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SOME OBSERVATIONS ON INTRAUTERINE CONTRACEPTIVE DEVICE (LIPPES LOOP)

DR. DOSSIBAI J. R. DADABHOY BOMBAY OBSTETRIC & GYNAECOLOGICAL SOCIETY'S SILVER JUBILEE ORATION

by

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It is a great honour to be here to deliver the Dr. J. R. Dadabhoy oration. Giants in Obstetrics and Gynaecology have preceded me in this memorial lecture and to follow them is a task beyond my competence. The life long service done by the late Dr. Dadabhoy in our speciality is a shining example to all of us, but how much we have emulated her is a moot question. She struggled hard against all odds to reduce the maternal and perinatal mortality and achieved results which would have been infinitely better had she but had half the facilities which we now have. All honour to her for her inspired labour in the cause of obstetrics.

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The subject which I have chosen to-day may, therefore, seem rather out of place in view of the nature of the work of Dr. Dadabhoy for which she is well remembered. But, I think it has got great relevance in that one of the ways and means of reducing maternal and perinatal mortality is by controlling and preventing high parity births. This is my only excuse for choosing this topic—namely, some observations on the intrauterine contraceptive device which is a means to that end.

With the development of modern intrauterine devices a method of conception control has become available, the importance and impact of which have yet to be fully recognised. The steadily increasing acceptance of intrauterine devices in many parts of the world and in all strata of different societies shows that they are generally considered to be effective and safe.

Within the last few years the number of modern devices in use has increased from a few thousand to well over a few million and the method has become the mainstay of the family planning programmes established by several Governments. In India it is reported that from July 1965 to July 1969 2,910,291 loops have been inserted (Centre calling, July 1969).

The devices appeal to all types of women in all parts of the world. Once the device has been inserted no further thought or action by either partner is required. So long as the device remains in position the woman is almost completely protected against conception (97-98%). The fact that it can be left there for long periods without constant medical supervision is a further big advantage, especially in areas where there are few doctors. Women who wish to conceive usually do so within 6 months to a year after removal of the device. In cases where an unplanned conception has occurred with a device in place no adverse effect on pregnancy, delivery or the health of the child has been demonstrated.

Many questions, however remain. Of these the most important is the mode of action of the I.U.D. which is indeed challenging. Spontaneous expulsion rate is still high and so far the answer to this problem is unsolved. Apart from these, two other problems of importance are, (1) the bleeding associated with I.U.D. and (2) the translocation of the loop or its external migration or perforation.

In India though various devices are under trial the one that is accepted by the Government in its programme is the Lippes loop.

The complications that follow the I.U.D. insertion are usually (a) bleeding, (b) infection and (c) translocation or perforation. Minor complications are leucorrhoea, pelvic pain and dysmenorrhoea.

The commonest of all the complications that follow the insertion of an I.U.C.D. is bleeding from the genital tract. This bleeding episode as has been so often reported may start with the insertion or later may be small in amount or profuse, may be in the form of menorrhagia or irregular bleeding and in some cases the patient is seldom dry for weeks together. In fact there is no definite pattern. It is also agreed that such bleeding often tends to subside by itself and with encouragement the majority of women could be made to continue wearing the device. There is a consensus of opinion that this complication is maximum during the first three months following the insertion after which it tends to stop. There is, however, controversy regarding the mechanism of its production.

During the last three years, 4864 patients were fitted with an I.U.C.D., 4582 with Lippes loop and 282 with Antigon. Of these 1846 were postpartum or postabortal, the insertions having been done within 2-10 days of delivery or abortion, except in 206 patients where the insertions were done between 11 and 41 days. It was possible to follow up only 3188 patients and even this not very satisfactorily. Among these, heavy bleeding was observed in 570 patients—an incidence of 18%. However, the device had to be removed only from 387 patients because of bleeding i.e. 12%. In 80% this bleeding occurred within the first three months. In the remaining it occurred much later. This

study is limited to 170 patients who started having profuse bleeding episodes 4 months after the insertion of the I.U.C.D., the bleeding being of such magnitude as to necessitate removal. One may call them late haemorrhages. In 167 patients Lippes loop, size 30, mm was the device employed. Three patients had Antigon inserted.

Twenty-four patients had postpartum insertions—18 within 2-10 days and the rest within 12-42 days. Further relevant data are presented in the tabular statements below. Age group—youngest was 20 years and oldest 40 (Table I).

TABLE I

Age group

Age	20-29 years	30-40 years	Total
No. of patients	109 (64%)	61 (36%)	170

Ninety-six or 57% had 4 or more children. There were one each of 11th and 14th para (Table II).

TABLE II

Parity

Parity	1	2	3	4	5	6	7	8	9	10	10+	Total
No. of patients	6	31	37	21	23	18	17	9	4	2	2	170

TABLE III

Time of onset of bleeding

Time interval in months	4-8	9-12	13-16	17-20	21-24	25-36	36+	Total
No. of cases	30	28	31	27	20	28	6	170

Type of bleeding

Menorrhagia—profuse periods lasting 7-12 days with passage of clots was observed in 120 patients. In the remaining 50, the bleeding was in the nature of irregular and intermittent discharge, profuse alternating with reduced bleeding continuing for days together so that the patient was seldom free of bleeding except for a few days in a month.

Relationship of bleeding episodes to insertion of I.U.C.D.

Prior to the insertion of the I.U.C.D. there was no history of any abnormal menstruation or bleeding in any of the patients. The cycles were regular, 26-30/3-5. In 52 of these patients there was some bleeding not significant during the first months following the insertion of the I.U.C.D., but this bleeding continued to increase necessitating removal at varying intervals from insertion—intervals not earlier than four months.

"Time" denotes the interval between date of insertion and removal of I.U.D. and D and C.

In 58 patients bleeding severe enough to warrant removal occurred during a period of 4-12 months, while in 112 the interval was 13-43 months. In the former group there were 18 postpartum cases.

To understand the significance of these late haemorrhages the devices were removed and the patients sub-

mitted to a curettage and cervical biopsy. The material so obtained was studied histologically. The results are shown in table IV.

TABLE IV

The Endometrium

Type of Endometrium	Proliferative	Secretory	Hyperplasia	Cystic glandular hyperplasia	Stromal hyperplasia	Adenomatus hyperplasia	Infection
No. of cases	86 (50.5%)	34 (20%)	12	10	16	7	5 (3%)
			(26.5%)				

The curettings were done in the bleeding phase. If it is accepted that hyperplasia of all types represents abnormal endometrium then in these 170 cases the incidence of such abnormal types amounted to 26.5%. Of patients showing abnormal endometrium, in 45 the loop had been in situ from 12-42 months and in 5 for 4-10 months.

lesion on the cervix which includes the so called "Erosion". All such cases are either investigated and treated and then the loop inserted or advised other methods of contraception. However, cytological screening has not been a routine. These 170 cases had prior to the insertion of the loop apparently healthy looking cervices. Within 4-52 months after the I.U.C.D. was inserted the following lesions were discovered on biopsy of the cervix at the time of curettage.

The 2 cases of carcinoma in situ were found in patients 28 and 32 years of age with 3 and 5 children each. These were subjected to conization. Multiple sections from the cone did not reveal any invasive can-

TABLE V

Correlation of age to type of endometrium

Age group	Endometrial pattern			Infection	Total
	Proliferative	Secretory	Hyperplasia all grades		
20-29	58	24	25	2	109
30-40	28	10	20	3	61

TABLE VI

Cervical pathology	Erosion	Chronic cervicitis	Basal cell hyperplasia	Carcinoma in situ	Polyp
No. of cases	36	64	5	2	1

The significance of these endometrial patterns will be discussed later.

The Cervix: The policy at the institute has been not to fit an I.U.C.D. if there is any obvious pathological

cer. One of these patients was subjected to hysterectomy. Three others also were subjected to hysterectomy because of dysfunctional uterine bleeding and multiparity with chronic endocervicitis.

The follow-up: It was possible to follow up only 107 patients. Except in 6, curettage had a definite therapeutic effect in that the menorrhagia and irregular bleeding stopped and normal cycles were established. The loop was reinserted in 3, eight patients accepted oral contraception, 11 were on Depot Provera injections, and the sheath and diaphragm were said to be used by the rest. Of the 107 followed up, 12 became pregnant —none in the group on oral contraceptive and injections.

Discussion

From the study of the 170 cases the uterine haemorrhages, either in the form of menorrhagia or irregular bleeding, clinically can be said to resemble dysfunctional uterine bleeding. Dysfunctional uterine bleeding is a very common gynaecological complaint. During a two year period among 10954 gynaecological admissions, 1,550 were cases of dysfunctional uterine bleeding, giving an incidence of 14.1%. In these 1,550 patients the age distribution was as follows:—

In the 170 patients under study, 64% of the patients with dysfunctional uterine bleeding belonged to the age group 20-29 as against 38.5% in whom no IUCD was inserted. This seems significantly a high incidence. In the age group 30-40 however, the incidence of 36% in those with the loop as against 26.2% in those without, does not seem to be of such significance. While no definite conclusion can be drawn, could it be that an intrauterine device induces a higher incidence of dysfunctional uterine bleeding in the younger age group? At this stage this is really a surmise and a much larger study and data are required to substantiate or disprove the suggestion.

It is rather difficult to assess the influence of parity in relation to bleeding. In the 170 cases under study, 57% had 4 or more children and 43% less than four. In the series of 1,550 cases of dysfunctional uterine bleeding 38% had four or more children and 41% less than four, while 21% did not have any at all. The two groups from this angle are not very comparable but it might be surmised that there is a higher incidence of increased parity in the IUCD group.

The endometrial patterns in the two groups also have been similarly compared. Table VIII shows the comparison.

Broadly speaking, the incidence of the different types of endometrium in

TABLE VII

Age in years	15-19	20-29	30-39	40-50	Total
No. of DUB cases	295	598 (38.5%)	405 (26.2%)	252	1550
IUCD cases	—	109 (64%)	61 (36%)	—	170

TABLE VIII

Type of endometrium	Prolife-rative	Secre-tory	Hyper-plasia all grades	Infec-tion	Others
IUCD group 170 cases	50.5%	20%	26.5%	3%	—
D.U.B. 1550 cases	41.6%	20.7%	29.9%	—	7.8%

the two groups appear to be very similar. Because of the small number of cases in the IUCD group further detailed comparison was not thought to be worth while till a larger series have been studied. Its significance at this stage is uncertain.

The cervical lesions observed also require comment. These 170 women had all clinically healthy looking cervices prior to insertion of a device. No cytological examination was done in any one of them prior to insertion. Within a period of 6-36 months, chronic cervicitis in 64, basal cell hyperplasia in 5 and carcinoma in situ in 2 were diagnosed after biopsy. It would be incorrect to suggest that these lesions developed as a result of insertion of an IUCD. They could obviously have been present at the time of insertion even though the cervices appeared healthy on inspection. It is also possible that these patients could have developed the lesions even without the insertion of an IUCD considering how common chronic cervicitis is in multiparous women. The occurrence of carcinoma in situ in 2 patients within 1½ and 2 years is a pointer. It emphazises the necessity for a proper follow up of cases, if possible with cytological screening in a country where carcinoma of the cervix is common.

Auilera (1967) in his studies of the endometrium in women fitted with a zipper ring retained for periods from 6 months to 60 months found functional alterations of the endometrium in 36.3% cases and particularly to a lack of concordance between the day of the cycle and the degree of progesterone maturity. In other words, in 36.3% of cases the histological pattern of the endometrium did not correspond to what is normally expected for that day of the cycle. He observed that it is not known whether this arises from a lack of response to the normal hormonal stimulus on the part of the endometrium or if the IUCD creates some neuro-endocrine reflex effects. The endometrial studies in 58 women who had menorrhagia or metrorrhagia showed in 41 or 70% an anatomico-pathological condition linking the abnormality to the I.U.D. In the remaining 30% the endometrium was normal. However, in his studies there was a high incidence of chronic endometritis — 34.5% of cases.

Many workers in India, I am sure, would have come across these late bleedings. It is also known that administration of the oral contraceptives with the loop in situ controls the menorrhagia and metrorrhagia. But, if the actual significance is to be

understood it is essential to study at least the endometrial patterns. I take this occasion to request my colleagues to undertake such a study so that a large series may be collected to prove or disprove the suggestion that one of the causes of bleeding occurring later after an I.U.D. is inserted is a dysfunctional type of bleeding due to alterations in endometrial patterns brought about by a mechanism unknown at present.

Translocation of the Loop—Perforation

The W.H.O. Scientific Group described an extrauterine and intrapelvic position of the I.U.D. as a uterine perforation. It states that this complication varied with the type of device—(bow 1 in 200 insertions, loop spiral and stainless steel ring combined 1 in 2000). Most perforation do not produce clinical symptoms and are only discovered at routine follow up examination. It is, therefore, impossible to determine with certainty the time and circumstances of the occurrence. It is believed, however, that most perforations take place at insertion and others during attempted removal of a device especially if it proves difficult. It has been claimed that an I.U.D. can make its way unaided through the wall of the uterus but this has never been unequivocally demonstrated (W.H.O. Techn. Ref. 322). A few interesting cases of translocation of the loop are presented.

Case 1

Mrs. R—age 28, 4 children Lippes loop, No. 3, inserted in March 67. In June 68 (15 months later) she missed her periods. In August, after 2 months' amenorrhoea she started bleeding. Thread not visible —digital exploration under anaesthesia was done on 11-8-68. As the loop was not found, on 12-8-68 dilatation and curettage was done during which the uterus was perforated. At laparotomy and hysterectomy the loop was found in uterovesical pouch adherent to the uterus and the bladder. Recovery uneventful.

Case 2

Mrs. M, age 28, 1 child, 2 abortions, last abortion 28-12-66. Lippes loop size 30, inserted on 4-1-67. Checked at clinic frequently.

Missed her period 1 year and 6 months later i.e. in June 1968. Thread was palpable and seen when she started bleeding on 14-8-68 (12 weeks pregnant). Spontaneous abortion. Four days later she was admitted for loop removal. The thread was visible on speculum examination—On traction it came off—Dilatation and exploration. No loop felt.

X-ray—H.S.G.—loop extrauterine—Colpotomy and removal. Loop in pouch of Douglas.

Case 3

Mrs. T, age 30, 4 children, last child 1½ years ago. Lippes loop (30 mm) inserted on 16-2-67—(7 days after last period).

Eleven months later on 17-1-68 patient came in with history of 2 months amenorrhoea. Thread seen on examination. Pregnancy confirmed. Patient had routine antenatal care. Natural delivery of normal child at term on 12-8-68. Loop was not expelled. X-ray showed loop in the pelvis. Ten days later, dilatation for loop removal performed. No loop felt in uterine cavity.

X-ray and H.S.G.—showed the loop extrauterine—colpotomy—No loop in pelvis. Laparotomy—Loop in omentum.

Case 4

R, 22 years, married 2 years, 1st delivery on 2nd November 1967. Loop inserted on 2-12-67. Missed her periods from 6-4-68. Thread felt and seen on examination on May 15th 1968.

Next examination on June 7th 1968, because of bleeding, thread was not felt or seen. Uterus 14 weeks size. Vaginal evacuation of vesicular mole was done on

19-6-68. No loop felt in uterine cavity. Because of continued bleeding and constant pain on right side of abdomen since the evacuaton, dilatation and curretage was done on 23-7-68. No loop felt. Plain X-ray of abdomen taken on 26-8-68—Loop seen on right side of pelvis.

Laparotomy on 14-9-68—Uterus and tubes normal. Loop was seen ¾" outside the vesicouterine fold of peritoneum. The tip had perforated the peritoneum and was hooked on to the omentum. After incising the peritoneal fold the loop came off on its own. The inner ¼" which was inside the uterine muscle had a localised fibrotic reaction around it. This was excised.

None of these patients have had any acute symptoms nor is it possible to locate the time of perforation. It is to be noticed that even if the thread is visible, the loop may not be attached to it and not be in situ as in case No. 2. The thread and loop may and can part company. Another point to be observed is that once the loop escapes into the abdomen it can and does orbit about. It may be located in the pouch of Douglas to-day and within the next few days it may travel away so that if you approach through the vagina, you may not sometimes get the loop. Laparotomy had to be performed after colpotomy in one case. The lesson is if you intend to remove the loop, do it as soon as possible after locating it and before it changes its place.

It is a moot question whether a loop can be left in the abdomen for long periods if it is not giving rise to symptoms. Many seem to think so. I have 2 patients who have been keeping the loop in the abdomen for nearly 1½ and 2 years now. I track them with X-rays occasionally. I wish I knew what is the correct answer. These are again problems to be solved.

Pelvic inflammatory disease (PID)

The incidence of pelvic inflammatory disease after I.U.D. is stated to be between 2.2—3.5 per 100 women during the first year after insertion. Only a quarter of these are however graded as severe. Consequently, acute pelvic inflammatory disease is said to occur in less than 1% of these women. While most cases of pelvic inflammation occur soon after insertion of a device some may appear only after months of use. At least half of the total incidence of pelvic inflammatory disease is considered to be an exacerbation of a condition existing before insertion of the device.

The report of the advisory committee on Obstetrics and Gynaecology of the Food and Drug Administration of the United States Department of Health is rather alarming. From a questionnaire sent out to 8506 Fellows of the American College of Obstetricians and Gynaecologists it was observed that 10 deaths had been registered due to pelvic inflammatory disease after insertion of a device, 8 of them due to infection from 6 days to 2 years of insertion. 11.6% of replies to the questionnaire had seen critical illness in their patient due to infection (369 cases and 192 complications and perforation). There were 15 cases of perforations followed by intestinal obstruction and in at least 12 of these a closed device had been used.

We have been rather fortunate in that among the cases followed up so far only 8 cases of pelvic infection requiring hospitalisation have been met with. Except one, all responded to antibiotics. In one case colpotom

had to be done for a pelvic abscess and she made an uneventful recovery. Careful selection of cases will go a long way in avoiding this complication.

There is no doubt the I.U.D. is an extremely useful method of contraception. Yet it has got its limitations and complications. Careful selection of patients, insertion of the I.U.D. by trained medical personnel only, and good follow up services are the three essentials which are very necessary if the I.U.D. programme is to be a success. All of us realise that the loop programme in India has had a set back—this I think is reversible and can be overcome if the above principles are observed. Even so, we should not be too sanguine about it as there are many factors requiring elucidation. The advice of Smellie is as wise to-day as it was two hundred years ago "We ought never to trust too much or be over sanguine in respect to any particular method of practice but vary the same as we feel it necessary".

References

1. Aguilera, E. (1967): Proceedings of the 8th International Conference and I.P.P.F., Page 323-327.
2. Centre Calling (1969)—Govt. of India publication, July.
3. Wld. Hlth. Org. (1966): Techn. Rep. Ser. 332.