



**Participating centre:  
Department of Obstetrics and Gynaecology,  
University of Szeged  
2015**

**13<sup>th</sup> December 2015**

### **Interim report**

**Project title: The effect of hormonal contraception on clinical course of migraine and tension-type headache-prospective follow-up study**

**Period: December, 2014 – December, 2015.**

#### **Summary of our activities**

- 1) Ethical approval of the study was sent to the Regional Ethic Committee of the University of Szeged. The approval procedure was successfully (88/2015-3614)
- 2) Project evaluating meetings have been organised on 24 March 2015, 1st April 2015, 13th May 2015, and 6st November 2015 in the Department of Obstetrics and Gynaecology, University of Szeged.
- 3) Questionnaire was developed and piloted on the relevant population. All participants completed a questionnaire containing 25 items compiled by our research team based on our clinical practice and recent international literature research.

The questions referred to socio-demographic characteristics, the menstruation cycle pattern (mean age at the first menses, duration of menses, characteristic of menstrual cramps and large amount of bleeding, the contraception habits, use of reliable and less reliable contraceptive methods and migraine characteristic (including number of headache days, intensity of headpain, use of acute and prophylactic anti-migraine drugs).

- 4) Validation procedure of the questionnaire were also performed. Cronbach alfa score 0,86
- 5) Based upon the pilot questionnaire-based study we have been created a mobile application for android devices and we created short questionnaire (5 item) for the follow up study.
- 6) Preliminary results based on the data of 186 questionnaire were analysed.

The purpose of the pilot study prior the follow up was to assess the connection between menstrual cycle, oral contraceptive use of women with migraine and the clinical characteristics of the migraine attacks.

We invited all women with migraine with or without aura in the Outpatient Headache Unit of the Department of Neurology, Szeged, Hungary to participate in the assisted questionnaire-based study

Women with migraine were diagnosed and classified according to the criteria of International Headache Society. Migraine group divided into MA and M0 subgroup. The number of headache days, initial and associated symptoms of migraine, characteristic, location and intensity of pain, use of acute and prophylactic pharmacological treatment were analysed. Headache severity was rated at a three-point scale (0=no pain, 1=mild, 2=moderate).

The statistical analysis was performed with SPSS 20.0 program. The associations between oral-contraceptive use, bleeding patterns and clinical characteristics migraine were compared by the Pearson correlation tests.

## I. Preliminary results

The average age of the patients at the diagnosis of migraine was  $18.79 \pm 6.97$  years. The mean body weight and the mean body height were  $65.73 \pm 15.9$  kg and  $165.59 \pm 9.87$  cm. The mean age at menarche was  $12.3 \pm 2.1$  years. The majority of patients (59.4 %) had regular menstrual cycle (mean duration of the cycle: 28 days, length of bleeding: 3-5 days. Only twenty-seven patients (11.54%) had a large amount of bleeding, 39.31 % of women suffering from menstrual cramps and 44.45% of patients had changes in body mass index in the last year. Regarding the sexual activity, 155 women (83.3 %) had regular (min.3 coitus/week) sexual life in our study population. Thirty-one women (16.7%) does not have sexual activity during the study period.

Regarding contraceptive practice of the migraineurs 54.3% of women used COC, 13.4% of women reported that used levonorgestrel containing intrauterine system and 3 women (1.61%) used vaginal ring. 26.61% of the 186 women have been used not reliable contraceptive methods as condom (22%), withdrawal (2.15%), spermicides (0.53%) and calendar method (1.61%). 3.27 % of women not used any contraceptive methods during the study period.

The Pearson correlation test revealed a relationship between duration of menstrual cycle and the intensity of headache pain ( $p=0.012$ ). The duration of oral contraceptive use was correlated with the intensity and duration of headpain in the MO groups ( $p=0.001$ ) and ( $p=0.021$ )

However there was no significant relation between the intensity of headache pain and other study parameters (e.g. use of condom or use of IUD length of bleeding, menstrual cramps, amount of bleeding, body mass index)

**Table 1. Characteristics of the migraine headache of the female migraineurs**

<b>Migraine characteristics</b>	<b>n</b>	<b>%</b>
<b>Intensity of headpain</b>		
<b>1</b>	<b>45</b>	<b>24.2</b>
<b>2</b>	<b>141</b>	<b>75.8</b>
<b>Duration of headpain</b>		
<b>1 day&lt;</b>	<b>40</b>	<b>21.5</b>
<b>1 day</b>	<b>61</b>	<b>32.8</b>
<b>&gt;1 day</b>	<b>85</b>	<b>45.7</b>

**Explanation: Headache severity was rated at a three-point scale (0=no pain, 1=mild, 2=moderate).**

**Table 2. The preferred contraceptive methods among migraineurs**

Reliable methods			Less reliable methods		
Methods	n	%	Methods	n	%
COC	101	54.9	condom	41	22
intrauterine system	25	13.4	withdrawal	4	2.15
intrauterine device	0	0	vaginal douche	0	0
sterilization	1	0.53	spermicide	1	0.53
vaginal ring	3	1.61	calendar method	3	1.61
			no method	5	3.27

## II. Next steps in the forthcoming year

- We will continue and promote the management of follow up and divided case and control group for further analysis
- Preparation work of the presentations for the forthcoming international conferences (FIAPAC, ESC meeting)

