

AGENCY FOR INTERNATIONAL DEVELOPMENT WASHINGTON, D. C. 20523 BIBLIOGRAPHIC INPUT SHEET	FOR AID USE ONLY Batch 81
---	-------------------------------------

1. SUBJECT CLASSIFICATION	A. PRIMARY Population	PC00-0000-0000
	B. SECONDARY Family planning	

2. TITLE AND SUBTITLE
 Patients' responses to IUD insertion

3. AUTHOR(S)
 Berger, G.S.; Edelman, D.A.; Regenie, S.J.

4. DOCUMENT DATE 1976	5. NUMBER OF PAGES 8p 10p.	6. ARC NUMBER ARC
--------------------------	-------------------------------	----------------------

7. REFERENCE ORGANIZATION NAME AND ADDRESS
 IFRP

8. SUPPLEMENTARY NOTES (Sponsoring Organization, Publishers, Availability)
 (In Int.j.of gynaecology and obstetrics, v.14, no.2, p.147-152)

9. ABSTRACT

10. CONTROL NUMBER PN-AAF-479	11. PRICE OF DOCUMENT
12. DESCRIPTORS Contraceptives Health aspects Intrauterine device Reactions	13. PROJECT NUMBER
	14. CONTRACT NUMBER CSD-2979 Res.
	15. TYPE OF DOCUMENT



Patients' Responses to IUD Insertion

F
OSD-2979 Box
IFRP
11/2-1-19

Gary S. Berger, David A. Edelman and Sandra J. Regenie

Reprint from

International Journal of Gynaecology and Obstetrics

Vol. 14, 1976, No. 2

Patients' Responses to IUD Insertion

GARY S. BERGER, DAVID A. EDELMAN and SANDRA J. REGENIE

From the Department of Obstetrics and Gynecology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, the International Fertility Research Program, Research Triangle Park, North Carolina, and the School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

ABSTRACT

Berger, G. S., Edelman, D. A. and Regenie, S. J. (Dept. of Obstetrics and Gynecology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, International Fertility Research Program, Research Triangle Park, North Carolina and School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA). *Patients' responses to IUD insertion.*

Int J Gynaecol Obstet 14: 147-152, 1976.

The immediate and early responses to insertion of a Lippes loop A or B, Dalkon shield, or Cu-7-200 were evaluated for 93 nulliparous patients. In isolated cases, significant, transient changes occurred in blood pressure, pulse and respiratory rates following the IUD insertion. The mean changes in these variables from before the IUD insertion to after the IUD insertion were too small to be of clinical significance. Vasovagal reactions, which usually became manifest at least ten minutes after the insertion, occurred in 7.5% of the patients. Among patients who were followed up, 95% experienced cramps attributable to the IUD. Cramps and bleeding occurred more frequently with the Lippes loops A or B and Dalkon shield during or immediately after insertion. With the Cu-7-200, cramps and bleeding occurred more frequently one hour or more after insertion. Neither the duration and amount of bleeding nor the severity of cramps was significantly different for the three types of IUDs.

INTRODUCTION

Intrauterine devices (IUDs) are an effective and widely practiced method of contraception. A major limitation of the IUD is the high rate of removals (20%) for pain, bleeding, or infection within one year after insertion (7). Although long-term use of the IUD has been studied extensively, little information is available on immediate and early responses to IUD insertion. A few investigators have reported the occur-

rence of bradycardia, cardiac arrhythmias, syncope and convulsions following IUD insertion (1, 2, 5, 6). In a study of 87 patients undergoing IUD insertions, Acker (1) reported that 13% of the patients demonstrated bradycardia or arrhythmias. Sobrero (6) indicated that syncope occurred in as many as 10% of all nulliparous patients. Sherrod (5), in a study of 25 patients, documented electrocardiographic changes consistent with increased vagal tone during sounding of the uterus and insertion of the IUD. This study was undertaken to provide additional data on patients' immediate responses to IUD insertion, as well as their subjective responses to IUD insertion during the first two weeks after insertion.

MATERIALS AND METHODS

From April 1974 to February 1975, 93 nulliparous patients underwent first insertion of an IUD at the Women's Health Clinic held one evening per week at the Student Health Service of the University of North Carolina at Chapel Hill. Parous women were excluded from this study since they comprised less than 10% of the population attending the clinic.

In addition to a standard history, physical examination and laboratory tests (GC culture, Papanicolaou smear), patients were questioned specifically about the duration, amount, and frequency of menstrual flow, as well as associated dysmenorrhea. During physical examination, baseline recordings of blood pressure, pulse, skin color, and respiration were made. IUD selection was made on the basis of the woman's stated preference and the availability of the different types of IUDs at the clinic at a given time. Twenty-seven patients accepted the Lippes loop (A or B), 28 the Dalkon shield (small), and 38 the Copper-7-200. Distributions of patients by age, previous induced abortion, contraceptive practice at the time of IUD insertion, and the timing of insertion relative to menstruation were similar for the three groups of patients (Table I).

Table I. Selected patient characteristics^a

	Lippes loops A and B (N=27)		Small Dalkon shield (N=28)		Cu-7 (N=38)	
	No.	%	No.	%	No.	%
Age						
<20	8	29.6	11	39.3	12	31.6
20-24	18	66.7	13	46.4	23	60.5
25+	1	3.7	4	14.3	3	7.9
Median	20.1		20.6		20.4	
Abortions						
0	23	85.2	25	89.3	33	86.8
1 or more	4	14.8	3	10.7	5	13.2
Contraceptive method previously used						
None	11	40.8	13	48.2	17	44.7
Conventional	7	25.9	6	22.2	9	23.7
Orals	9	33.3	8	29.6	12	31.6
Time of insertion						
During menses	9	33.3	7	25.0	11	29.0
Intermenstrual	17	63.0	12	42.9	21	55.2
Unknown	1	3.7	9	32.1	6	15.8

^a Patients with unknown characteristics excluded from the appropriate panel.

All IUD insertions were performed in a standard manner. The cervix was cleansed with benzalkonium chloride solution and stabilized with a Jacob's tenaculum. The position and size of the uterus and cervix were verified with the help of a metal sound and the IUD was inserted. The patient's vital signs were recorded two to five minutes after insertion and subjective assessments of the patient's experience of pain during insertion were made independently by the clinicians and assisting nurses.

One to two weeks after insertion, information on cramps, bleeding, or other responses to the IUD, as well as any measures undertaken by the patient to alleviate these complaints, were recorded for 85 (91.4%) of the patients who were followed up by telephone call from one of the two clinicians.

Definitions and data analysis

Assessment of pain at insertion, post-insertion cramps, and amount of blood flow was subjective and categorized simply as mild, moderate, or severe. Vaginal response was diagnosed by the clinician if the patient became bradycardic or if the attending clinician prescribed atropine and the patients developed hypotension or marked diaphoresis.

For each IUD, the data were analyzed to evaluate changes between vital signs recorded during the physical examination and at 2-5 minutes after the IUD insertion, complications and complaints during IUD in-

sertion, and the time of onset and duration of cramps and/or bleeding following the IUD insertion.

From the statistical tests used to evaluate the data, only the significance levels, the *p*-values, are given.

RESULTS

Immediate response to IUD insertion

Changes between vital signs recorded during the physical examination and after the IUD insertion are shown in Table II. The mean changes in systolic and diastolic blood pressures, respiratory rate, and pulse rate were not clinically significant, although mean changes in systolic and diastolic blood pressures for the group of patients who had Dalkon shields inserted were statistically significant ($p < 0.05$). The ranges of values in all parameters given in Table II reflect the significant changes observed among individual patients.

The proportions of patients with minimal change in systolic or diastolic blood pressure (-10 to +10), pulse rate (-10 to +10), or respiratory rate (-2 to +2) were not significantly different ($p > 0.10$) among the three IUD groups. Compared to the other two groups, the patients who had Dalkon Shields inserted showed statis-

Table II. Changes between vital signs recorded during physical examination and after IUD insertion

	Lippes loops A and B (N=27)		Small Dalkon shield (N=28)		Cu-7 (N=38)	
	No.	%	No.	%	No.	%
<i>Change in systolic blood pressure (mmHg)</i>						
Less than -10	5	19.2	5	19.2	3	8.3
-10 to 10	18	69.2	21	80.8	25	69.5
Over 10	3	11.5	0	0.0	8	22.2
Mean change	-3.9±2.3 ^a		-6.1±1.9		-1.0±1.7	
Range	-30 to 20		-25 to 10		-20 to 50	
<i>Change in diastolic blood pressure (mmHg)</i>						
Less than -10	3	12.0	7	25.9	3	8.3
10 to 10	21	84.0	20	74.1	30	83.4
Over 10	1	4.0	0	0.0	3	8.3
Mean change	-3.1±2.1		-5.8±2.0		-1.8±1.9	
Range	-30 to 20		-26 to 10		-20 to 30	
<i>Pulse</i>						
Less than -10	4	16.0	2	7.7	4	11.8
-10 to 10	16	64.0	21	80.8	24	70.6
Over 10	5	20.0	3	11.5	6	17.6
Mean change	3.0±2.3		1.3±1.6		1.7±1.9	
Range	-20 to 38		-20 to 14		-20 to 32	
<i>Respiration</i>						
Less than -2	5	20.8	6	23.1	5	15.6
-2 to 2	16	66.7	16	61.5	25	78.1
Over 2	3	12.5	4	15.4	2	6.3
Mean change	-0.5±0.7		-0.7±0.7		-0.9±0.5	
Range	-12 to 8		-8 to 4		-8 to 4	

^a Standard error of mean.

tically significant differences ($p < 0.05$) in mean systolic and diastolic blood pressures. The magnitude, however, of these differences did not appear to be important clinically.

Table III summarizes the immediate responses of patients to IUD insertion. The majority of

women (65.6%) appeared to have either no pain or only mild discomfort, regardless of the type of IUD inserted. Six patients (two in each group) appeared to experience severe pain immediately after insertion of the IUD. In one case, pain was so severe that the Lippes loop B was removed

Table III. Immediate response to IUD insertion

Response	Lippes loops A and B (N=27)		Small Dalkon shield (N=28)		Cu-7 (N=38)	
	No.	%	No.	%	No.	%
<i>Pain immediately after insertion</i>						
None/mild	18	66.7	17	60.7	26	68.4
Moderate	7	25.9	9	32.1	10	26.3
Severe	2	7.4	2	7.2	2	5.3
<i>Vasovagal response</i>						
No	22	81.5	26	92.9	38	100.0
Yes	5	18.5	2	7.1	0	0.0

Table IV. Onset and duration of cramps following IUD insertion

	Lippes loops A and B (N=27)		Small Dalkon shield (N=28)		Cu-7 (N=38)	
	No.	%	No.	%	No.	%
<i>Onset of cramps</i>						
None	2	7.4	1	4.8	1	3.1
During insertion	14	51.9	12	57.1	8	25.0
After insertion	11	40.7	8	38.9	23	71.9
<i>Duration of cramps (days)</i>						
None	2	7.4	1	4.5	1	3.3
<1	15	55.6	17	77.3	18	60.0
1-2	6	22.2	4	18.2	3	10.0
Over 2	4	14.8	0	0.0	8	26.7
<i>Severity of cramps</i>						
None	2	7.4	1	3.8	1	3.1
Mild	4	14.8	8	30.8	13	40.6
Moderate	7	25.9	6	23.1	8	25.0
Severe	14	51.9	11	42.3	10	31.3

and the patient was observed in the infirmary overnight. She was discharged without further complications the following morning. The IUDs were not removed for the other five women. They were treated with analgesics and allowed to return home.

Seven (7.5%) women had vasovagal reactions. This occurred most frequently among patients accepting Lippes loops (5/27 or 18.5%); it did not occur at all among patients accepting the Copper-7. The vasovagal response became

manifest by bradycardia (pulse rate of 40-50 per min) and developed at 10 minutes or more after the IUD insertion.

Delayed response to IUD insertion

Among the patients with follow-up, 95% experienced cramps attributed to the IUD (Table IV). The time of onset of cramps was similar ($p>0.10$) for patients who had Lippes loops or Dalkon shields, and in over half of these patients (54%), the cramps began during or im-

Table V. Onset, duration, and amount of bleeding following intermenstrual IUD insertions

	Lippes loops A and B (N=17)		Small Dalkon shield (N=12)		Cu-7 (N=21)	
	No.	%	No.	%	No.	%
<i>Onset of Bleeding</i>						
No bleeding	2	11.8	0	0.0	4	19.1
At insertion	3	17.6	7	58.3	2	9.5
Same day as insertion	12	70.6	5	41.7	12	57.1
After day of insertion	0	0.0	0	0.0	3	14.3
<i>Duration of bleeding (days)</i>						
1-2	2	13.3	5	41.7	4	23.5
3-4	6	40.0	1	8.3	4	23.5
5+	7	46.7	6	50.0	9	53.0
<i>Amount of flow</i>						
Minimal	9	60.0	8	66.6	13	76.5
Moderate	3	20.0	2	16.7	3	17.6
Severe	3	20.0	2	16.7	1	5.9

mediately after the insertion. The time of onset of cramps was significantly different ($p < 0.05$) for the Cu-7 patients than for the Lippes loop and Dalkon shield patients. For 23 (71.9%) of the Cu-7 patients, cramps occurred only after insertion was complete, and in 10 of these women (43.5%), cramps did not begin for at least one hour after insertion. Insertion of the Dalkon shield resulted in immediate cramping more often than insertions of the other devices, but the duration of cramps associated with the Dalkon shield was significantly less than that associated with loops or Cu-7s.

More than 40% of all patients reported having had severe cramps during the 1–2 week post-insertion period. There were no significant differences ($p > 0.10$) in the severity of cramps reported among the three groups of women. Analysis revealed no apparent associations between the severity of cramps and the timing of the IUD insertion in relation to the onset of the last menstrual period.

Table V shows the bleeding responses associated with the various IUDs. Patients who were menstruating at the time of IUD insertion were excluded from this analysis. Ten women (18.5%) reported no bleeding until the onset of their next regular menstrual period. For the remaining patients, bleeding occurred significantly more often ($p < 0.05$) among Dalkon shield acceptors (58.3%) than among Lippes loop (20.0%) or Copper 7 (11.8%) acceptors. The duration or amount of bleeding did not differ significantly ($p < 0.10$) among the three groups.

COMMENT

This study was undertaken to record patients' immediate and early responses to IUD insertions. The need for this kind of information was made apparent to us by the questions university students asked during counseling sessions on intrauterine contraception. Despite the limitations of this study—the small number of patients and the subjective aspects of various study items—the following comments can be made.

(a) In isolated cases, significant transient changes (either increases or decreases) in blood pressure, pulse or respiratory rate may occur at the time of IUD insertion. Similar results have been reported by Sherrod (5) in a study of electrocardiographic changes occurring during insertion of the Dalkon Shield among nulliparous patients. However, the mean changes for pa-

tients in the present study were too small to be of clinical significance.

(b) Seven (7.5%) of the 93 nulliparous patients had vasovagal reactions after IUD insertion. The highest incidence (18.5%) was associated with Lippes Loop insertions, and the lowest (0%) with Cu-7 insertions. Similar responses, termed "cervical shock", were reported for five (1.7%) of 303 women undergoing insertion of the Margulies IUD (3). Although none of our patients developed syncope or convulsions, these neurovascular sequelae can occur after IUD insertion (2, 6). In our patients, vasovagal reactions did not usually become manifest until at least ten minutes after the insertion. The most common sign of this reaction was bradycardia.

(c) The clinician's impression of the patient's response to the IUD while the patient is in the clinic or office may be incomplete and therefore misleading. For example, before the study it was our impression that pain and cramps were less frequent with Cu-7 insertions than with other IUDs. The follow-up information from this study indicated that the Cu-7 patients were just as likely to experience these side effects, but that they were less likely to have them until *after* leaving the clinic.

(d) There was a notable discrepancy between the clinicians' assessments of pain at the time of IUD insertion, and the patients' subsequent assessments of the severity of cramps. Only 6.5% of the patients were judged by clinicians or the assisting nurses to have experienced severe pain at IUD insertion, but 41.2% of the patients subsequently reported having had severe cramps. However, the patient's evaluation was of the total pain experienced and not just the degree of discomfort immediately following the IUD insertion. These differences might reflect bias on the part of nurses and physicians, or it may be that pelvic pain caused by the IUD intensified in most women after they left the clinic. This observation may have practical significance in counseling patients about what to expect after IUD insertion. It might be helpful, for example, to have patients take an analgesic such as naproxen, a non-steroidal anti-inflammatory analgesic, which has been shown to be effective in attenuating pain (4) at the time of the IUD insertion even if the patients are comfortable at the time, since in over half the cases cramps would not be expected to occur until after the patient leaves the office. This would apply particularly to women undergoing in-

sersion of a Cu-7. In this study many of the patients who took mild analgesics *after* the IUD insertion reported that the medication was not effective in relieving discomfort.

(e) Alternatively, the use of a paracervical block may be helpful, not only in attenuating pain after insertion, but also in protecting against the development of a vasovagal reaction following IUD insertion. Further study seems warranted to determine the efficacy, as well as the relative risks and benefits, of paracervical blocks for IUD insertions.

ACKNOWLEDGEMENT

This work was supported in part by grants from the International Fertility Research Program, Research Triangle Park, North Carolina (AID/csd-2979).

REFERENCES

1. Acker, D., Boehun, F. H., Ashew, D. E. & Rothman, H.: Electrocardiogram changes with intrauterine contraceptive device insertion. *Am J Obstet Gynecol* 115: 458, 1973.
2. Conrad, C. C., Ghazi, M. & Kitay, D. Z.: Acute neurovascular sequelae of intrauterine device insertion or removal. *J Reprod Med* 11: 211-212, 1973.
3. Johnson, F. L., Doerffer, F. R. & Tyson, J. E. A.: Clinical experience with the Margulies intrauterine contraceptive device. *Can Med Assoc J* 95: 14-20, 1966.
4. Massey, S. E., Varady, J. C. & Henzl, M. R.: Pain relief with Naproxen following insertion of an intrauterine device. *J Reprod Med* 13: 226, 1974.
5. Sherrod, D. B. & Nicholl, W.: Electrocardiographic changes during intrauterine contraceptive device insertion. *Am J Obstet Gynecol* 119: 1044, 1974.
6. Sobrero, A. J.: Intrauterine devices in clinical practice. *Fam Plann Perspect* 3: 16, 1971.
7. Tietze, C.: Evaluation of intrauterine device. Ninth Progress Report. Cooperative Statistical Program, *Stud. Fam. Plan.*, No. 55, July 1970.

Address for reprints:

Dr Gary S. Berger
International Fertility Research Program
Research Triangle Park, N.C. 27709
USA