EVALUATION OF INTRA-UTERINE DEVICE AFTER MENSTRUAL REGULATION PROCEDURE

by

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Introduction

Menstrual regulation procedure is now a uniformly accepted surgical procedure performed on a woman who has missed her periods and is still within 14 days after the expected date of her last menstrual period. The main indication for the procedure is that the patient does not want the pregnancy to continue which she fears to be present.

This procedure is therefore a form of post coital contraceptive. It is a simple, safe and effective procedure and has a very high acceptability rate; these aspects have been presented by Kochhar and Suchdeva in 1976. However, the procedure is not completely free from complications, and therefore cannot replace pre-coital contraception.

Intra-uterine device used as a contraceptive method is safe and effective. This method of contraception had fallen into disrepute in India due to over enthusiastic approach in early days of its use by those responsible for implementation of Family Planning Programme. The availability of copper bearing devices in the recent years has gained the device its lost popularity, mainly due to lower incidence of side effects. Greater vigilance and follow-up by the Family Welfare Staff is an added factor for its recent popularity.

The simultaneous use of menstrual regulation procedure and insertion of intra-uterine device relieves the patient of the torturing anxiety of a suspected pregnancy and the continuous fear of one occurring at a later date. The volunteers for menstrual regulation procedure are already in a better state of self motivation for use of some contraceptive method. Very little effort is required to motivate them to accept one such method.

Material

The present study is based on 1000 menstrual regulation procedures carried out at the Menstrual Regulation Clinic at the Armed Forces Medical College, Pune. This clinic was started in January 1976 and provides service to the families of Armed Forces Personnel as well as civilians attending the Out Patient Department of the College.

In the First phase of the study, the procedure was not combined with the insertion of intra-uterine device. The simplicity of the procedure appeared to have adverse effect on the pre-coital contracep-

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tion with more and more patients reporting for repitition of the procedure. The results of the first 500 cases of menstrual regulation have been presented by Kochhar and Suchdeva (1976).

In the second phase of the study, the patients were offered intra-uterine device as a contraceptive soon after the completion of the menstrual regulation procedure. The acceptance rate was very encouraging inteed.

In the early part of the second phase, when only Lippes loop was available, the first 104 patients were fitted with this device. In the later part all acceptors were fitted with T Cu-200 which has completely replaced the Lippes loop. This has afforded opportunity for the comparative study of these two devices when inserted after menstrual regulation procedure.

Methods

The menstrual regulation procedure was carried out with 50 ml. plastic syringe and plastic cannula marketed by M/s. Chimco Bio-Medical Engineering Co. of Bombay. The cannulae used had single hole and were specially supplied on demand. The incidence of buckling with single hole cannula is very low. Where buckling did occur, a blind cannula was passed as a first step. This blind cannula acted as a dilator. No anaesthesia is used.

Immediately after the completion of menstrual regulation procedure, an intra-uterine device was inserted. The Lippes loop was inserted by "PUSH OUT" technique, while T Cu-200 was inserted by "withdrawal" technique.

All cases, acceptors of intra uterine device as well as non-acceptors, were called after 1 week, again after further 4 weeks and then at 3 months intervals.

The last case in the present analysis had undergone menstrual regulation procedure 6 months prior to compilation of this data.

Observations

1. *Acceptance Rates in Different Categories of Cases*

All the 1000 cases were offered pre-coital contraceptive methods with special stress on intra-uterine device. Most of them accepted some form of contraceptive method but 564 patients accepted intra uterine device, an acceptance rate of 56.4 per cent.

(a) *Officers Wives:* These cases belong to a high middle income group and are usually well educated. There were 249 cases in this category and 121 (49.59 per cent) accepted the intrauterine device, 104 fitted with T Cu-200 and 17 with Lippes loop.

(b) *Junior Commissioned Officers and Other Ranks Wives:* These cases belong to low middle income group and have primary to middle class education. In this group of 515 cases, 310 (60.19 per cent) accepted intra-uterine device, 249 were fitted with T Cu-200 and 61 with Lippes loop.

(c) *Civilian Families:* These patients generally belonged to low income group with poor educational background. There were 236 cases in this category and 133 (56.3 per cent) accepted the device; 107 were fitted with T Cu-200 and the remaining 26 with Lippes loop.

The overall high acceptance rate of 56.4 per cent shows a favourable trend in acceptance of intra-uterine device when immediate help is pormised in the event of any side effects. These cases showed no hesitancy in accepting Lippes loop when such help was promised. Undertaking to remove the device on demand,

irrespective of reasons for such a demand, was also given.

The non-acceptance of intra-uterine device should not be interpreted as non-acceptance of contraception as large number of device non-acceptors had accepted other methods, including sterilisation operations.

2. *Age-Group Distribution*

The age group distriubtion is analysed in Table II which reveals that 437 acceptors (77.48 per cent) were in age group of 20-29 years. Very few acceptors (31) were above the age of 35 years as majority of them preferred sterilisation. Similarly there were only 17 acceptors who were below 20 years.

3. *Marital Status*

There were 16 unmarried cases who were subject to menstrual regulation procedure. In this group 4 of them (26 per cent) accepted intra-uterine device. Nine unmarried cases were below 20 years.

4. *Parity Profile*

The parity is realistically analysed in terms of living children. Four hundred and twenty-six acceptors (75.5 per cent) had 1 or 2 children only. The intra-uterine device was accepted by them for spacing the births. Some of them accepted the device to postpone sterilisation to a later suitable date after their children had crossed the "high risk" age.

Of the 35 women without a living child, 16 were unmarried. Mothers with 3 or more children were mainly motivated for sterilisation operation.

5. *Removal Rate*

The acceptors were promised removal of the device at any time when demanded, irrespective of the reasons for such a demand.

The removal was undertaken on 114 occasions (20.21 per cent). On 59 occasions (51.75 per cent) removal was demanded for reasons other than the side effects; transfer of the husband and plan for another pregnancy were by far the most common reasons.

In the remaining 55 cases (48.24 per cent) the removal was necessitated because of the side effects. Menorrhagia and metrorrhagia were the commonest side effects (29 acceptors) followed by pain (9 acceptors).

Three cases developed infection which responded well to removal of the device and antibiotics administration.

The incidence of side effects was higher with Lippes loop as compared with T Cu-200.

6. *Insertion Removal Interval*

Sixty-two removals (54.38 per cent) were undertaken after 3 mnoths and up to 12 months of use. Two factors emerged from the study of insertion removal intervals. Some continued the use for 3 months hoping that the side effects will subside. When this did not happen they demanded removal, a very genuine cause for removal. There were more removals in asymptomatic group, which reveals that motivation gradually wanes in 3 to 12 months use.

The overall removal rate was nearly twice with Lippes loop (32.69 per cent) as compared with T Cu-200 (17.39 per cent).

7. *Spontaneous Expulsion*

This occurred in 14 acceptors. The relation of device expulsion with parity are analysed in Table I which reveals that spontaneous expulsion is 6 times higher with Lippes loop. Definite relation of ex-

pulsion to parity could not be established due to small number of expulsions.

TABLE I
Spontaneous Expulsion Parity Ratio

Parity	T Cu-200		Lippes Loop	
	Number	Per cent	Number	Per cent
Nulli	Nil (11)		Nil (—)	
One	3 (144)	0.65	3 (26)	2.88
Two	1 (202)	0.21	4 (54)	3.84
Three	2 (80)	0.43	1 (17)	0.96
Four	Nil (14)		Nil (2)	
Above four	Nil (9)		Nil (5)	
Total	6 (460)	1.3	8 (104)	7.69

Figures in brackets show number of acceptors.

The insertion expulsion intervals shown in Table II reveal that majority of the expulsions (9 cases) occurred within 3 months of insertion. Incidence of expulsion steeply falls after 6 months of use.

TABLE II
Insertion Expulsion Time Relation

Interval	T Cu-200		Lippes Loop	
	Number	Per cent	Number	Per cent
Within 3 months	4	66.66	5	62.5
3- 6 months	1	16.66	2	25.0
6-12 months	—		1	12.5
More than 1 year	1	16.66	—	
Total	6 (460)		8 (104)	

Most expulsion occurred during menstruation time.
Figures in brackets show total number of cases.

8. *Failures*

There were two types of failures i.e. failure to terminate pregnancy with menstrual regulation procedure, and failure of the device to prevent pregnancy.

(a) *Failure to Terminate Pregnancy*: This occurred in 6 cases. In 2 cases failure could be attributed to bicornuate and bicorpus uterus. Termination of pregnancy was carried out in 3 cases whereas 2 continued with pregnancy and delivered normal healthy babies and 1 case was lost for follow-up.

Coincidentally all the 6 cases were among non-acceptors of the device.

(b) *Device Failure*: Six women became pregnant with the intra uterine device being present in the uterine cavity. As shown in Table III pregnancy occurred 4 times with Lippes loop and 2 times with T Cu-200, a 9 times higher incidence with the Lippes loop. However Lippes loop has been followed up for longer interval than T Cu-200.

TABLE III
Pregnancy with Device in Utero

Type of Device	Number of Failures	Percentage
T Cu-200 (460)	2	0.43
Lippes Loop (104)	4	3.84

This was device failure not menstrual regulation.

9. *Additional Advantages*

The insertion of intra-uterine device immediately after the menstrual regulation procedure has following added advantages:

(a) The insertion procedure was easy as the cervical canal had been opened with cannula.

(b) There is very little risk of device perforating the uterine wall if the cervical canal permits easy passage of introducer.

(c) The lower abdominal pain as a result of insertion of the device was masked by the mild discomfort of menstrual regulation procedure.

(d) Slight bleeding associated with device insertion was masked by bleeding associated with the menstrual regulation procedure.

Discussion

At the First International Conference on Intra-Uterine Devices held in 1962 at New York, the intra-uterine device was medically accepted as a safe and effective contraceptive. It was also at this conference that Jack Lippes described his experience with the now well-known Lippe's loop.

Since then, the intra-uterine devices have been extensively used as a contraceptive. In India, Lippes loop was introduced for this purpose. This device gained immediate popularity with very high acceptance rate. But this was short lived because of the high incidence of side effects and non availability of timely and adequate medical aid—a result of inadvertent and over enthusiastic approach.

With the introduction of copper bearing intra-uterine devices which have lower incidence of side effects, and more careful attitude of Family Planning Staff, this device is gaining its appropriate place among various contraceptives.

Intra-Uterine device as a contraceptive has been established beyond doubt. Further research continues for a more comfortable device and one causing least bleeding.

In contrast to intra-uterine device, the menstrual regulation procedure is of recent origin. At the Menstrual Regulation Conference held in December 1973 at Honolulu, the procedure was adopted as a simple, safe and effective procedure with minimal rate of complications. This has been further established by subsequent extensive trials.

The combination of the menstrual regulation procedure followed by insertion of intra-uterine device is of still recent origin. The literature available on this combination is scanty and observations are further diluted because the studies have not been carried out exclusively on this combination. The present study has been designed exclusively to study the feasibility of this combination.

The patients' response towards acceptance of device has been very encouraging even in the early phase of study when Lippes loop alone was available as an intra-uterine device.

Whereas 114 devices were subsequently removed but more than 51.75 per cent cases were asymptomatic. This shows that there is progressive decline in motivation,

especially in the first 12 months of its use. Even after these removals, 82.5 per cent cases continued its use upto one year or more. Similar observations have been made by other authors when the insertion of device is done as a pre coital contraceptive. Tietze (1970) has reported continuation rates at 77.4 and 76.5 per cent at the end of one year for Lippes loop size D and C respectively. Lippes (1968) has reported continuation rate of 80.1 for size D at the end of one year. Therefore, the continuation rate of the combination procedure is quite promising.

Rate of spontaneous expulsion was 1.3 per cent with T Cu-200 and 7.69 per cent with Lippes loop in this series. These rates have been differently reported by different authors like Lewit (1973) and Liedholm (1974) but the expulsion rates observed in this series are lower than their figures. Nag (1978) has reported expulsion rate of 8.5 per cent for interval insertions and 10.1 per cent in post-abortion insertions using Lippes loop size 30 mm. In Deshmukh *et al* (1977) series of interval insertions, expulsion rates have been 5.37 per cent for T Cu-200 and 3 per cent for Lippes loop. It therefore appears that spontaneous expulsion rate is not increased by timing the insertion after menstrual regulation procedure.

The major causes for symptomatic removals were pain and bleeding. Similar observations are made by Lewit (1973) Liedholm (1974), Tietze (1970), Deshmukh *et al* (1977), Bhargava *et al* (1978) and Nag and Eduljee (1978). The incidence of these complications is not affected by the preceding menstrual regulation procedure. However, the incidence reported for T Cu-200 is appreciably lower than that for Lippes loop.

Six cases became pregnant inspite of device being in situ. Pregnancy rate for T Cu-200 in this series was 0.43 per cent. Lewit (1973) and Liederman (1974) have reported pregnancy rates as 1.2 and 2.2 per 100 women year use with T Cu-200. Deshmukh *et al* (1977) has reported pregnancy rate of 1.07 per cent for interval insertions with T Cu-200. Similarly pregnancy rate with Lippes loop in this series is 3.84 per cent. Tietze (1970) reported pregnancy rate of 3 per cent in his series of Lippes loop. Pregnancy rate with Lippes loop is reported to be higher by all observers except Deshmukh *et al* (1977). However the rates are 9 times higher with Lippes loop in this series.

It is observed that the combination procedure of menstrual regulation and intrauterine device insertion does not increase the incidence of complications of either procedure. However complication rates with Lippes loop are higher than T Cu-200.

It is therefore recommended that the two procedures can be safely combined and T Cu-200 is a much better device than Lippes loop.

Conclusions

The following conclusions are drawn from the study of simultaneous menstrual regulation procedure and insertion of intra uterine.

1. The acceptance of intra-uterine device, specially the copper bearing device, is gaining popularity in our clinic.

2. The acceptance rate for the intrauterine device is very high after menstrual regulation procedure. Age, educational status and socio-economic status had no effect on acceptance rate. The method was mainly used for spacing births or postponing sterilisation operation.

3. The insertion procedure is easier and immediate side effects, pain and bleeding, are masked by menstrual regulation procedure.

4. By combining the menstrual regulation and intra-uterine device insertion, the incidence of side effects is not increased. The incidence of side effects is higher with Lippes loop.

5. Spontaneous expulsion rate is not affected by combining the two procedures. The spontaneous expulsion rate with Lippes loop is 6 times higher than T Cu-200.

6. Removal rate of 20.21 per cent appears high. In 51.75 per cent cases of request for removal, the device did not give rise to any symptoms. It appears that motivation starts waning off after 3 months of its use.

7. Failure of device occurred in 6 cases. The failure rate with Lippes loop was 9 times higher. However, this device has been used for a longer time also.

8. The search for a more comfortable device causing least bleeding must continue.

Summary

This report is based on analysis of 1000 cases of Menstrual Regulation Procedure carried out at the Menstrual Regulation Clinic, Armed Forces Medical College, Pune.

Five hundred and sixty four (56.4%) cases accepted the intra-uterine device as a contraceptice immediately after the procedure.

The "Age Groups" and the "Parity" of the acceptors and non-acceptors are analysed. The device was removed in 114 cases. The various reasons of removal are described. This indicates that continued motivation is required amongst acceptors.

The "Expulsion" rates are analysed and the expulsion time as well as relation of parity and expulsion are discussed.

There were 6 failures but failure rate was 9 times higher in Lippes Loop Acceptors.

Combining the two procedures did not rssult in increase of complications and side effects.

References

1. Bhargava, A. et al: J. Obstet. Gynec. India. 28: 392, 1978.
2. Deshmukh, K. K. et al: J. Obstet. Gynec. India. 27: 672, 1977.
3. Kochhar, K. and Suchdeva, J. K.: J. Armed Forces India. 33: 447, 1976.
4. Lewit, S. Quoted in Population Reports Series B Number 2, 1973.
5. Liedholm, P. Quoted in Population Reports Series B Number 2. 1974.
6. Nag M. K. and Eduljee, S. Y.: J. Obstet. Gynec. India. 28: 397. 1978.
7. Tietze, C.: Quoted in Population Reports Series B Number 2, 1970.