

DO RETROVERTED UTERI ADVERSELY AFFECT INSERTIONS AND PERFORMANCE OF IUDS?

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ABSTRACT

A large international multi-center IUD data set (N=5520) coordinated by Family Health International was analysed to determine if the uterine position of a woman (anteverted, mid-positioned or retroverted) affects the ease of IUD insertion and if knowledge of uterine position would diminish insertion-related problems and improve IUD performance. Findings showed that insertion-related events were rare irrespective of uterine position. Women with retroverted uteri were not associated with higher termination rates for accidental pregnancy, expulsion or removal for bleeding and/or pain after 12 months of IUD use, as compared to the other two uterine position groups. All insertions in this data set were performed by experienced obstetricians/gynecologists, and our findings suggest that women with retroverted uteri should be equally good candidates for IUD contraception.

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INTRODUCTION

Does the position of a woman's uterus affect the ease of insertion of an IUD? Would the knowledge of uterine position through pelvic examination facilitate IUD insertion, diminish insertion-related problems and improve IUD performance? An extensive literature search produced only one report focusing on these issues. The report, published in 1986 (1) by the United Kingdom IUD Research Network, presented the following findings: 1) fitting difficulty of an IUD was almost twice as frequent in women who had retroverted uteri, as compared to those with anteverted uteri; 2) the IUD expulsion rate was slightly higher among women when fitting difficulties had been reported and among women with retroverted or mid-positioned uteri. In addition, the investigators were "puzzled" with their finding of a lower pregnancy rate among women with reported fitting difficulties.

We will answer the above-posed questions using the large international multi-center IUD dataset originally collected for clinical trials by Family Health International (FHI).

METHODS AND MATERIALS

Our analysis is limited to parous women who had copper IUDs inserted by obstetricians/gynecologists at least 42 days after their last live birth ended. Women having anatomical uterine abnormalities (e.g., uterine fibroma/myoma) were excluded. The IUD types included for study were: the T-shaped copper devices (the TCu 200, TCu 380A or TCu 380AG) and the horseshoe-shaped multiload devices (the MLCu 250 and MLCu 375). Centers meeting the following criteria were included in the analysis: 1) performed 50 or more insertions using one of the above study device types; 2) collected information on the uterine position for at least 90% of their cases; and 3) achieved a six-month follow-up rate of 80% or higher with their patients. A total of 5603 women came from centers which met the above criteria. The IUD insertions were performed between January 1977 and December 1987 at 23 international centers, all except one located in less developed countries (LDCs) by Sivard's definition (2). Excluded from the analyses were 83 (1.5%) women with no information on uterus position; 5520 women remained as our study population.

We divided our study population into three uterine position groups based on the findings at pelvic examination by the insertors immediately before IUD insertion: anteverted (N=3135, 56.8%), mid-positioned (N=852, 15.4%) and retroverted (N=1533, 27.8%). The three groups of women were first compared on a number of characteristics including age, parity, educational level, desire for additional children, contraceptive method used within the month prior to this insertion, menstrual status and breast-feeding status at the time of IUD insertion, and the IUD type inserted at this admission. Comparisons were then performed on two sets of outcome variables: 1) the IUD insertion-related problems including insertion failure, uterine perforation, syncope and other vasovagal reactions, moderate/severe insertional pain, cervical laceration and cervical dilatation required for IUD insertion; and 2) subsequent IUD performance in terms of termination rates due to pregnancies, expulsions

and removals for bleeding and/or pain, as well as the continuation rates at six and 12 months post-insertion.

Because of the low incidence of insertion-related events, comparisons were performed by Fisher's exact test between women with either an anteverted or mid-positioned uterus collapsed as one group and women with retroverted uteri as another group. Cumulative gross life-table rates of the pertinent termination events were calculated by the Tietze-Potter method (3) and compared by the log-rank method (4). Women's characteristics which showed statistically significant differences among the three groups were considered confounding variables and were adjusted for, one at a time, using Herson's method (5).

To determine whether our findings could be influenced by possible differences between centers, similar comparisons of IUD performance among the three uterine position groups were made on a sub-data set from one Asian center. For the 1290 insertions performed in this center, 1250 had information on uterine position (contributing 22.6% of the cases in our study population): 615 were using TCU 380A and 635, the MLCu 250.

A p-value of <0.05 (two-tailed) was considered statistically significant for all tests of significance.

RESULTS

1. Selected characteristics of the women (Table I)

The mean parity of the three groups of women hovers around two. Compared to the other two groups, women in the retroverted group were younger and less educated. The proportion of women wanting no more children in the retroverted group was higher than those women in the mid-positioned group, but lower than those in the anteverted group.

Women in the retroverted uterus group were less likely to have used oral contraceptives or the IUDs in the month prior to this insertion and were more likely to be amenorrheic and breast-feeding at the time of insertion, as compared to women in either the anteverted or mid-position group. The distribution of device types inserted at admission also differed among the three groups.

All these differences were statistically significant ($p < 0.01$) because of the relatively large numbers of cases in each uterine position group. The magnitude of the differences in age and parity were, however, considered not to be clinically important.

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Table I. Characteristics of Women with Anteverted, Mid-positioned or Retroverted Uteri by Means and Percentage Distributions, the FHI International Multi-center IUD Data Set, 1977-1987

Characteristics of Women	Uterus Position		
	Anteverted (N=3135)	Mid-positioned (N=852)	Retroverted (N=1533)
Age in years (Mean± SD)	27.1±5.4	26.9±5.7	26.5±5.4
Number live births (Mean± SD)	2.1±1.4	2.0±1.6	2.0±1.2
Education in years (Mean± SD)	8.7±4.8	7.5±5.1	7.3±4.8
% Wanting no more children	53.0	44.1	46.5
% Contraceptive method used last month			
Orals	27.9	29.6	23.9
IUDs	9.0	7.5	5.9
Other or no methods	63.1	62.9	70.2
Menstrual status*			
Still amenorrheic	17.5	16.1	29.8
Menses resumed	82.5	83.9	70.2
Breast-feeding status			
Yes (including partial)	31.9	31.3	43.1
No	68.1	68.7	56.9
% IUD Type inserted this time			
TCu 200	33.5	30.0	25.6
TCu 380A	21.2	36.0	31.4
TCu 380AG	17.4	8.5	11.4
MLCu 250	11.3	17.2	22.6
MLCu 375	16.6	8.3	9.0

*Sixty women with unknown values in menstrual status were excluded from calculation of percentages.

2. The insertion-related events (Table II)

A total of 10 insertion failures occurred, five in the anteverted group, two in the mid-positioned group and three in the retroverted uterus group. The incidence rates hovered around two per 1000 insertions. The

Table II. Number and Incidence of Insertion-related Events among Women with Anteverted, Mid-positioned or Retroverted Uteri, the FHI International Multi-center IUD Data Set, 1977-1987

Insertion-related Events	Uterus Position					
	Anteverted (N=3135)		Mid-positioned (N=852)		Retroverted (N=1533)	
	No.	Incidence	No.	Incidence	No.	Incidence
<u>Incidence per 1000 insertions</u>						
Insertion failure*	5	1.6	2	2.4	3	2.0
Uterine perforation	0	0.0	1	1.2	0	0.0
<u>Incidence per 100 insertions</u>						
Moderate and severe insertional pain	39	1.2	20	2.4	26	1.7
(Severe only)	(0)	(0.0)	(1)	(0.1)	(2)	(0.1)
Syncope & other vasovagal reactions	6	0.2	0	0.0	4	0.3
Cervical laceration**44		1.4	24	2.8	15	1.0
Cervical dilatation	43	1.4	8	0.9	15	1.0

* For calculation of incidences for all other insertion-related events, insertion failures were excluded from numerators and denominators.

**The difference between women with anteverted uteri and the other two groups of women is statistically significant at <0.01.

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incidence rate was found to be slightly higher in the mid-positioned group than in the other two groups. The difference, however, was not statistically significant.

Insertion failures were then excluded from analyses when other insertion-related events were compared. One confirmed fundal perforation was reported; a woman with an anteverted uterus (MLCu 375). This woman was breast-feeding at the time of insertion. One cervical perforation was suspected, but not confirmed, in a non-breast-feeding woman with a mid-positioned uterus (TCu 380Ag). The overall incidence of uterine perforation (including the one suspected perforation) was less than one per 1000 insertions for the total study population. Cervical laceration occurred less often ($p < 0.01$) in the retroverted group than in the other two groups.

Other insertion-related events, such as moderate/severe insertional pain, syncope and other vasovagal reactions and the need for cervical dilatation, also rarely occurred. No significant difference in their incidences were detected between women with retroverted uteri and others.

These rare events occurred sporadically among the device types. No clustering phenomenon was detected.

3. The pertinent event rates (Table III)

The gross cumulative life-table rates for accidental pregnancy, expulsion and removal due to bleeding and/or pain at 6-month post-insertion were generally similar for the three groups of women, and the continuation rates were almost identical. The 12-month accidental pregnancy and expulsion rates also were similar. The rate for removals due to bleeding and/or pain at 12 months of use was, however, significantly higher ($p < 0.05$) in the mid-positioned group than in the other two uterine position groups. The continuation rates at 12 months of use were also similar between the three groups.

These findings did not substantially change when adjusted, one at a time, by age, parity and education of the women, desire for more children (yes vs. no), contraceptive method used during last month prior to the insertion (yes vs. no), menstrual status (still amenorrheic vs. menses resumed) and breast-feeding status (yes, including partial vs. no) as well as IUD types (TCu 200 vs. other devices*) used at this insertion.

*Previous studies (6) have consistently revealed an inferior performance for the TCu-200, as compared to other newer copper devices which, among themselves, generally show similarly better performances. Hence, when the termination rates were adjusted for IUD types, we dichotomized the device types into TCu-200 versus others.

The 12-month removal rate for bleeding and/or pain, adjusted for any of the above variables, remained significantly higher ($p < 0.01$) in women with mid-positioned uteri than in women with anteverted uteri. The adjusted 12-month bleeding/pain removal rates for women with retroverted uteri were situated between the above two uterine groups and were not significantly different from either of the two groups.

Table III. Gross Cumulative Termination Event Rates* (Unadjusted) per 100 Insertions of Women with Anteverted, Mid-positioned or Retroverted Uteri, the FHI International Multi-center IUD Data Set, 1977-1987

Termination Events	Uterus Position		
	Anteverted (N=3130)	Mid-positioned (N=850)	Retroverted (N=1530)
<u>Six-month Rates</u>			
Pregnancy	0.6±0.1	0.4±0.2	0.7±0.2
Expulsion	2.7±0.3	1.7±0.5	2.5±0.4
Bleeding/pain removal	2.1±0.3	2.3±0.5	2.6±0.4
Total method-related termination**	5.8±0.4	5.3±0.8	6.0±0.6
Continuation	93.2	92.8	92.7
Follow-up***	91.5	89.6	88.6
Woman-months	17026.5	4592.0	8123.0
<u>12-month Rates</u>			
Pregnancy	0.9±0.2	0.7±0.3	0.9±0.3
Expulsion	3.5±0.3	2.2±0.5	3.5±0.5
Bleeding/pain removal****	3.5±0.4	6.3±0.9	4.2±0.6
Total method-related termination**	8.5±0.5	10.0±1.1	9.2±0.8
Continuation	89.1	86.1	88.0
Follow-up***	81.6	78.5	76.8
Woman-months	31371.0	8314.5	14715.5

*Insertion failures were excluded from numerators and denominators.

**Include pregnancy, expulsion, removal for bleeding/pain and removal for other medical reasons.

***Follow-up is defined as percentage of women not previously terminating their IUD use who returned for scheduled check-ups.

**** $p < 0.05$

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In the Asian center that had the largest caseload (N=1250), no consistent differences in total method-related termination (including pregnancy, expulsion and medical removal) rates or in continuation rates were found among the three uterine position groups for users of either the TCu 380A or the MLCu 250 device (Table IV). Age and parity distributions among the three groups by device type also were similar.

Table IV. Six- and 12-Month Gross Cumulative Removal Rate for Bleeding and/or Pain, Total Method-related Termination Rates (Unadjusted) by Device Type, per 100 Insertions of Women with Anteverted, Mid-positioned or Retroverted Uteri in an Asian Center with Large Case Load (N=1250), the FHI International Multi-center IUD Data Set, 1977-1987

	Uterus Position		
	Anteverted	Mid-positioned	Retroverted
<u>TCu 380 Ag</u>	(N= 220)	(N=143)	(N=252)
6-month Rates			
Bleeding/pain removal	2.5±1.1	0.8±0.8	1.4±0.8
Total method-related termination*	4.9±1.5	3.7±1.6	4.4±1.4
Follow-up**	93.7	94.8	94.3
12-month Rates			
Bleeding/pain removal	3.6±1.3	3.7±1.8	4.2±1.4
Total method-related termination	7.1±1.8	6.5±2.2	8.6±2.0
Follow-up**	79.7	74.6	74.8
<u>MLCu 250</u>	(N=231)	(N=141)	(N=263)
6-month Rates			
Bleeding/pain removal	2.4±1.1	0.9±0.9	3.7±1.2
Total method-related termination	8.4±1.9	3.9±1.7	6.3±1.6
Follow-up**	90.9	94.6	92.5
12-month Rates			
Bleeding/pain removal	3.5±1.3	1.8±1.2	4.2±1.3
Total method-related termination	12.0±2.3	4.7±1.9	9.3±1.9
Follow-up**	82.3	78.8	74.3

*Total method-related termination includes pregnancy, expulsion, removal for bleeding/pain, and removal for other medical reasons.

**Follow-up is defined as the percentage of women not previously terminating their IUD use who returned for scheduled check-ups.

DISCUSSION

Our findings show that the occurrences of insertion-related events were rare, and that the incidences were generally comparable between the three uterine position groups. Only one of the 5520 women (0.2 per 1000 insertions) reportedly suffered a fundal perforation. Another woman suffered a cervical perforation (unconfirmed), an event which usually occurs some time after IUD insertion. Incidence of cervical laceration was lowest among the retroverted group.

Women with retroverted uteri did not suffer a higher termination rate, either in the crude or in the adjusted termination rates, compared to the other two uterus groups. When analyses was limited to a center having the largest caseload, similarly nonsignificant findings between the three uterine groups were found. The device-specific termination rates in our study were generally within the ranges with regards to the respective device types as reported by other investigators (6). Our findings suggest that experienced obstetrician/gynecologist insertors usually can effectively deal with "difficult" uterine positions such as retroverted uteri by using measures such as sounding to detect direction and curvature of uterine lumen and/or the tenaculum to straighten the uterus*.

We did find a higher bleeding/pain removal rate after 12 months of IUD use in women with mid-positioned uteri than among women with anteverted uteri. Whether this is an artifact due to multiple comparisons needs to be further studied.

It should be noted that all women included in this analysis were parous, and had had interval insertions performed by experienced obstetricians/gynecologists at active family planning centers. Thus, the implications of our findings may not be applicable to nulliparous women, post-abortion/postpartum insertions and/or inexperienced insertors and low-volume centers.

*In our dataset, sounding was used in 72.7% of total insertions. We do not know the exact proportion of women in our study population in whom the tenaculum was used, since on the FHI record forms, the question of whether the tenaculum was used was asked only when cervical lacerations were reported.

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In spite of the above cautionary notes, our study population represents the majority of women who would have an IUD inserted; namely, parous women who are not recently pregnant. It has generally been agreed that IUDs should not be recommended for use among nulliparous women. Moreover, the IUD types studied here are either the ones currently available and are commonly used or those with the potential to be commonly used in the near future. Our findings, therefore, should be useful for both service providers and prospective IUD users, whether in a developing or a developed country. Also while not indicated by these data, it does not seem to take long for an obstetrician/gynecologist insertor to obtain the needed experience for successful IUD insertion, especially at an active center.

With regard to the study methodology, the original design of FHI's multi-center studies using identical record forms and similar study protocols among centers certainly facilitated our analysis. The fact that all insertions in our study population were performed by obstetricians/gynecologists enhances the validity of our "exposure" variable, the ascertainment of uterus position. The comparably high follow-up rates of the three uterine position groups (close to 90% at 6 months of use) similarly enhances the validity of our study results concerning termination events.

One potential bias in our results is the possibility that some women with severely retroverted uteri, generally considered more difficult to be inserted with an IUD, may have been denied IUD contraception. Thus, our findings may be applicable only to women with less "abnormal" uterine positions. The nature of our data prevents us from answering this question. However, even if this selection had occurred, our findings still reflect the fact that experienced obstetrician/gynecologist insertors can do a good screening of IUD candidates with regard to the women's uterine position, thereby maximizing the efficiency and efficacy of IUD contraception. In fact, among our study population, the proportion of women with anteverted uteri is smaller than that estimated in the general population (7), and the proportion of women with retroverted uteri was greater than that of the study population included in the United Kingdom study (1).

Another possible bias in our analysis is that women with a given uterine position could have been selected (or rejected) for the insertion of a specific type of IUD. This bias is not likely in the data analyzed here. Approximately 62% of the data used in this analysis were from randomized clinical trials. In these trials, once a woman was admitted, she was then randomly assigned to one of the two study device types and was not supposed to be arbitrarily switched to another device type. Furthermore, when we controlled for IUD types in our analysis, this did not substantially change our findings.

One of our previous case-control analyses (8) detected an increased risk (odds ratio of 3.2) of suffering syncope or other vasovagal reactions at IUD insertions for women with retroverted uteri, as compared to women with anteverted uteri. That analysis, however, was limited to users of the Lippes Loop D IUD, a larger and relatively stiffer device in which insertions were done using the "push" technique. The findings may not be comparable to the copper devices studied here. Also, another FHI study (9) did not find that insertion-related problems would affect the IUDs' subsequent performance. In that dataset, moderate and severe insertional pain or cervical laceration comprised 84.7% of the insertion-related problems.

In summary, we did not find a higher incidence of the rarely occurring insertion-related events, nor a higher termination (including expulsion) rate in women with (moderately) retroverted uteri, compared to women with anteverted or mid-positioned uteri. Our results suggest that women with retroverted uteri should be good candidates for IUD contraception if the insertions are performed by an experienced obstetrician/gynecologist. One possible reason for the paucity of existing literature examining the possible effect of uterine position on IUD performance may be that most obstetrician/gynecologist insertors having a degree of experience in IUD insertions, believe that they can easily deal with the uterine position problem and consider it a "non-issue" for IUD insertions. Based on our findings here, they are probably correct. Without knowing the details of the data set used in the United Kingdom study (1), we do not know the answer as to why our results differ from theirs. Whether our findings would be applicable to insertors other than obstetricians/gynecologists (a reality we must face in numerous LDCs for many years to come), is an issue that needs to be addressed in future studies.

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