ATTEMPTS AT CHEMICAL BLOCKING OF THE FALLOPIAN TUBE FOR FEMALE STERILISATION

by

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Introduction

The idea of chemical blocking of the uterine tubes simulating natural blockage of infertile women had been conceived by the author and a series of animal and human experiments on women volunteers coming for hysterectomy for non-malignant pathology were undertaken since early 1964. The results of the experiments were published from time to time as per references given at the end of this article.

At first chemical irritants like quinine, urethane, etc. were used in a vehicle of commercial gum and P.V.P. (Polyvinyl pyrollidone) solution. Minute particles of sterile marble dusts, chalk dusts and Bentonite powder were also used in a suspension of P.V.P. solution. Foreign particles and urethane solution produced block in human subjects but in case the block was not complete danger of causing ectopic pregnancy could not be ruled out. In animals the resolution of the tubes were very quick and block did not persist. The author had therefore been looking out for any substance which could form a slow precipitate within the tube when instilled per vaginam. Use of silastic brand of liquid silicon plastics with catalyst 'M' (Stannous Octoate) manufactured by Dow Corning showed some prospect of achieving the objective. There is also a reasonable chance of reversing the sterilisation by pulling out the solidified plastic by laparotomy.

The present paper is a compilation of the work done after November 1967 upto March 1970. The study was made during last one year with a grant from the Indian Council of Medical Research. Part of the earlier results were presented in an International Conference on Human Sterilisation held at Cherry Hill, near Philadelphia, in October 1969 and are being published in the Transactions of the Conference. Some of these photographs are also being published there and reproduced here with their consent.

Methods

These liquid silicon plastics manufactured by Dow Corning, become solid after addition of a catalyst. The time of solidification depends on the amount of catalyst used. A proportion of diluted catalyst has been worked out which gives a working

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The author has brought the result of his work upto March 1970.

time of ten to fifteen minutes. Fifteen per cent barium sulphate is added to make the plastic radio opaque. Ten ml. of the material is put in a syringe fitted to a wide bore uterine cannula of a size suitable for the size of the cervical os. The plastic is taken for each injection and requisite amount of catalyst is added and briskly stirred up within the syringe. The piston is then put in, air gap is dispersed and the liquid is filled upto the tip of the cannula. The cannula is then put inside the uterine cavity through the cervix and it is ensured that it tightly fits to the cervical os. About 5 to 6 ml of the liquid is then pushed in. The cannula is then withdrawn and both the syringe and the cannula are quickly washed out in xylol before the liquid sets.

After withdrawal of cannula, the plastic from the uterine cavity pours out. To facilitate cleaning up of the uterine cavity, the cervix is dilated up and mopped out with gauze with a uterine dressing forceps. Before injection of plastic the same cannula is utilised for an insufflation test and only when the test is positive plastic injection is made. Recently, the uterine cavity is no longer being deliberately cleaned up by dilating the cervix. The uterine cavity is only a potential cavity and it empties out itself automatically.

In the series of cases already published (Rakshit, 1968) all attempts were made through the cervix. The few failures were due to (i) loosely fitting cannula; (ii) doubtfully positive insufflation test at high pressure; (iii) use of too much Barium Sulphate making the substance too thick and (iv) blockage inside cannula. In later trials, attention to these points prevented many failures.

It is very much expected that barium sulphate used for demonstrating by x-ray during these stages of the study may be discarded from now on and this will give almost a cent per cent success in instillation of the silicon plastics.

In some cases during ligation of tube by the abdominal route, plastic has been instilled through the abdominal ostium of the tube, making only a ligature near the uterine end, with or without resection of a small portion of the tube. This was neessary to allow money incentive to the patients which was sanctioned by the Government. The object was to (i) study the question of rejection of the plastic by the tube in future; (ii) to study the possibility of restoring the patency by removing the plastic, should occasion arise in future and (iii) to use plastic only, by the abdominal route also in place of ligation of tube, in order to prevent many of the known adverse sequelae of ligation and resection. During subsequent studies six cases have been instilled abdominally leaving the tube intact. The results of these tests are tabulated below.

Animal Experiments

Rabbits — Fifteen animals have been operated—3 died during anaesthesia and 2 died within 2-3 days.

Of the remaining ten—2 had been injected with sodium morrhuate and 8 were instilled with liquid plastics (S 521—5 cases and 68—110 fluid—3 cases).

X-ray study after 2 weeks showed that the liquid plastics were rejected in 6 out of the eight cases.

Fertility trial of the plastic instilled rabbits at the Calcutta zoo demonstrated that 4 cases with x-ray negative shadow conceived within 6 weeks. Two cases with positive shadow in x-ray conceived after 18 weeks, apparently after subsequent rejection of the plastics.

Two rabbits injected with sodium morrhuate showed partial blockage of the fallopian tubes and no damage to the uterus.

Five other animals were instilled with liquid plastic 68-110 on one side and silver nitrate 10% urethane 5% and sodium morrhuate on the other side. Results were failures of complete blockage but no toxicity was observed.

Attempt at demonstration of the scope of reversibility by trial on 2 Rhesus monkeys, failed due to very narrow and small fallopian tubes in such animals. Fallopian tube of one langur monkey was injected with liquid plastic 68-110 by the abdominal route. The animal lived for over one year and then died of pulmonary tuberculosis. Reversibility could not be tested due to serious labour trouble at the Calcutta Zoo. Attempt to carry out further such experiments at Chandigarh did not materialise due to faults of "Red Tapeism".

TABLE I

Experiments on Human Volunteers

Vaginal Instillation with S. 521 & 68-110 *Silastic*

No. of cases	Salpingectomy or hysterectomy or ligation	Intact tubes	Result of instillation		
			Satisfactory block	Doubtful block	failure
30	20	10	21	6	3
Follow-up Study					
	Rejection	Pregnancy			
	No rejection upto 15 months	In one case (with doubtful shadow in X-ray)			

TABLE II

Vaginal Instillation with S. 5392

No. of cases	Salpingectomy or hysterectomy or ligation	Intact tube	Result of instillation			Reversibility
			Satisfactory block	Doubtful block	Failure	
7	7	Nil	Nil	4	3	One case had 'S' 5392 removed at laparotomy

TABLE III

Abdominal Instillation with S. 521 & 68-110 Silastic

No. of cases	Intact tube	Simple ligation at one end	Ligation & excision of loop	Results	
				Rejection	Pregnancy
10	6	2	2	Nil upto 18 months	One case of simple ligation

The Results

The result of last series of animal experiments has established that the material is harmless to the tissues. Even though the material is spilled around the area no gross adhesion was formed as found at subsequent laparotomy.

In the present series of human trial forty-seven cases have been instilled with the liquid plastic (Tables I, II and III), thirty-seven cases through the cervix and ten cases through the abdominal ostium of the fallopian tube at laparotomy. There were two failures in the cervical route cases with silastic 521. In all twenty-one cases show satisfactory block of the liquid plastic in the tubes. Six cases have doubtful block. There has been no spilling in the peritoneal cavity except in one case. Seven cases have been instilled with silastic 5392. As silastic 5392 is sticky, it solidified all atonce and more quickly, only a small quantity of it has been found to enter the tubes in four cases only. The results are unsatisfactory, The material silastic 521 gave much better results than silastic 68-110 fluid. The latter curdles up with Barium and solidified irregularly and therefore gave more failures. Unfortunately S. 521 is no longer being manufactured.

A follow up study by x-ray on all the cases who did not have salpingectomy so far shows that none of the cases rejected the material. Two of them are retaining it for upto eleven and fifteen months (vide photographs). Sixteen of the cases have been instilled with plastic only and no ligation or excision of tube has been done. So they are the only cases so far, who can be studied for effectiveness of the resulting infertility. None of these cases has conceived upto about three years. As the Government is paying money as an incentive for sterilisation it is difficult to get cases for trial with instillation of the liquid plastic alone. In future more such trial is contemplated. The author also appeals to other workers to conduct such human trials on volunteers in their own sphere of work after satisfying themselves with animal experiments regarding any adverse effects of the substances used.

So far the present series of experiments has established the following:

(1) Such silicon plastics are harmless to the tissues as found by animal and human experiments. Many such plastics are already in use by the plastic surgeons and during operations on blood vessels.

(2) These liquid plastics can be pushed blindfolded through a tightly

fitting uterine cannula to reach the fallopian tubes and solidify there. The plastic solidifies near the ampullary wider end due to peristalsis and contraction of the narrow part of the tube. The uterine cavity can be easily emptied out and none of the radiographs show any plastic in the uterus. There is not much danger in case of spilling.

(3) There has been no spilling of the plastic into the peritoneal cavity because of high viscosity and quick solidification in the present series, except in one case. In one human trial case of previously reported series, there was failure of solidification due to stale catalyst and spilling in the peritoneal cavity did occur but no adverse symptom. In another case reported here excess material was injected due to wrong reading at the syringe and spilling did occur causing peritoneal symptom. The pelvic cavity was cleaned out during salpingectomy and patient had uneventful recovery. In animal experiments deliberate spilling was allowed in the peritoneal cavity but no adverse tissue reaction or gross adhesion was found. There will be no spilling if the limit of 4.5 to 6 c.c. is not exceeded in human volunteers and proper strength of catalyst is used.

(4) The plastic completely fills up the lumen and the block is complete and no danger of ectopic is anticipated.

(5) The plastic is not rejected by the tube—at least fifteen months follow up has not shown any rejection.

(6) The plastic being very soft and pliable it does not cause local pain or damage to tubal wall. The soft plastic allows free movement of the tubes.

The experiments are likely to establish the following in near future:

(i) That the plastic can be withdrawn from the tube per abdomen, should occasion arise and patency of tube and fertility restored. In one case plastic material could be removed by nicking the tubes during subsequent laparotomy.

(ii) That the plastic can be instilled without anaesthesia on a mass scale when the method is accepted as a recognised procedure.

(iii) That effective contraception can be achieved by this much simpler and less costly procedure than ligation of tube by any route. It will save a lot of hospital beds. The trial on animals and human volunteers will finally establish this by studying fertility rate against controls.

(iv) Even if we instil the tubes with plastic at laparotomy without any ligation or excision of the tubes, it will be quite effective and at the same time prevent many of the known complications of ligation of the tubes, such as menstrual derangements, pelvic pain and hydrosalpinx as no anatomical alteration is made.

Summary

Attempt at sterilisation by this method has not been attempted before by any author. Shubeck (1965) tried formation of mould inside uterus and Roy Pitkin (1966) tried fibrosis of remaining portion of tube after abdominal ligation by instilling sodium morrhuate with a view to prevent formation of hydrosalpinx.

The method is not intended to replace the loop but it should replace ligation of the tubes. Even if recanalisation be not possible in future

trials, this will be superior to ligation of tubes in all respects.

A much wider trial is required in different centres to corroborate the author's findings. The author is willing to train up and advise workers in the technical details of the method.

It is likely to be possible without using anaesthesia. In a few cases of trial with chemical irritants, instillation was made without anaesthesia. In case of plastic, if it is not removed from the uterus by dilatation and sponging, majority of the liquid flows out spontaneously. It is expected that the remaining liquid and even the solidified portion will come out spontaneously (Shubeck, 1965). It may, therefore, be possible to instil a large number of cases as an outdoor procedure without anaesthesia.

In case we are obliged to use anaesthesia in all cases, this procedure will be much simpler and less troublesome than ligation of the tubes.

Even if abdomen is opened and then, instead of ligation plastic is instilled, we may expect to avoid many of the known adverse sequelae of ligation of the tube because no anatomical alteration is made. The plastic is rubbery soft and adapts easily to movements of the tube and is not likely to cause perforation of the tube or any local pain.

However, vaginal instillation is the aim of the author and a lot of success has been achieved in this respect. It will be necessary to perform a wider trial in different centres by different workers, to establish how far it will succeed in sterilisation effect and whether future restoration of tubal patency may be possible. It is expected by the author that use of chemicals and even bacterial toxins may be successful if wider trials are made by future workers. At first, cases for hysterectomy having patent tubes may be experimented with. Animals show quick healing but such is not expected in human subjects.

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See Figs. on Art Paper I-II-III