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CONTRACEPTION

USE OF THE FLUID-FILLED TECNA DEVICE IN LJUBLJANA, YUGOSLAVIA

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ABSTRACT

Efforts to develop intrauterine devices that conform well to the shape of the uterine cavity have met with mixed success. The fluid-filled Tecna device was designed on the assumption that the pain and bleeding experienced with large IUDs resulted from the mechanical action of the device on the endometrium. The fluid transmits pressure from the contracting uterus in order to avoid localized areas of endometrial compression. Results from a study of 290 cases suggest that the performance of this device is suboptimal relative to the three events pertinent to the design of any intrauterine device--pregnancy, expulsion and bleeding/pain removals. The one-year rates per 100 women for these three events were 4.6, 23.1, and 8.0, respectively. These rates are higher than previously reported rates for the M-device, the Loop D and Dalkon Shield in this clinic. Bleeding associated with the use of this device was heavy and persistent. In addition the physician encountered difficulties in inserting the device. Results from this study indicate that changes in the design will be necessary to improve performance and acceptability of this device.

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INTRODUCTION

Efforts to develop intrauterine devices that conform well to the shape of the uterine cavity have met with mixed success. Two early stainless steel devices, the M-device(1) and the Majzlin Spring (2), were designed to conform to the contracting uterus, and thus reduce the possibility of expulsion. With these two devices, expulsions were minimal, but their use was discontinued when embedding in the myometrium was suspected (3, 4). The plastic Saf-T-Coil was also designed to respond passively to uterine contractions and at the same time to be sufficiently rigid to prevent the device from collapsing(5). While the large bulk and area of endometrial coverage probably account for its contraceptive efficacy, which is similar to that of the Loop D, its stabilizing tail appears to act as a focal point for its expulsion(6). Recent reports on the Ypsilon device have indicated that it conforms well to the uterine cavity and provides good endometrial coverage. Although results with the Ypsilon device are inconclusive, they suggest that it is associated with low rates of pregnancy and medical removals and reasonably low rates of expulsion even though its tail, like the Saf-T-Coil, points to the os (7). Each of these devices was designed to be compliant in a plane parallel to the anterior-posterior walls of the uterus. The fluid-filled Tecna device, however, was designed to comply primarily in a plane vertical to the anterior-posterior walls of the uterus (Figure 1). The fluid transmits pressure from the contracting uterus in order to avoid localized areas of endometrial compression. This design concept is based on the assumption that the pain and bleeding experienced with large IUDs result from the mechanical action of the device mass on the endometrium(8). This is a report of a single-clinic experience with the Tecna device. Results from this study of 290 patients suggest that the performance of this device is suboptimal relative to the three events pertinent to the design of any intrauterine device--pregnancy, expulsion and bleeding/pain removals. Pertinent event rates of this device are compared with those from previous studies of other devices in Ljubljana, Yugoslavia (9).

MATERIALS AND METHODS

From September 1973 to June 1974, 290 patients had Tecna devices inserted at the Family Planning Clinic of Ljubljana. The age and parity medians for the acceptors were 29.5 years and 1.9 live births (Table I). Patients were excluded from study if there was evidence of (a) uterine malignancy or endometrial disease, (b) atypical vaginal cytology, (c) uterine fibroids associated with menstrual disorders, (d) uterine abnormalities which distort the uterine cavity, (e) a history of infection of tubes or ovaries, (f) a history of uterine infection after delivery, or (g) infected abortion in the past three months.

TABLE I
AGE AND PARITY OF 290 TECNA IUD RECIPIENTS

Parity	<20		20-24		25-29		30-34		35-39		40+		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
0	1	0.3	2	0.7	0	0.0	0	0.0	0	0.0	0	0.0	3	1.0
1	3	1.0	37	12.8	27	9.3	10	3.4	8	2.8	1	0.3	86	29.7
2	0	0.0	24	8.3	42	14.5	53	18.3	28	9.7	6	2.1	153	52.8
3	0	0.0	1	0.3	6	2.1	18	6.2	9	3.1	4	1.4	38	13.1
4+	0	0.0	0	0.0	2	0.7	2	0.7	4	1.4	2	0.7	10	3.4
Total	4	1.4	64	22.1	77	26.6	83	28.6	49	16.9	13	4.5	290	100.0

The deflated IUD is wrapped around an inserter and is held in place by a gelatin capsule 4 mm in diameter. The device is inserted to the fundus and the gelatin capsule is allowed to dissolve. The IUD is then inflated with saline through a prefilled syringe attached to a small-diameter rubber tube connected to the IUD. A knot in the small rubber connecting tube is tightened to seal the device. To remove the IUD, the physician simply cuts the rubber tube above the knot and allows the fluid to drain before gently pulling the empty pouch through the cervical canal.

Data for this study were analysed by use of the net event rates (Table II) based on first-segment use only. No significance tests are used to compare the performance of this device with that of other individual devices in the Ljubljana baseline because such tests may not account for possible variations in time and different insertors. Instead, the performance of the device will be measured by ranking it according to pregnancy, expulsion, and bleeding/pain removal rates with other devices in the Ljubljana baseline.

TABLE II
ONE-YEAR NET EVENT RATES FOR 290 USERS OF THE FLUID-FILLED TECNA IUD

Event	Month			
	1	3	6	12
Pregnancy	0.0	0.0	2.2	4.6 ± 1.3*
Expulsion	1.4	9.8	15.2	23.1 ± 2.6
Removal				
Bleeding	0.0	0.4	0.7	5.0
Bleeding and pain	0.0	0.7	1.1	3.0
Pain	0.0	0.0	0.0	0.0
Planned pregnancy	0.0	0.0	0.0	0.0 ± 1.0
Personal reasons	0.0	0.0	0.0	0.8 ± 0.6
Net cumulative continuation	98.6	88.7	79.7	61.2
Adjusted number of women completing span	287.0	256.5	224.5	156.5
Cumulative woman months of use	287.0	816.5	1524.0	2592.0
Admission period	September 73-June 74			
Computation cut-off date	July 75			

* *Standard errors.*

RESULTS

Through October 1975, 4034 woman-months of use have been reported. One year after insertion, the pertinent discontinuation rate per 100 acceptors was 35.7. Loss to follow-up was less than 10 per 100 women at the end of one year.

Pregnancy

The one-year pregnancy rate for the Tecna device in this study was 4.6 pregnancies per 100 acceptors. Within one year after insertion, 12 of the 290 patients (4%) were pregnant. In two of these 12 patients (17%) the device was displaced at the time pregnancy was diagnosed. All of these pregnancies were terminated with elective abortions and the device was removed without difficulty during the procedure.

Expulsion

The expulsion rate at the end of one year was 23.1 per 100 acceptors. Of the 63 expulsions occurring within the first 12 months after insertion, 28 (44%) occurred during the first three months of use. The cumulative rate of expulsions showed no tendency to stabilize throughout the 12 months of use. In addition, there was no evidence of an insertor learning period, i.e. patients who had insertions early in the study did not appear to be at greater risk of expelling the device than those who had insertions later in the study.

Bleeding/Pain Removals

In the first year of use no patient had the device removed primarily because of pain. Twenty-one of the 290 patients (7%) had it removed primarily because of bleeding. Of these 21, 8 (38%) also experienced episodes of either moderate or severe dysmenorrhea or intermenstrual pain. The bleeding removal rate 12 months after insertion was 8.0 per 100 women. No difficulties in removing the Tecna device were reported.

Bleeding among users who were continuing or terminating use of the Tecna device was characteristically excessive during and between menses. Users having removals for bleeding differed from continuing users primarily in an increased incidence of intermenstrual spotting and an increased amount of blood loss in the sixth month of use (Table III). More than 75 percent of all users reported an increase in the duration of menses through the first six months of use. For approximately two thirds of these, the increase continued through the first year of use.

Hospitalization

One patient, a 23-year-old para 1, gravida 2, was hospitalized in the 10th month of use. She was admitted with excessive intrauterine bleeding, pain, and an elevated temperature. The preliminary diagnosis was ectopic pregnancy and acute adnexitis. Antibiotics were administered immediately after admission. The IUD was removed on the third day of hospitalization. Test results ruled out ectopic pregnancy. Antibiotic treatment was continued for treatment of adnexitis. She was discharged twelve days after admission without further complications.

TABLE III

BLEEDING REPORTS OF CONTINUING USERS AND USERS TERMINATING BECAUSE OF BLEEDING AT ONE, THREE, AND SIX MONTH FOLLOW-UP PERIODS

Bleeding	Month After Insertion											
	1				3				6			
	Removals		Continuing		Removals		Continuing		Removals		Continuing	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Menstrual*												
Normal	9	64.3	67	65.0	7	77.8	31	75.6	8	47.1	70	70.7
Heavy	5	35.7	36	35.0	2	22.2	10	24.4	9	52.9	29	29.3
Intermenstrual**												
None	3	16.7	47	42.7	4	36.4	18	41.9	9	45.0	59	54.6
Staining/spotting	10	55.6	55	50.0	5	45.5	23	53.5	9	45.0	39	36.1
Moderate	2	11.1	4	3.6	2	18.2	2	4.7	2	10.0	8	7.4
Severe	3	16.7	4	3.6	0	0.0	0	0.0	0	0.0	2	1.9

** Includes only those women reporting a normal amount of menstrual flow during the period just before insertion.*

*** Includes only those women reporting no intermenstrual bleeding during the period just before insertion.*

Other Related Problems

In this study approximately 15 percent of the devices were spoiled during the insertion process because saline often leaked at the joint of the tube and syringe while the IUD was being filled. Leakage was a problem throughout the admission period. Another problem was that many of the devices which were removed had a distinctive odor, possibly associated with the material composition of the device.

DISCUSSION

The fluid-filled Tecna device in its present state of development compares unfavorably with other devices in the Ljubljana baseline (Table IV). The pregnancy rate of 4.6 per 100 acceptors at the end of one year is the highest rate for all devices constituting this baseline. The Tecna device has the highest rates of expulsion and bleeding/pain removal.

TABLE IV
ONE-YEAR NET EVENT RATES* FROM LJUBLJANA IUD BASELINE OF POSTMENSES TRIALS

Pregnancy		Expulsion		Bleeding/Pain Removals	
Device	Rate	Device	Rate	Device	Rate
Loop II-D	1.4 (0.8)**	Dalkon	0.4 (0.4)	Loop II-D	3.2 (1.2)
Spiral	1.9 (1.0)	M-211	0.4 (0.4)	Loop D	4.0 (0.9)
M-211	2.3 (0.8)	M-213	0.5 (0.4)	Spiral	4.3 (1.4)
Beospir	2.6 (1.0)	Loop II-D	5.9 (1.6)	Dalkon	4.6 (1.3)
M-213	3.2 (1.0)	Beospir	7.6 (1.6)	Loop C	4.7 (1.5)
Loop D	3.8 (0.9)	Spiral	9.3 (2.0)	M-213	5.0 (1.2)
Dalkon	4.2 (1.2)	Loop C	9.4 (2.0)	M-211	5.3 (1.2)
Loop C	4.3 (1.4)	Loop D	16.1 (1.7)	Beospir	5.5 (1.4)
Tecna	4.6 (1.3)	Tecna	23.1 (2.6)	Tecna	8.0 (1.6)

* *Rates based on 200 or more insertions.*
** Numbers in ( ) represent standard deviations.

The high rate of discontinuations with this device compared to the rate for other devices in the Ljubljana baseline cannot be explained by differences in the acceptor groups. If women less than 30 years of age and of parity less than three are considered the highest risk group for discontinuation of any device, the Tecna device acceptors rank sixth out of the nine acceptor baseline groups in the percentage of high risk acceptors (Table V).

TABLE V
AGE AND PARITY DISTRIBUTION OF ACCEPTORS IN THE LJUBLJANA IUD BASELINE OF POSTMENSES STUDIES

Device	<30				≥30			
	0-2		3+		0-2		3+	
	No.	%	No.	%	No.	%	No.	%
Loop II-D	121	54.8	8	3.6	71	32.1	21	9.5
M-211	238	52.1	18	3.9	142	31.1	59	12.9
Beospir	148	51.7	1	0.4	92	32.2	45	15.7
M-213	191	49.7	14	3.7	136	35.4	43	11.2
Dalkon	124	47.2	14	5.3	90	34.2	35	13.3
Tecna	136	46.9	9	3.1	106	36.6	39	13.4
Loop C	100	45.4	7	3.2	75	34.1	38	17.3
Loop D	195	38.5	36	7.1	167	33.0	108	21.4
Spiral	74	33.2	14	6.3	72	32.3	63	28.2

Pregnancy and expulsion rates in this study of the Tecna device were higher than in a study conducted by 12 gynecologists in the San Francisco area(10).Difficulties in inserting the device may explain in part the rate differential.

Given the high surface area of the Tecna device (1020 mm^2), the pregnancy rate in the Ljubljana study was particularly high. This high rate may in part be due to unnoticed displacement of the device. Studies with high expulsion rates often have high pregnancy rates as well. Improper insertion of the device, as noted by Mishell (11), may also increase. Proper insertion may be of more importance to the effectiveness of an IUD than the design itself since improper insertion may cause an increase in rates of bleeding, expulsion, and pregnancy (11). However, while improper placement of the device may have affected the rates in this study, it should be noted that the Ljubljana Family Planning Institute is comprised of doctors with a large and varied experience in inserting IUDs. There were no apparent differences in the experiences of the insertors in this study.

One cause of bleeding may be the possibly irritating action of the "apron" around the pouch containing the fluid. Bleeding might be decreased by either softening the materials or reducing the apron size. Probably more important is the rigidity of the device. While the Tecna

IUD is compliant in a plane vertical to the anterior-posterior walls, it is quite rigid in the plane parallel to these walls. Models suggested by Wheeler et al. (12) include longitudinal compression, thickness, and surface area as the most important factors affecting pain and bleeding. This device has little compliance either in the longitudinal or transverse directions. Because of its compressability in the plane vertical to the anterior-posterior walls, thickness is most likely not a major factor leading to the incidence of bleeding.

Finally, the report of a distinctive odor suggests that the use of Silastic in intrauterine devices may be the source of this problem. A previous study of the Anderson Leaf (13), a silicone rubber device, also resulted in some complaints of an odor thought to be associated with this material. However, more systematic reporting of the incidence and severity of this side effect is needed in order to judge its significance.

Interest in the Tecna IUD has centered on the potential of this device for releasing drugs locally. The results of this study indicate a need for design changes to improve performance and acceptability of this device among both physicians and patients before it can be considered as a carrier for drugs.

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