Coll. Antropol. **32** (2008) 4: 1059–1068
Original scientific paper

Evaluation of Quality of Life and Sexual Functioning of Women Using Levonorgestrel-Releasing Intrauterine Contraceptive System – Mirena

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A B S T R A C T

The advantages ensuing from the high contraceptive efficacy, positive effect on the parameters of the menstrual cycle as well as other values of the levonorgestrel-releasing intrauterine system may play an important role in women's sexual life. The aim of the study was to evaluate the effect of the levonorgestrel-releasing intrauterine system on the quality of life and sexual functioning of women. The research encompassed 200 women aged between 30 and 45. 52 women using the levonorgestrel-releasing intrauterine system were qualified to the study as the research group (Mirena Group). The control groups consisted of 48 women using a different type of intrauterine device (Control Group I – Other IUD) and 50 women using no contraception (Control Group II). A specific questionnaire with a general part concerning socio-demographic conditions, a part dealing with contraception and Polish version of self-evaluation inventories: Short Form-36 Health Survey, Female Sexual Function Index and Mell-Krat Scale was used as a research tool. Quality of life parameters for women using the Mirena system were higher than for the control groups, especially in the aspect of general health, energy/fatigue and emotional well-being. A significant beneficial effect of the levonorgestrel-releasing intrauterine system on sexual functioning (sexual desire and arousal) was also revealed in the study. Sexual dysfunctions were diagnosed in 20.8% of Other IUD, 34.7% of Control Group II and 9.6% of Mirena Group. Levonorgestrel-releasing intrauterine system increases female quality of life and sexual functioning parameters.

Key words: *levonorgestrel, intrauterine contraceptive system, quality of life, sexual functioning, sexual dysfunctions, questionnaire*

Introduction

One of the most modern methods of hormonal contraception is the intrauterine system. The contraceptive efficacy and safety of the levonorgestrel-releasing intrauterine device – Mirena (LNG IUD) were approved by the Food and Drug Administration (FDA) in 2001[1,2]. The contraceptive effect of the Mirena intrauterine system is based on local activity of levonorgestrel (LNG) within the uterine cavity (20μg LNG released a day), which causes the thickening of the cervical mucus, inhibition of the motility and activity of sperm cells in the uterus and the oviducts, prevents endometrial hyperplasia, stimulates endometrial production of glycodelin A – a glycoprotein inhibiting the bonding of sperm with the egg cell in the middle phase of the cycle. In some women ovulation is also inhibited and there may be a weak reaction to the presence of a foreign body[1,3,4,5]. Based on the above-described mechanisms of action, the system ensures high contraceptive efficacy, comparable to that of sterilisation, for a period of 5 years, but at the same time it enables a complete return to fertility after its removal[5]. The pregnancy index in the first year equals 0–0.2%, and the cumulative index for the period of 5 years is 0.5–1.1%; the Pearl index in a group of over 12,000 women observed for 12 months is 0.14[1,3–5].

Besides its contraceptive action, the levonorgestrel-releasing intrauterine system causes a significant de-

Received for publication May 10, 2007

crease in the volume and duration of menstrual bleeding, alleviates the symptoms of dysmenorrhoea as well as prevents endometrial hyperplasia[1,3–6]. In approximately 60% of patients using the Mirena intrauterine system there is a cessation of menstruation, and less than half the women report breakthrough bleeding, intensified mainly in the first 3 months of use[1,3–5,7].

However, the levonorgestrel-releasing intrauterine system might cause, in low percent, some deleterious effects such as: irregular bleeding, amenorrhea and hormonal side-effects (weight gain, nausea, headache and breast tension) which might interfere with female quality of life (QoL)[1,3,5].

According to the international and domestic consensus, the levonorgestrel-releasing contraceptive system may be safely used by women 6 weeks after labour and throughout breastfeeding[2,8,9]. It has been shown that the amount of levonorgestrel released into the mother's blood and milk (approximately 0.1% of the hormone concentration in general circulation) is very low and does not interfere with the baby's development and growth. The Mirena intrauterine system is recommended in this group of patients due to its high contraceptive efficacy, complete reversibility as well as safety to the mother and child[2,8,9].

The advantages ensuing from the high contraceptive efficacy, positive effect on the parameters of the menstrual cycle as well as other values of the system may play an important role in women's sex life. It has been demonstrated that, unlike some oral contraceptives (OCs), Mirena does not diminish the libido. In fact, in many cases women's sexual activity increases as the awareness of safety and full protection against unwanted pregnancy enhances the comfort and frequency of the patient's intimate life. Moreover, the level of estradiol does not become lower and therefore there is no worsening of lubrication while using the Mirena system[5,7,10,11].

The aim of the present study was to evaluate the effect of levonorgestrel-releasing intrauterine system (Mirena) on the quality of life and sexual functioning of women. In the first stage the study group was compared with the two controls in the aspect of respondents' ages, social status, general health state, education, occupational activity, quality of life and sexual functioning to determine whether or not females using hormone-releasing intrauterine system have better general and sexual QoL than controls. The study estimated women's compliance of using levonorgestrel-releasing intrauterine system.

Materials and Methods

The research encompassed 200 women aged between 30 and 45 who reported to Outpatient Gynaecological Clinics for routine gynaecological examination, cytological screening or continuation of contraceptive therapy. After taking a medical history, performing main gynaecological examination with ultrasonographic scan, inclusion criteria were analyzed.

The study inclusion criteria (Mirena and other IUD Groups) were: age between 30 and 45, use of intrauterine contraception systems for at least three months, regular menstrual cycles, normal size of the uterus at clinical or ultrasonographic examination, normal cervical smear, maintained sexual activity, good general health and written informed consent to participate in the study. The inclusion criteria for control group II were identical but also using no contraception within at least the previous year and apart from the use of intrauterine contraception systems. Logically, reasons for exclusion included hepatic dysfunction, severe hypertension, severe diabetes mellitus, gynaecological disorders (e.g., uterine fibroids, endometriosis, congenital or acquired uterine abnormalities, current genital infections), pathological bleeding from the uterus in the last six months, hormone-dependent neoplasia, medical history of thromboembolic disease, pelvic inflammatory disease, ectopic pregnancy, or depression, treatment with drugs possibly impeding sexual function, diagnosed organic causes of sexual disorders as well as time less than six weeks after labour.

Because they did not meet all inclusion criteria, 50 patients were excluded. For the final analysis, 150 women fulfilling all criteria were enrolled in the study. The research population was then divided into three groups depending on the modality of contraception. The research group or Mirena Group (MG) was composed of 52 women using levonorgestrel-releasing intrauterine system; control group I (n=48) consisted of women using a different intrauterine device type (Other IUD – oIUD), and control group II (CGII; n=50) constituting sexually active women using no contraception within at least the previous year as it was planned to evaluate the QoL and sexuality of females not taking IUDs. It seemed to be interesting whether that fact might correlate with some general well-being and sexual dysfunctions or improvements compared with IUDs groups.

The research programme was approved by the Bioethical Commission of the Medical University of Silesia in Katowice, Poland.

The research tool was a questionnaire voluntarily and anonymously filled in by the respondents of the research and control groups. The questionnaire comprised a general part concerning socio-demographic conditions (age, marital status, education, occupational activity, type of work, profession, physical activity, medical history, health problems, obstetric and gynaecological history, stress exposure); a part dealing with contraception (type and duration of use of the contraception); self-evaluation inventories: Polish version of the Short Form-36 Health Survey (SF-36), the Female Sexual Function Index (FSFI) and the Mell-Krat Scale (SFK-K) evaluating general QoL as well as female sexual behaviour and sexual dysfunctions within the previous four weeks. It took them about 20–25 minutes to fill in the questionnaire.

Short Form-36 Health Survey (SF-36)

SF-36 is a standard diagnostic tool evaluating various aspects of the quality of life connected with health over

the previous 4 weeks[12–14]. Its usefulness in determining specific parameters has been approved based on a number of studies in over 130 different clinical conditions[14–16]. The validity, sensitivity, reliability, internal consistency and stability, as well as test-retest reliability have frequently been confirmed and documented by approximately 4000 publications[14,16,17].

SF-36 contains 36 questions grouped into 9 categories: general health, health change, physical functioning, limitations due to physical health, limitations due to emotional problems, social functioning, pain, energy/fatigue, emotional well-being. These categories are grouped into two collective domains: physical health and mental health[13,14,18]. The score in each category may be from 0 to 100 points (mean value calculated on the basis of individual items encompassed within a given category), which results in a linear dependence – the higher the score the higher the evaluation of a given category of the quality of life[13,14,18].

Female Sexual Function Index (FSFI)

FSFI is a multidimensional self-evaluation instrument for all spheres of female sexual functions: sexual desire, sexual arousal, orgasm and sexual satisfaction within the previous 4 weeks[19–21]. FSFI has been confirmed and clinically documented with regard to validity, sensitivity, reliability, internal consistency, stability and test-retest reliability in the diagnosing of disorders in sexual desire[20,21], arousal[19,21], orgasm[20,21] as well as pain-related sexual disorders[21].

FSFI is composed of 19 items divided into 6 collective domains (subscales): I – sexual desire, II – sexual arousal, III – lubrication, IV – orgasm, V – sexual satisfaction and VI – dyspareunia[19–21]. Final results are obtained separately for each of the subscales by summing up the elementary points encompassed within each of the 6 domains and a selected coefficient. The interpretation of partial results is a linear dependence: the higher the score, the better the sexual functioning within a given category[19–21]. The next stage is a global evaluation of the entire FSFI scale. Clinically significant female sexual dysfunctions are diagnosed at values lower or equal to 26 points (cut-off point)[21].

Mell-Krat Scale (SFK-K)

Mell-Krat Scale (SFK-K) (Kromierzyńska's version) is an instrument evaluating women's sexual needs and reactions[22]. The SFK-K questionnaire is composed of 20 items in a 0 to 4 gradation scale. Final results are obtained by summing up the elementary points. The maximum result is 80 points and clinically significant female sexual dysfunctions are diagnosed at values lower than 55 points[22]. Mell-Krat Scale (SFK-K) is also useful in retrospective research because it reveals retrospectively the changes in female sexual behaviour and dynamics of sexual reactions within the previous four weeks (reliability of female version = 0.69)[22]. SFK-K results can be compared with those of other researchers – Kratochvil (1974), Lew-Starowicz (1977,1980)[22].

Statistical analysis

For statistical analysis STATISTICA 5.5 for Windows was used. Differences between indices were considered significant at the level of 0.05. The following tests were carried out: Kruskal-Wallis test, Mann-Whitney U test, CHI^2 with Yates' continuity correction, accurate Fisher test, ANCOVA analysis of covariance, regression analysis and Bonferroni test as a »post hoc« test.

The normality of distribution of the analyzed values was examined by means of the Shapiro-Wilk test, which in almost all cases gave a significant result. For this reason, the comparison of results of monofactor analysis between three groups was performed with the use of Kruskal-Wallis test and for analysis between two groups (if the result of Kruskal-Wallis test was significant) U Mann-Whitney non-parametric test was used. For the statistical comparison of values after their classification (based on critical values), the CHI^2 test with Yates' continuity correction and accurate Fisher test were implemented.

In the multifactor analysis the covariance analysis (ANCOVA) was used. The concomitant variable (covariant) in the ANCOVA analysis was the age of respondents. In our work, the assumption of ANCOVA implementability for normal distribution was violated; however, cell frequency was sufficiently high and therefore the deviation from normal distribution was negligible due to the central limit theorem according to which the distribution of mean values from the trial tends towards normal distribution regardless of the distribution of the variable in a population. The regression analysis along the system's cells was carried out by means of parallelism test; it was subsequently revealed that all regression equations (direction coefficients) for the examined dependent variable are not statistically significantly different. Additionally, with the ANCOVA analysis Kruskal-Wallis test was performed. In ANCOVA analysis Bonferroni correction in post hoc test was used for comparison of differences between two groups.

Results

Research group – (Mirena Group – MG) and controls (Other IUD – oIUD and Control Group II – CGII) were heterogeneous with regard to age (average MG age was 38.2 ± 4.6 years, oIUD 39.3 ± 4.3 years and CGII 27.3 ± 9.3 years; $p<0.00001$). The three groups (MG, oIUD and CGII) were comparable with regard to type of work performed, accompanying diseases, medicines used as well as stress exposure (Table 1).

Statistically significant differences concerned: education, marital status, physical and occupational activity, menstrual cycle parameters, cigarette smoking as well as body mass index (BMI) and waist to hip ratio (WHR) (Table 1). The highest BMI index was observed in oIUD (26.88 ± 5.41; $p<0.00001$). In the other groups it was respectively: MG-22.19 ± 2.1 and CGII-22.15 ± 3.07. However, WHR index was the highest in MG (0.79 ± 0.05) ($p<0.000001$, Table 1).

TABLE 1
SOCIODEMOGRAPHIC CHARACTERISTICS OF STUDY POPULATION

Factor		Mirena Group		Other IUD		Control Group II		Kruskal-Wallis test/CHI^2
		N	%	N	%	N	%	
Education	Primary or vocational	6	11.5	0	0	1	2.0	p<0.000001
	Secondary	22	42.3	48	100.0	23	46.0	
	Higher	24	46.2	0	0	26	52.0	
Occupational activity		36	69.2	48	100.0	39	79.6	p<0.0002
Type of work performed	Manual	4	11.1	0	0	2	5.1	NS (p=0.07)
	White-collar	32	88.9	48	100.0	37	94.9	
Physical activity	Every day	1	2.0	1	2.1	2	4.3	p<0.00002
	Once a week	32	62.7	10	20.8	22	47.8	
	Several times a week	12	23.5	10	20.8	11	23.9	
	Once a month	6	11.8	27	56.3	11	23.9	
Marital status	Single	0	0	18	37.5	34	68.0	p<0.000001
	Married	51	100.0	30	62.5	13	26.0	
	Divorced	0	0	0	0	2	4.0	
	Widow	0	0	0	0	1	2.0	
BMI (X ± SD)		22.19 ± 2.10		26.88 ± 5.41		22.15 ± 3.07		p<0.00001
WHR (X ± SD)		0.79 ± 0.05		0.75 ± 0.02		0.77 ± 0.08		p<0.000001
Cigarette smoking		7	13.5	19	39.6	6	12.0	p<0.0009
Number of cigarettes a day (X ± SD)		11.4 ± 8.4		14.0 ± 3.2		7.8 ± 6.1		NS (p=0.08)
Duration of cigarette smoking in years (X ± SD)		11.3 ± 2.5		18.1 ± 6.0		12.8 ± 7.8		p=0.02
Number of pregnancies	0	0	0	18	37.5	36	72.0	p<0.000001
	1	25	48.1	10	20.8	11	22.0	
	2 or more	27	51.9	20	41.7	3	6.0	
Miscarriages in medical history		5	9.6	9	18.8	2	4.0	NS (p=0.06)
Menstrual cycle characteristics	Regular menstrual cycles	45	90.0	48	100.0	42	85.7	p<0.03
	Length of menstrual cycle in days (X ± SD)	28.6 ± 2.5		30.0 ± 1.2		29.0 ± 2.4		p<0.00001
	Length of menstruation in days (X ± SD)	5.0 ± 1.4		5.35 ± 30.8		5.2 ± 1.2		NS (p=0.10)
Accompanying diseases		7	13.5	9	18.8	7	14.0	NS (p=0.07)
Medicine uses		7	13.5	9	18.8	4	8.0	NS (p=0.08)
Stress exposure		24	46.2	22	45.8	23	46.0	NS (p=0.15)

BMI – Body Mass Index, WHR – Waist to Hip Ratio, SD – Standard Deviation

The highest percentage of smokers, including smoking for the longest period, was observed among women using different types of intrauterine devices (oIUD – 39.6%; 18.1 ± 6.0 months) in comparison to 13.5% of MG and 12% of CGII ($p<0.0009$). However, analysis of the number of cigarettes showed statistically significant homogeneity between groups: MG, oIUD and CGII ($p=0.08$) (Table I). 100% of women from Mirena Group and 62.5% of other IUD users were married compared to only 26% of women in the control non-using group. In contrast, 68% of non-users were single and another 6% were divorced or widowed (Table 1). Women using levonorgestrel-releasing intrauterine system were the most physically active – almost 65% exercised at least one a week compared to 23% of the other IUD group and 52% of Control Group II (Table 1). Menstrual cycles were regular among 90% of Mirena users, 100% of other IUD users and 85.7% in the control non-using group (Kruskal-Wallis test: $p<0.03$) and did not differ statistically between MG/oIUD and MG/CGII (Tables 1 and 2). The three groups were comparable with regard to length of menstruation but statistically significant differences concerned the mean length of menstrual cycle between MG and oIUD groups (U Mann-Whitney test; $p<0,00002$, Tables 1 and 2) and oIUD/CGII (U Mann-Whitney test; $p=0.04$, Tables 1 and 2). There were significant differences between each group resulting from monofactor analysis (MG/oIUD, MG/CGII, oIUD/CGII, Table 2).

The total duration of levonorgestrel-releasing intrauterine system (Mirena) use was on average approximately 2 years (average 23.8 ± 19.0 months), whilst for control group I (oIUD) – using other types of intrauterine devices, it was significantly longer – on average over 3 years (average 37.9 ± 6.9 months; $p<0.000001$).

Quality of life

Research has shown that the quality of life parameters for women using levonorgestrel-releasing intrauterine system – Mirena are generally higher than for the control groups (oIUD and GCII) and this concerns categories: general health, health change, limitations due to emotional problems, energy/fatigue and emotional well-being (Table 3). On performing a detailed analysis, statistically significant differences in most SF-36 scale parameters (general health, health change, social functioning, pain, energy/fatigue and emotional well-being) were found (Table 3). Moreover, the age of the studied women generally did not correlate with changes in the quality of life parameters, with the exception of negative influence on physical functioning and pain occurrence (multifactor analysis – ANCOVA, Table 4). The most evident differences in subjective evaluation of the QoL between women using the Mirena system and the control groups (oIUD, CGII) concerned three parameters of SF-36 research questionnaire: general health, energy/fatigue and emotional well-being (Tables 3 and 4).

In the aspect of general health, women with the Mirena contraception system (MG) evaluated very highly their actual general health state (MG-76.9 ± 24.2) in comparison to the control groups (oIUD-55.1 ± 17.4; CGII-57.8 ± 19.7; Kruskal-Wallis test: $p<0.000001$; ANCOVA: $p<0.000001$, Tables 3 and 4). The studied women of the control groups (oIUD, CGII) manifested significantly higher disorders to energy/fatigue and the emotional-psychological sphere in comparison to the study group (MG) (energy/fatigue: MG-80.5 ± 20.0; oIUD-70.0 ± 8.4; CGII-55.6 ± 22.5 respectively) (ANCOVA: $p<0.000007$), (emotional well-being: MG-81.8 ± 17.2; oIUD-60.8 ± 33.2; CGII-64.8 ± 17.0 respectively) (ANCOVA: $p<0.00003$, Tables 3 and 4).

TABLE 2
SOCIODEMOGRAPHIC CHARACTERISTICS – SIGNIFICANT DIFFEREBCES BETWEEN GROUPS (RESULTS OBTAINED FROM MONOFACTOR ANALYSIS)

Factor	Kruskal-Wallis test/Chi^2	U Mann-Whitney test/accurate Fisher test		
	MG/oIUD/CGII	MG/oIUD	MG/CGII	oIUD/CGII
Education	$p<0.000001$	$p<0.000001$	NS ($p=0.16$)	$p<0.000001$
Occupational activity	$p<0.0002$	$p<0.00009$	NS ($p=0.34$)	$p=0.003$
Physical activity	$p<0.00002$	$p<0.00006$	NS ($p=0.26$)	$p<0.003$
Marital status	$p<0.000001$	$p<0.000005$	$p<0.000001$	$p<0.001$
BMI	$p<0.00001$	$p<0.000001$	NS ($p=0.52$)	$p<0.000001$
WHR	$p<0.000001$	$p<0.000001$	$p<0.04$	NS ($p=0.10$)
Cigarette smoking	$p<0.0009$	$p<0.006$	NS ($p=0.94$)	$p<0.004$
Duration of cigarette smoking in years	$p=0.02$	$p<0.02$	NS ($p=0.67$)	NS ($p=0.10$)
Menstrual cycle characteristics				
Regular menstrual cycles	$p<0.03$	NS ($p=0.06$)	NS ($p=0.73$)	$p<0.02$
Length of menstrual cycle	$p<0.00001$	$p<0.00002$	NS ($p=0.15$)	$p=0.04$

MG – Mirena Group, oIUD – other IUD Group, CGII – Control Group II, BMI – Body Mass Index, WHR – Waist to Hip Ratio

TABLE 3
SHORT FORM-36 HEALTH SURVEY AMONG WOMEN – MEAN VALUES AND THEIR 95% CONFIDENCE INTERVALS

Short Form-36	Mirena Group	Other IUD	Control Group II	Kruskal-Wallis test
General Health	76.9 ± 24.2	55.1 ± 17.4	57.8 ± 19.7	p<0.000001
Health Change	50.5 ± 13.5	41.0 ± 18.6	50.0 ± 16.0	p<0.02
Physical Functioning	91.4 ± 8.9	91.5 ± 9.2	91.6 ± 13.5	NS (p=0.59)
Limitations due to Physical Health	89.8 ± 24.2	90.6 ± 19.7	81.5 ± 29.4	NS (p=0.09)
Limitations due to Emotional Problems	88.5 ± 16.6	79.2 ± 41.0	78.1 ± 34.4	NS (p=0.13)
Social Functioning	89.3 ± 7.4	91.5 ± 16.7	73.3 ± 22.4	p<0.000001
Pain	86.1 ± 20.1	89.6 ± 13.6	68.2 ± 25.9	p<0.00001
Energy/Fatigue	80.5 ± 20.0	70.0 ± 8.4	55.6 ± 22.5	p<0.000001
Emotional Well-Being	81.8 ± 17.2	60.8 ± 33.2	64.8 ± 17.0	p<0.00001

MG – Mirena Group, oIUD – other IUD Group, CGII – Control Group II, b – regression coefficient

TABLE 4
SHORT FORM-36 HEALTH SURVEY AMONG WOMEN – MULTIFACTOR ANALYSIS

Short Form-36	ANCOVA		Bonferroni correction in post hoc test		
	MG/oIUD/CGII	Age	MG/oIUD	MG/CGII	oIUD/CGII
General Health	p<0.000001	NS (p=0.44)	p<0.000002	p<0.00002	NS (p=0.99)
Health Change	p<0.02	NS (p=0.22)	p<0.01	NS (p=0.99)	p<0.02
Physical Functioning	NS (p=0.26)	p<0.01 (b=–0.35)	–	–	–
Limitations due to Physical Health	NS (p=0.10)	NS (p=0.31)	–	–	–
Limitations due to Emotional Problems	NS (p=0.13)	NS (p=0.33)	–	–	–
Social Functioning	p<0.00001	NS (p=0.57)	NS (p=0.99)	p<0.000009	p<0.000001
Pain	p<0.01	p<0.03 (b=0.57)	NS (p=0.99)	p<0.00004	p<0.000001
Energy/Fatigue	p<0.000007	NS (p=0.18)	p<0.01	p<0.000001	p<0.0004
Emotional Well-Being	p<0.00003	NS (p=0.75)	p<0.0005	p<0.001	NS (p=0.99)

MG – Mirena Group, oIUD – other IUD Group, CGII – Control Group II, b – regression coefficient

Sexual functioning of women

The holistic evaluation of the FSFI scale and its six collective domains (sexual desire, sexual arousal, lubrication, orgasm, sexual satisfaction and dyspareunia) showed that women from the study group (Mirena Group) display higher sexual functioning as compared with the controls (oIUD, CGII) (Table 5). The total FSFI scores were statistically significant – revealing better sexual life in women using the Mirena intrauterine system in comparison with patients with other intrauterine devices – oIUD (U Mann-Whitney test: $p<0.001$; Bonferroni post hoc test: $p<0.04$) and the control group with no contraception – CGII (U Mann-Whitney test: $p<0.0004$; Bonferroni post hoc test: $p<0.00002$) (MG--32.0 ± 4.3; oIUD-29.9 ± 4.0 and CGII-25.9 ± 9.9 respectively, Tables 5 and 6).

In detailed analysis statistically significant differences between the groups (MG and oIUD, CGII) were also found in categories: sexual desire, sexual arousal, orgasm, sexual satisfaction and dyspareunia, which confirmed higher sexual functioning in women with the Mirena system. The clearest differences between the groups concerned three parameters of sexual functioning: sexual desire, sexual arousal and dyspareunia (Tables 5 and 6). The age of the studied respondents did not have an impact on any parameters of sexual quality of life (Table 6). In the sexual desire and arousal domains MG women obtained the highest, significant FSFI scale scores as compared both with oIUD and CGII (desire: MG-4.7 ± 1.11; oIUD-4.08 ± 1.01; CGII-3.8 ± 1.03 respectively) (Kruskal-Wallis test: $p<0.0003$; ANCOVA: $p<0.0006$), (arousal: MG-5.28 ± 0.87; oIUD-4.64 ± 1.27; CGII-4.12 ± 1.91 respectively) (Kruskal-Wallis test: $p<0.0004$; ANCOVA: $p<0.002$), which verifies the particular dominance of the Mirena system over other intrauterine devices with regard to its beneficial influence on female sexual quality of life (Tables 5 and 6).

TABLE 5
EVALUATION OF FEMALE SEXUAL FUNCTIONS – FEMALE SEXUAL FUNCTION INDEX – MEAN VALUES AND THEIR 95% CONFIDENCE INTERVALS

FSFI – collective domains	Mirena Group	Other IUD	Control Group II	Kruskal-Wallis test
FSFI	32.00 ± 4.3	29.90 ± 4.0	25.9 ± 9.9	p<0.0004
Desire	4.70 ± 1.1	4.08 ± 1.0	3.80 ± 1.0	p<0.0003
Arousal	5.28 ± 0.9	4.64 ± 1.3	4.12 ± 1.9	p<0.0004
Lubrication	5.54 ± 0.7	5.41 ± 0.7	5.41 ± 0.7	NS (p=0.08)
Orgasm	5.42 ± 0.7	5.30 ± 0.7	4.29 ± 2.0	p<0.001
Sexual satisfaction	5.40 ± 0.8	5.32 ± 0.9	4.53 ± 1.8	p<0.02
Dyspareunia	5.62 ± 0.9	5.14 ± 1.6	4.57 ± 2.1	p<0.0004

FSFI – Female Sexual Function Index

TABLE 6
FEMALE SEXUAL FUNCTION INDEX – MULTIFACTOR ANALYSIS

FSFI – collective domains	ANCOVA		Bonferroni correction in post hoc test		
	MG/oIUD/CGII	Age	MG/oIUD	MG/CGII	oIUD/CGII
FSFI	p<0.006	NS (p=0.27)	p<0.04	p<0.00002	p<0.009
Desire	p<0.0006	NS (p=0.98)	p<0.01	p<0.0001	NS (p=0.58)
Arousal	p<0.002	NS (p=0.90)	p<0.045	p<0.0002	NS (p=0.21)
Lubrication	NS (p=0.12)	NS (p=0.10)	–	–	–
Orgasm	p<0.02	NS (p=0.14)	NS (p=0.99)	p<0.00005	p<0.0004
Sexual satisfaction	p<0.03	NS (p=0.65)	NS (p=0.99)	p<0.002	p<0.006
Dyspareunia	p<0.04	NS (p=0.12)	p<0.045	p<0.03	NS (p=0.54)

MG – Mirena Group, oIUD – other IUD Group, CGII – Control Group II, FSFI – Female Sexual Function Index, b – regression coefficient

Implementing the cut-off point, clinical sexual dysfunctions prevailed in women of the two control groups: CGII-34.7% and oIUD-20.8%; they were the least frequent in the study group MG-9.6%. The analysed dependence was statistically significant in relation: MG – CGII (p<0.005). The research established that the frequency of occurrence of sexual dysfunctions among women using the Mirena system did not differ from those using other intrauterine devices (oIUD) (p=0.2, Figure 1).

The Mell-Krat Scale (SFK-K), which was used concurrently, confirmed in a total score the above-shown dependencies – the best sexual functioning in women using

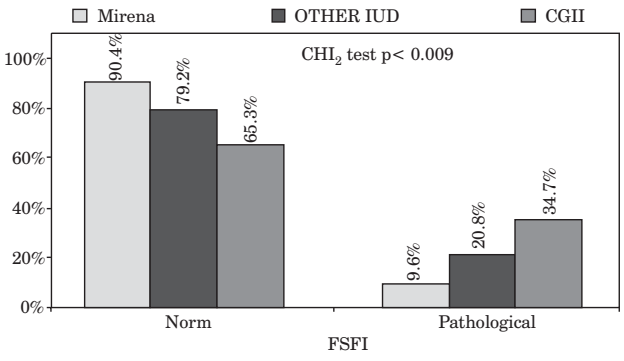

Fig. 1. Evaluation of Female Sexual Function Index (norm and pathological scores). CGII – Control Group II, FSFI – Female Sexual Function Index.

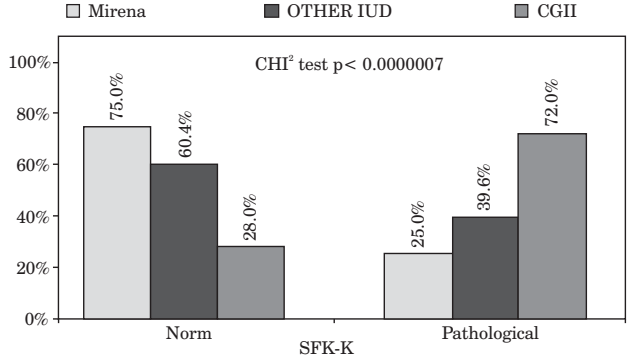

Fig. 2. Evaluation of female sexual functions – Mell-Krat Scale (SFK-K) – norm and pathological scores. CGII – Control Group II, SFK-K – Mell-Krat Scale.

levonorgestrel-releasing intrauterine system (Mirena) (MG-62.1 ± 10.5) as compared with control groups (oIUD-55.4 ± 8.2; U Mann-Whitney test: $p<0.003$ and CGII-45.0 ± 17.9; U Mann-Whitney test: $p<0.000001$ respectively). Implementing the cut-off point facilitated the diagnosing of clinically significant sexual dysfunctions among 39.6% of oIUD, 72% of CGII and only 25% of MG (statistically significant difference between MG and CGII: CHI^2 test $p<0.000005$, Figure 2).

Discussion

Analysing the available literature it seems that too little attention is paid to the effect of intrauterine devices, and in particular those hormonal containing levonorgestrel, on the quality of life and sexual functioning. Most clinical research, evaluating this issue, generally focuses on the comparison of intrauterine systems with oral contraceptives; on the other hand intrauterine devices are rarely compared with intrauterine hormonal systems. Our research analysed those parameters with the use of Short Form-36 Health Survey (SF-36), Female Sexual Function Index (FSFI) and Female Sexual Scale – Mell-Krat Scale (SFK-K). The results of our research indicate an improvement in selected parameters of the quality of life and better sexual functioning of women utilising the levonorgestrel-releasing intrauterine system (Mirena).

Suhonen et al.[7] in their work compared, among others, the quality of life and sex life of 94 women aged between 18 and 25 using a levonorgestrel-releasing intrauterine system (LNG IUD) and 99 women using OCs at the moment of therapy commencement and after 12 months of its implementation. The authors demonstrated a positive effect of LNG IUD on the quality of life of the examined women, as well as a reduction of profuse and painful menstrual bleeding; they did not observe any statistically significant differences in the sexual functioning of women using LNG IUD and OCs[7].

Similar results were obtained by Hurskainen et al.[6] in the analysis of quality of life, the occurrence of depression or anxiety and sex life disorders in 236 women with menorrhagia treated with LGN IUD or subjected to hysterectomy. The research tool was a questionnaire comprised of Short Form-36 Health Survey (SF-36) and 5-Dimensional EuroQoL. The examined women treated with LNG IUD, subjectively evaluated their quality of life as higher, showed a good acceptance of the treatment method and withdrawal of symptoms at a level comparable to the hysterectomy group[6].

The high acceptance of LNG IUD, its beneficial effect on the patients' quality of life and correct sexual functioning have been frequently confirmed by other researchers[10,23,24]. In our material we obtained similar results – a positive, clinically significant effect of the hormonal intrauterine contraceptive system (Mirena) on the quality of life (domains: general health, health and well-being improvement, social functioning, pain, energy and vitality as well as emotional well-being) and women's sexual functioning (domains: desire, arousal, sexual satisfaction, orgasm and dyspareunia) as compared with other IUD and non-contraception users.

Martin-Loeches et al.[11] in their prospective research, evaluating sexual desire, analysed 1073 women using IUD and OCs at the Family Planning Center žMarina Alta', Alicante, Spain. Evaluated were also the relative risk factors in libido decrease following contraception: age, education, obstetrical history, relationship, age of sexual initiation, earlier contraception methods and the duration of current contraception method. No differences were observed in sexual desire between the group implementing IUD and that with OCs (OR-1.32; 95% CI 0.70–2.49). Statistically significant negative modifiers of sexual desire were: the examined women's ages (OR--1.05; 95% CI 1.01–1.10), lack of progeny (OR-1.57; 95% CI 1.00–2.47) and bad rapport with the partner (OR-4.69; 95% CI 1.93–11.4) (11). Sexual desire increased in the case of good awareness of methods of family planning (OR-0.64; 95% CI 0.41–1.01) and in the first 6-12 months of using contraception[11].

The research of other authors (Li et al.)[25] concerning the quality of life and sexual functioning of women ($n=361$) using for the first time: OCs, progestagen injections, IUDs or who underwent female sterilisation (research methods used: World Health Organization Quality of Life – WHOQOL and Derogatis Sexual Functioning Inventory – DSFI) showed the highest satisfaction ($p=0.004$), sexual activity ($p=0.003$) and quality of life ($p=0.009$) in the group of women after surgical sterilisation. No statistically significant changes in the quality of life and sexual functioning were observed in the group of women using OCs, progestagen injections and IUDs ($p>0.05$)[25]. Our research did not comprise comparative analysis of contraceptive IUD with other methods of contraception (e.g. OCs).

The design of the study has important advantages for understanding the association between the use of different IUD types and no contraception use and quality of life and sexuality of Polish women. It might have valuable implications for health care professionals – gynaecologists, sexologists, psychiatrists and clinical psychologists. The scales used in the study have been used in many other studies and it is thus unlikely that any systematic error was introduced by using these instruments.

The limitations of this study must also be recognized. Firstly, a relatively small number of investigated population is not sufficient to generalize the results for healthy female population. Secondly, the three groups (Mirena Group, other IUD Group and Control Group II) were not randomised and it affects the reliability of the analysis which was carried out. It was not a double blind randomized trial and little was known about the influence of the patients' expectations and motivations regarding the treatment with different IUDs or no contraception. Thirdly, women using no contraception (CGII) differed significantly from the others in being mainly the youngest, single and nulligravid. Therefore results concerning

differences between the three groups might not be completely direct and objective. It was shown that being married positively correlates with better QoL, general health and sexual functioning. Fourthly, it might be speculated that women who have high levels of sexual desire and function well sexually seek good contraception, while women with low levels of desire, interest and sexual function may not use contraception. Finally, individuals who were particularly uncomfortable talking about their sexual life may have been less likely to respond.

In summary, future research in which these associations are examined longitudinally is clearly warranted. Prospective methods and randomisation should be used, which might be helpful in appropriate evaluation of QoL and sexual life among women using different types of IUDs.

Conclusions

The analysis of our research material showed that women using the levonorgestrel-releasing intrauterine system display, independently of age, a higher level of quality of life, especially in the aspect of general health, energy/fatigue and emotional well-being. A significant beneficial effect of the Mirena intrauterine system on sexual desire and arousal as well as less frequent prevalence of clinically significant sexual dysfunctions were also revealed in the study group.

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PROCJENA KVALITETE ŽIVOTA I SEKSULANIH FUNKCIJA ŽENA KOJE SU KORISTILE LEVONORGESTREL-OTPUŠTAJUĆI INTRAUTERINI KONTRACEPTIVNI SUSTAV – MIRENA

SAŽETAK

Prednosti koje proizlaze iz visoke efikasnosti kontraceptiva, pozitivni učinci na parametre menstrualnog ciklusa, kao i ostale vrijednosti levonorgestrel-otpuštajućeg intrauterinog kontraceptivnog sustava mogu imati značajnu ulogu u seksualnom životu žene. Cilj ovog istraživanja bilo je procijeniti učinak levonorgestrel-otpuštajućeg intrauterinog kontraceptivnog sustava na kvalitetu života i seksualnih funkcija žena. Istraživanje je obuhvatilo 200 žena od 30–45 godina starosti. 52 žene koje su koristile levonorgestrel-otpuštajući intrauterini kontraceptivni sustav bile su određene kao istraživačka skupina (Mirena skupina). Kontrolna skupina sastojala se od 48 žena koje su koristile drugačije tipove intrauterinih sustava (kontrolna skupina I – IUD) te od 50 žena koje nisu koristile kontracepciju (kontrolna skupina II). Kao istraživačko sredstvo korišteni su posebni uptnici s općim dijelom koji se odnosio na sociodemografske uvjete, s dijelom koji se odnosio na kontracepciju i samoprocjenu: kratko istraživanje o zdravlju, indeks spolnih funkcija žene i

Mell-Krat skala. Parametri kvalitete života za žene koje su koristile Mirena sustav bili su viši nego kod kontrolnih skupina, posebno u aspektu općeg zdravlja, odnosu umora i energije i emocionalnog blagostanja. U istraživanju je također potvrđen značajan blagotvorni učinak levonorgestrel-otpuštajućeg intrauterinog kontraceptivnog sustava na seksualne funkcije (spolna želja i uzbuđenje). Seksualne disfunkcije dijagnosticirane su kod 20,8% kontrolne skupine I, 34,7% kontrolne skupine II te kod 9,6% Mirena skupine. Levonorgestrel-otpuštajući intrauterini kontraceptivni sustav povećava parametre kvalitete života i seksualnih funkcija žene.