapore. In *The Congress Proceedings: VI Asian Congress of Obstetrics and Gynaecology*, Kuala Lumpur, Malaysia, July 20-27, 1974 (T.A. Sinnathuray, Editor) Scientific Subcommittee VI Asian Congress of Obstetrics and Gynaecology, Kuala Lumpur, 1974, p. 321-328.
3. Pachauri, S., Kessel, E. and Gordon, J. Menstrual regulation --results of early studies. In *Proceedings of the First International Scientific Congress of the Family Planning Association of Sri Lanka*, Colombo, January 21-26, 1974 (S. Chinnatamby and N.D.W. Lionel, Editors) Family Planning Association of Sri Lanka, Colombo, 1975, p. 194-208.
4. Laufe, L.E. The menstrual regulation procedure. *Stud Fam Plann*, 8:253-256 (1977).
5. Fortney, J.A. and Laufe, L.E. Menstrual Regulation--Risks and Benefits. *Risks, Benefits and Controversies in Fertility Control* (J.J. Sciarra, G.I. Zatuchni and J.J. Speidel, Editors) Harper and Row, Hagerstown, 1978, p. 274-281.
6. Osborne, N.G., Wright, R.C. and Grubin L. Genital Bacteriology: A Comparative Study of Premenopausal Women with Postmenopausal Women. *Am J Obstet Gynecol*, 135:195-198 (1979).
7. Spence, M.R., King, T.M. and Brockman, M. The Cold Sterilization of Abortion Cannulae. *Int J Gynaecol Obstet*, 15:369-372 (1978).