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Editorial

Pembaca yang budiman,

Jumpa kali ini redaksi mencoba menampilkan komposisi tulisan berupa hasil penelitian dan tinjauan pustaka. Memang ini bentuk ideal yang redaksi idamkan. Oleh karena itu dari meja redaksi kami tetap berharap semoga nomor kali ini akan selalu menggairahkan nuansa kita semua. Mulai dari survei terhadap kinerja kader kesehatan desa dalam mengisi Kartu Menuju Sehat untuk anak, masalah diare, hubungan antara pendidikan seks remaja dan lingkungan keluarga, program imunisasi, faktor risiko diabetes mellitus, penyakit tuberculosis, dan masih banyak lagi tulisan lainnya yang tidak bisa disebutkan satu persatu. Mudah-mudahan beberapa tulisan kali ini tetap menambah minat baca kita dan bahkan meningkatkan gairah untuk turut menyumbang karya sejawat pada nomor mendatang.

Semoga tulisan pada terbitan ini merangsang sejawat untuk menulis, dan mengirimkannya ke redaksi. Jurnal ini memang tetap mengharapkan tulisan dari sejawat, utamanya berupa hasil penelitian. Selamat membaca

Salam Redaksi

Artikel Penelitian

1. Kelengkapan dan Kebenaran Pengisian Kartu Menuju Sehat di Kecamatan Betung Kabupaten Banyuasin Propinsi Sumatera Selatan. <i>Mohammad Zulkarnain</i>	3004
2. Analisis Implementasi Kegiatan Promotif Dan Preventif Penyakit Diare Pada Puskesmas Kenten Palembang Tahun 2010. <i>Mariatul Fadillah</i>	3008
3. Pregnancy Rate, Expulsion Rate And Safety Of Flexi-T 300 IUD. <i>Rizani Amran</i>	3016
4. Hubungan Antara Pendidikan Seks Remaja dan Lingkungan Keluarga Dengan Kejadian Seks Bebas di Kalangan Remaja. <i>Nurdjani, Y. Widyastuti</i>	3022
5. Hubungan Antara Pengetahuan Dan Sikap Ibu Mengenai Imunisasi Dengan Kelengkapan Imunisasi Polio Di Puskesmas Makrayu. <i>Bahrin Indawan Kasim</i>	3028
6. Angka Kejadian Dan Faktor Risiko Diabetes Melitus Tipe 2 di 24 RT di Kota Palembang. <i>Muhammad Aziz</i>	3034
7. Hubungan Tingkat Pendidikan, Pengetahuan, Sikap, dan Peran Keluarga Dengan Kepatuhan Berobat Pada Penderita TB Paru di Rumah Sakit Khusus Paru Palembang Tahun 2010. <i>Devi Mediarti, Rehana, Eni Inarni</i>	3044
8. Karsinoma Sel Skuamosa Tidak Berkeratin Dengan Ekspresi AE1/3 Negatif Pada Telinga Tengah. <i>Mezfi Unita</i>	3052
9. Penatalaksanaan Keloid Lobulus Telinga Bilateral Rekuren Pada Anak Usia 12 Tahun. <i>Abla Ghanie</i>	3058
 Tinjauan Pustaka	
10. Aspek Sitopatologi Kanker Paru. <i>Mezfi Unita</i>	3064
11. Aplikasi Dan Strategi Konsep <i>Family Centered Care</i> Pada Hospitalisasi Anak Pra Sekolah. <i>Arie Kusumaningrum</i>	3074
12. Faktor-Faktor Kerentanan Terhadap Hipotermia Pada Anak Dengan Malnutrisi. <i>Myrna Alia, M.Nazir, Fauziah Zen</i>	3080
13. Malformasi Susunan Saraf Pusat. <i>Mimi Marleni, Msy.Rita Dewi, M.T.Kamaludin</i>	3086
14. Terapi Oksigen. <i>Sheila Noberta, Silvia Triratna, Wen Krismadi</i>	3092

PREGNANCY RATE, EXPULSION RATE AND SAFETY OF FLEXI-T 300 IUD

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Abstract

Before 1970, intrauterine devices were used with relatively high pregnancy rates between 3.0 to 6.0 per 100 women. The FLEXI-T 300 IUD which consists of plastic body with total surface of copper approximately 300 mm² with the shape, high flexibility, anti expulsion design, no anchoring protusions and monofilament integrated in the shaft without a knot which have been adapted with the uterine shape so that it could reached the highly use-effectiveness.

To determine the pregnancy and expulsion rate and safetiness of FLEXI-T 300 IUD with evaluating the pregnancy, expulsion and drop out events, and side effects of bleeding and pain among FLEXI-T 300 users.

Women who wish to take the reversible contraception at Hospital Family Planning Clinic (PKBRS) Obstetrics and Gynecology Department Mohammad Hoesin Hospital Palembang or at the other hospitals and maternal clinics in Palembang. All subjects were given informed consent. Of the 73 subjects who included in this study, the pregnancy rate until 12 months observation was 0%. The expulsion rate until 12 months observation was 2.8%. The FLEXI-T 300 IUD acceptors who complained of side effect of bleeding on observation at 1st week, 1st month, 3rd month, 6th month and 12th month was 5.47%, 2.73%, 1.36%, 0% dan 0% respectively. The side effect of pain on observation at 1st week, 1st month, 3rd month, 6th month and 12th month was 4.10%, 2.73%, 1.36%, 0% and 0% respectively. The continuation rate until 12 months evaluation was 97.2%.

The acceptance rate of FLEXI-T 300 IUD users until 12 months observation was 97.2% with the side effects of pain and bleeding showed a decreased frequency until 12 months observation.

Key words: FLEXI-T 300 IUD, pregnancy, expulsion, bleeding, pain.

Abstrak

Sebelum 1970, perangkat intrauterin digunakan dengan tingkat kehamilan yang relatif tinggi antara 3,0-6,0 per 100 wanita. Para FLEXI-T 300 AKDR yang terdiri dari tubuh plastik dengan total permukaan tembaga sekitar 300 mm² dengan bentuk, fleksibilitas tinggi, desain anti pengusiran, ada protusions penahan dan monofilamen terintegrasi dalam poros tanpa simpul yang telah disesuaikan dengan bentuk uterus sehingga dapat mencapai efektivitas yang sangat digunakan.

Untuk menentukan tingkat kehamilan dan pengusiran dan safetiness dari FLEXI-T 300 AKDR dengan mengevaluasi kehamilan, pengusiran dan drop kejadian-kejadian, dan efek samping perdarahan dan nyeri antara FLEXI-T 300 pengguna.

Wanita yang ingin mengambil kontrasepsi reversibel di Klinik Rumah Sakit Keluarga Berencana (PKBRS) Departemen Obstetri dan Ginekologi Rumah Sakit Mohammad Hoesin Palembang atau di rumah sakit dan klinik ibu lainnya di Palembang. Semua subyek diberikan informed consent.

Dari 73 subyek yang termasuk dalam penelitian ini, tingkat kehamilan sampai 12 bulan pengamatan adalah 0%. Tingkat pengusiran sampai 12 bulan pengamatan adalah 2,8%. Para FLEXI-T IUD 300 akseptor yang mengeluhkan efek samping perdarahan pada pengamatan di 1s `minggu, bulan 1s`, bulan 3, bulan ke-6 dan bulan ke-12 adalah 5,47%, 2,73%, 1,36%, 0% dan 0% masing-masing. Efek samping rasa sakit pada pengamatan di Apakah `minggu, 1s `bulan, 3" Aku bulan, bulan ke-6 dan bulan ke-12 adalah 4,10%, 2,73%, 1,36%, 0% dan 0% masing-masing Tingkat kelanjutan sampai 12 bulan evaluasi. adalah 97,2%.

Tingkat penerimaan FLEXI-T 300 AKDR hingga pengamatan 12 bulan adalah 97,2% dengan efek samping rasa sakit dan perdarahan menunjukkan frekuensi yang menurun sampai 12 bulan pengamatan.

Kata kunci: FLEXI-T 300 IUD, kehamilan, pengusiran, perdarahan, nyeri.

of Medicine Sriwijaya University Palembang and at the other hospitals and maternal clinics in Palembang from July 2001 until June 2002. The respondents were evaluated until 12 months from the insertion of the IUD. The population of study were the acceptors of IUD who came to Obstetrics and Gynecology Department Mohammad Hoesin Hospital Palembang or to the other hospitals and clinics in Palembang. In this study, the sample were all the acceptors of Flexi-T 300 IUD which inserted during the study period. The total sample size were 73.

The inclusion criteria were women in their reproductive age, prefer a method which could work effectively for long term, interval or post abortion period, breast feeding and intend to have a contraception, have one child or more, willing to have an IUD inserted, have been given counseling for family planning and willing to enter the study.

The exclusion criteria were presumed pregnant or pregnant, unexplained vaginal bleeding, history of PID or PID, genitalia tumor, prefer other kind of contraceptive method other than IUD.

Procedure

1. A complete history, history of reproduction, obstetric, severe illness and operation were taken
2. General condition, physical and gynecologic examination were performed
3. Insertion of IUD as follows:
 - a. Aseptic and antiseptic to the vulva area
 - b. Insert speculum and inspect the cervix
 - c. Apply tenaculum to cervix, pull gently to straighten the uterus axis, pass uterine sound to measure the position and depth of uterine cavity.
 - d. Set the depth-gauge to the measured depth
 - e. Insert the inserter and hold the inserter tube with the thumb and second finger until it reaches the fundal of the uterine or until resistance felt
 - f. Withdraw the inserter tube slowly. Be sure that the IUD was placed correctly.
 - g. Cut the string approximately 2 cm from the cervical os with sharp scissors
4. After insertion, informed consent the acceptor as follows:
 - a. Spotting could be happen several days after application
 - b. Be sure the IUD do not expel during the first menstrual period after insertion
 - c. Sexual intercourse can be done as usual. It is recommended not to have sexual intercourse during the first week of insertion
 - d. Immediately come to the hospital if it is any discomfort felt
5. Five times of evaluation will be carried out :
 - 1 (one) week after insertion

- 1 (one) month after insertion
 - 3 (three) months after insertion
 - 6 (six) months after insertion
 - 12 (twelve) months after insertion
- During evaluation, anamnestic and gynecologic examination was done to assess the side effects studied.

Operational limitation

1. Continuation rate is the continuity usage of the Flexi-T 300 from the first insertion until the expiry of the Flexi-T 300 (five years). In this study the acceptors were observed until 1 year after the insertion.
2. Discontinuation usage of IUD is the discontinuation usage of Flexi-T 300 acceptors during evaluation period.
3. Expulsion is the spontaneous expel of the Flexi-T 300 IUD.
4. Bleeding is the disturbance of menstruation, consists of the cycle length, duration and the amount of the blood more than usual and need more tampon and disturb the daily activities
5. Pain is the cramping sensation at the lower part of the abdomen during or beyond the menstrual cycle
6. Drop out is the discontinuation usage of Flexi-T 300 IUD caused by expulsion, bleeding/ pain, pregnant and lost of follow up.
7. Infection is the complain of the lower abdominal pain with thick and smelly mucous from the vagina, whether or together with fever and need medical care.
8. Pregnancy will be confirmed by bimanual examination and the positive result of urine pregnancy test.

Data recruitment

The data was drawn from the examination and evaluation performed during insertion, first week, first month, third month, sixth month and twelfth month after insertion.

Results And Discussion

There were 73 acceptors participated in this study during 12 months evaluation. All the characteristic of the acceptors will be described below.

1. Distribution of age of the acceptors

Table 1 . Distribution of age of the acceptors

Age (years old)	n	%
< 20	1	1.4
20-24	9	12.3
25-29	25	34.2
30-34	14	19.2
≥ 35	24	32.9
Total	73	100%

Table 7. Expulsion in Flexi-T 300 IUD acceptors

Bleeding	n	%
1 st week	0	0.00
1 st month	1	1.36
3 rd month	0	0.00
6 th month	1	1.36
12 th month	0	0.00
Total	2	2.72

Table 7 shows the two expulsion events of Flexi-T 300 IUD users, which occurred at the first and sixth month of usage.

The expulsion rate at the end of the first year observation was 2.72%. This was higher than the study conducted by Kurz KH (0.6), and lower than the study conducted by Sivin I (5.8).^{10,16}

8. Pregnancy event in Flexi-T 300 acceptors

Table 8. Pregnancy event in Flexi-T 300 acceptors

Pregnancy	n	%
1 st week	0	0.00
1 st month	0	0.00
3 rd month	0	0.00
6 th month	0	0.00
12 th month	0	0.00
Total	0	0.00

Table 8 shows that none of the pregnancy occurred until twelve months observation. The pregnancy rate at the end of the first year observation was 0%. This was lower than the study conducted by Kurz KH and Sivin I which were 0.6 and 0.9.^{10,16}

9. Drop out event in Flexi-T 300 IUD acceptors

Table 9. Drop out event in Flexi-T 300 IUD acceptors Bleeding

Bleeding	n	%
1 st week	0	0.00
1 st month	1	1.36
3 rd month	0	0.00
6 th month	1	1.36
12 th month	0	0.00
Total	2	2.72

Table 9 shows the two drop out events of Flexi-T 300 IUD acceptors, one occurred at the first month and the other occurred at the sixth month. Both of them were caused by the expulsion of the Flexi-T 300 IUD. Thus, the continuation rate of Flexi-T 300

IUD until 12 months observatio

Conclusion And Suggestion

The pregnancy rate of Flexi-T 300 users on the follow up on 12 months observation was 0%. Flexi-T 300 users on the follow up on 12 months observation was 97%.

Long period of observation up to 5 years is needed to evaluate the long term safety of Flexi-T 300 IUD and to consider Flexi-T IUD as an contraception device in Indonesia.

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