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**THE EFFECT OF VITAMIN E INTAKE IN PREGNANCY
FOR BIRTH OUTCOMES**

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1. INTRODUCTION

The vitamin E that is primary used as antioxidant, belongs to the fat-soluble vitamins and more molecule, the tocopherols are belonged to it. The effect to the pregnancy of vitamin E hasn't cleared fully yet, but there are several data and formally it was used as a medicine to pregnant women. The first indication to that is the treatment of the returning and threatening abortion, but the data, are connecting to that, are controversial, because some of the examinations didn't show this therapeutic effect. The other indication is the prevention of preeclampsia, which has been also the object of the argument for years. Moreover, in a Dutch case-control study, Smedts and colleagues showed a nine-fold increased risk of cardiovascular malformations in children born to women who had taken vitamin E doses above 14,9 mg/day as periconceptional supplements or dietary intake. It is really important for Hungarian gynecologists, because in Hungary dose vitamin E treatment is much more higher, then in Smedts's study.

2. THE INVESTIGATIONS OF THE AUTOR

2.1. THE AIM OF THE EXPERIMENTS

The aim of my studies was to evaluate the association between vitamin E treatment in pregnant women and the pregnancy, the birth-outcomes, the preeclampsia, and congenital abnormalities, mainly cardiovascular malformation, in a population – based study.

2.2. MATERIALS AND METHODS

In my research works I used a population – based large data set of the Hungarian Case-Control Surveillance of Congenital Abnormalities (HCCSCA). The HCCSCA is based on the comparison of different exposures in the study pregnancy of women who had cases with congenital abnormalities and delivered healthy newborns and controls. Cases are selected from the data set of Hungarian Congenital Abnormality Registry, 1980-1996 for the HCCSCA. Controls were identified from the National Birth Registry of the Central Statistical Office for the HCCSCA. Controls were defined as newborn infants without congenital abnormalities. In general, two controls were matched to every case according to sex, birth week in the year when the case was born, and district of parents' residence. Moreover, I examined the maternal ages, birth orders, pregnancy orders, maternal family status, maternal employment status, frequently used drugs, including the treatment which were used to the preeclampsia or other pregnancy anomaly, for the treatment/prevention of threatened abortion or preterm delivery and folic acid/multivitamin supplementation in the first trimester, the maternal diseases, including preeclampsia. Our source documents are quite exactly in pregnancy, because the prenatal care is mandatory for every pregnant women in Hungary, and every mother has got Prenatal Maternity Logbook, other side the final reports from the hospitals and the outpatient departments are regular and available.

2.3. STATISTICAL ANALISYS

Statistical analyses were performed using software package SAS version 8.02 (SAS Institute Ins., Cary, North Caroline, USA).

First, frequency tables were made for the main maternal variables in order to describe the study groups of mothers with vitamin E treatment and of mothers without vitamin E treatment. Student t probe was used for quantitative, while chi-square test for categorical variables. Second, the incidence of pregnancy comlitations and acute maternal diseases, the prevalence of chronic maternal diseases, related drug treatments and other pregnancy supplements used during the study pregnancy were compared between control mothers with or without vitamin E treatment, and crude odds ratios (OR) with 95% confidence interval (CI) were calculated. Third, birth outcomes of pregnant women with or without vitamin E treatment were compared using adjusted OR with 95% CI. The latter OR were adjusted for maternal age (<20 years vs. 20-29 years vs. 30 years or more), birth order (first delivery vs. one or more previous deliveries), maternal employment status (professional – managerial – skilled worker vs. semiskilled worker – unskilled worker – housewife vs. others), frequently used drugs for the treatment/prevention of threatened abortion or preterm delivery (yes/no) and folic acid/multivitamin supplementation in the first trimester (as a dichotomous variable).

3. THE RESULTS OF THE EXPERIMENTS AND THE REVIEW

3.1. THE EFFECTS OF THE VITAMIN E TREATMENT

TO THE ISSUE OF PREGNANCY

The total number of births in Hungary was 2 146 574 during the study period between 1980 and 1996. Thus the 38 151 newborns represented 1,8% of all Hungarian births, and among those controls, 2 287 (5,99%) were born to mothers with oral vitamin E treatment. Of 2 287 control mothers, 1 438 (62,9%) had medical recorded vitamin E treatment in the prenatal maternity logbook. The dose of vitamin E treatment was not mentioned in about one third of pregnant women. About half of pregnant women were treated by daily 600 mg of vitamin E treatment (2x3 tablets). The rest used 2x1-2 tablets. Thus the calculated daily mean dose was 450 mg. The mean duration of vitamin E treatment was $3,3 \pm 2,5$ months.

Table 1 summarizes the birth data of newborn infants born to mothers with vitamin E treatment and without vitamin E treatment during the study pregnancy. The mean gestational week at delivery was 0,2 week longer. The mean birth weight of newborn infants born to mothers with vitamin E treatment was 7 g lower, but this difference has no clinical importance. However, **vitamin E treatment associated with a significant decrease in the rate of preterm birth in pregnant women with vitamin E treatment compared to the reference group (crude OR with 95% CI: 1,68, 0,58 - 0,81).**

1. Table Birth outcomes of live-born infants born to mothers with or without vitamin E treatment (VET) (SD: standard deviation, N: case number, OR: odds ratios, CI(95%): OR with 95% confidence interval)

	Mothers				Comparison of mothers	
	VET without (N=35 864)		VET (N=2 287)		EVT +/-	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>t</i>	<i>p</i>
Gestational age/weeks*	39,4	2,1	39,6	2,0	4,2	<0,0001
Birth weight/g**	3 276	510	3 269	530	0,6	0,54
	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>	<i>EH</i>	<i>K (95%)</i>
Preterm births*	3 346	9,3	150	6,6	0,2	(0,63 – 0,84)
Low birthweight**	2 023	5,6	144	6,3	1,10	(0,94 – 1,33)

*adjusted for maternal age, parity, employment status, drugs and folic acid/multivitamins

**adjusted for maternal age, parity, employment status, drugs and folic acid/multivitamins

Bold numbers show significant associations.

3.2 THE VITAMIN E TREATMENT AND THE PREECLAMPSIA

The total number of births in Hungary was 2 146 574 during the study period, thus 38 151 controls represented 1,8% of all Hungarian births. Of these 38 151 newborns, 1 017 (2,7%) had mothers with medically recorded pre-eclampsia in the prenatal maternity logbook.

Of 37 134 pregnant women without preeclampsia, 2 206 (5,9%) had vitamin E treatment, while of 1 017 pregnant women with preeclampsia, 81 (8,0%) were born to mothers with vitamin E treatment.

The effect of vitamin E treatment was evaluated in pregnant women with preeclampsia compared to pregnant women with preeclampsia, but without vitamin E treatment. The mean gestational age was longer (0,2 hét) and it associated with a lower rate of preterm birth (8,6%) due to vitamin E treatment (OR with 95% CI: 0,8 0,7-0,9). The difference in mean birth weight was small (plus 16 g) but it is not associated with significant increase in the rate of low birthweight newborns (8,6%; OR with 95% CI: 1,1 0,8-1,4).

In the basic of the analyse of the dates, my impression is that the most important factor for birth outcomes of preeclamptic pregnant women is the pre-eclampsia, and the vitamin E treatment can not compensate it, in spite of any beneficial effect. It is the reason, that the preterm birth and the low birth weight was more frequent in mothers with preeclampsia, than mothers without pre-eclampsia and vitamin E treatment.

2. Table Birth outcomes of newborn infants in the study groups (PE: preeclampsia, N: number of cases, SD: standard deviation, wk: week)

	Pregnant women									
	without PE without VET (N=34 928)		without PE VET (N=2 206)		PE VET (N=81)		PE without VET (N=936)		PE VET +/- (N=1 017)	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>
Gestational age /wk	39,4	2,1	39,6	2,0	39,5	2,0	39,3	2,1	39,4	2,0
Birth weight/g	3 275	508	3 267	524	3 331	666	3 315	578	3 316	586
	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>	<i>N°</i>	<i>%</i>
Preterm birth	3 249	9,3	143	6,5	7	8,6	97	10,4	104	10,2
Low birth weight	1 950	5,6	137	6,2	7	8,6	73	7,8	80	7,9

3.3. THE VITAMIN E TREATMENT AND THE CONGENITAL ABNORMALITIES

The total number of births in Hungary was 2 146 574 during the study period between 1980 and 1996. Thus the 38 151 controls without congenital abnormalities represented 1,8% of all Hungarian births. Among the controls, 2287 (5,99%) were born to mothers who had vitamin E treatment. The case group consisted of 22 843 newborns or fetuses („informative offspring”) with congenital abnormalities, of whom 1418 (6,21%) had mothers who

received vitamin E treatment. The patient control group comprised 834 newborn infants or fetuses with Down syndrome and 43 (5,16%) had mothers who received vitamin E treatment. Vitamin E treatment was medically recorded in the prenatal maternity logbook for 631 of 1418 case mothers (44,5%), 1438 of 2287 control mothers (63,0%) and 23 of 43 patient control mothers (53,5%).

The table 3. shows the different congenital abnormalities groups with matched controls.

The adverse results of the connection of vitamin E treatment and cardiovascular congenital abnormalities facilitated us to further examinations. We wanted to know, was it just a statistical discrepancy, or a relevant data for the clinical practice. In the next step we analyzed all 306 cases with isolated cardiovascular congenital abnormalities (all were live-born babies), gave the type of abnormalities subgroups, the number of cases, and observed/expected rates. In the basis of our statistical analyses there was no significant cluster of any specific cardiovascular congenital abnormalities with vitamin E treatment.

The distribution of components congenital abnormalities within 97 multiformed cases did not show any characteristic pattern.

In the next step, **vitamin E treatment** was analyzed only during the **second and/or third gestational months**, the critical period of most major congenital abnormalities including esophageal and renal/anal atresia/stenosis, cardiovascular congenital abnormalities and multiple congenital abnormalities. **A significant association between maternal vitamin E treatment and higher risk of esophageal atresia/stenosis, cardiovascular congenital abnormalities and multiple congenital abnormalities was not found.** There was only a higher risk for rectal/anal

atresia/stenosis. That result was unexpected, and we planned more exposition.

We repeated this analyses based only in medically recorded vitamin E treatment and the adjusted OR did not indicate any association of vitamin E treatment with higher risk of total congenital abnormalities or any specified congenital abnormalities group.

We wanted to clear, that the different vitamin E treatment doses influenced the results, but there **was no higher risk for cardiovascular congenital abnormalities in the group receiving the higher doses than in the group receiving the lower doses** (322,2 mg vs 84,4 mg, adjusted OR 1,2; 95% CI 0,5 to 1,8).

Finally, the frequency of vitamin E treatment was compared between case mothers with different congenital abnormalities and patient control mothers, and higher risk was not found in any congenital abnormalities group, including cardiovascular malformations.

3. Table Estimate of risk for different congenital abnormalities (CAs) by comparing vitamin E treatment (VET) as exposure in the mothers of cases and matched controls during any time of pregnancy and in the second and/or third gestational month using a conditional logistic regression model. Bold numbers show significant associations. (OR: odds ratios, CI: with 95% confidence interval)

Study groups	Grand total	Any time of pregnancy				Second and/or third months				Second and/or third months (medically recorded)			
		N°	N°	%	OR	CI	N°	%	OR	CI	N°	%	OR
Controls	38 151	2 287	6,0	-	-	1 487	3,9		-	965	2,5	-	-
Neural-tube defects	1 202	58	4,8	1,1	0,8-1,6	42	3,5	1,5	0,9-2,4	25	2,1	1,3	0,7-2,3
Cleft lip±palate	1 375	75	5,5	0,9	0,7-1,3	51	3,7	1,0	0,7-1,4	27	2,0	1,0	0,6-1,6
Cleft palate	601	26	4,3	0,9	0,6-1,5	16	2,7	0,9	0,5-1,7	10	1,5	0,9	0,4-2,0
Esophageal atresia /stenosis	217	25	11,5	2,2	1,1-4,4	15	6,9	1,5	0,7-3,5	9	4,2	1,7	0,6-4,6
Pyloric stenosis, congenital	241	15	6,2	0,7	0,3-1,4	11	4,6	0,9	0,4-2,0	6	2,5	0,9	0,3-2,9
Intestinal atresia /stenosis	158	6	3,8	0,7	0,3-2,0	2	1,3	0,3	0,1-1,6	1	0,7	0,3	0,0-2,4
Rectal /anal atresia /stenosis	231	23	10	2,6	1,2-5,2	16	6,9	3,3	1,4-7,8	8	3,6	2,9	0,9-9,2
Renal a /dysgenesis	126	6	4,8	0,9	0,3-2,8	4	3,2	0,5	0,1-2,0	0	0,0	-	-
Obstructive CAS of urinary tract	343	28	8,2	1,9	0,9-3,7	20	5,8	2,1	0,9-4,8	9	2,3	2,2	0,6-7,5
Hypospadias	3 038	166	5,5	1,0	0,8-1,2	110	3,6	1,0	0,8-1,2	39	1,3	0,6	0,4-0,8

Undescended testis	2 052	124	6,0	1,0	0,8-1,2	70	3,4	0,9	0,6-1,2	20	1,0	0,4	0,2-0,6
Exomphalos/gastroschisis	255	19	7,5	1,8	0,9-3,7	11	4,3	1,5	0,6-3,4	7	2,9	1,0	0,4-2,7
Mikrocephaly, primary	111	8	7,2	1,4	0,4-4,7	5	4,5	1,4	0,3-6,5	3	2,8	2,1	0,3-16,4
Hidrocephaly, congenital	314	18	5,7	1,3	0,7-2,5	15	4,8	2,1	0,9-4,7	10	3,2	2,0	0,8-5,1
Eye CAs	100	5	5,0	1,2	0,3-4,5	2	2,0	0,8	0,1-4,6	2	2,0	2,1	0,3-15,7
Ear CAs	354	26	7,3	1,6	0,9-2,8	15	4,2	1,9	0,8-4,1	5	1,4	0,9	0,3-2,9
Cardiovascular CAs	4 480	306	6,8	1,2	1,0-1,4	190	4,2	1,1	0,9-1,3	101	2,2	0,8	0,7-1,1
Genital organs CAs	127	6	4,8	0,9	0,3-2,8	4	3,1	0,7	0,2-2,8	2	1,6	1,0	0,2-6,0
Clubfoot	2 425	127	5,2	1,0	0,8-1,3	86	3,5	1,1	0,9-1,5	37	1,5	0,7	0,5-1,1
Limb deficiencies	548	36	6,6	1,2	0,8-1,9	24	4,4	1,2	0,7-2,2	12	2,2	1,0	0,5-2,0
Poly/syndactyly	1 744	103	5,9	1,0	0,8-1,3	67	3,8	1,0	0,7-1,3	28	1,6	0,6	0,4-0,9
Musculoskeletal system CAs	585	61	10,4	1,4	0,9-1,5	44	7,5	1,1	0,7-1,7	26	4,3	0,9	0,5-1,5
Diaphragmatic CAs	244	19	7,8	1,6	0,9-3,0	12	4,9	2,0	0,9-4,7	7	2,9	2,2	0,8-6,4
Other isolated CAs	623	35	5,6	1,2	0,8-1,7	21	4,9	1,1	0,7-1,7	11	1,9	0,9	0,5-1,7
Multiple CAs	1 349	97	7,2	1,3	1,0-1,8	66	4,9	1,4	0,9-2,0	33	2,5	1,1	0,7-1,7
Total CAs	22 843	1418	6,2	1,1	1,0-1,2	919	4,0	1,1	1,0-1,2	438	1,9	0,7	0,7-1,0

4. CONCLUSIONS, SUMMARY

The inconsistent data about vitamin E treatment in pregnancy, and the effectivity of vitamin E treatment in pregnancy gave the aim of my study, when I analyzed it. I examined too the connection between vitamin E treatment and pre-eclampsia, vitamin E treatment and congenital abnormalities, include cardiovascular malformations. Moreover, in Hungary in pregnancy for different indications, the obstetricians used very high dose vitamin E, what was another important basic of my scientific work.

The Hungarian Case-Control Surveillance System of Congenital Abnormalities is a worldwide unique dataset, what is a large, population-based dataset of ethnically homogeneous (white) Hungarian people. The other important was, that we matched healthy and patient controls for every cases. Moreover, the source datas, like final papers from medical institutes were exact, and available, and at least, the nonrespondent percent of the questionnaire was low.

The major part of infant mortality is caused by preterm births in Hungary, thus an extremely important task to identify the different causal factors in the origin of preterm births and/or to find effective preventive methods to reduce the rate of preterm births. Our study showed that vitamin E treatment in pregnant women contributed to the reduction of preterm birth, and the mean gestational week at delivery was 0,2 week longer. It is the reason, why we recomend the vitamin E treatment for the prevention of preterm births.

We have notice, that it shold be a question, just vitamin E treatment for threatened abortion and/or preterm delivery is the reason lower risk of preterm births, or other drugs, lifestyle, or any unknown factor is the cause of the results. The efficacy of other drug treatments such allylestrenol,

diazepam, promethazine, drotaverine in preterm delivery is debated. The preterm preventive effect of clotrimazole was shown and this drug was used more frequently by pregnant women with vitamin E treatment. However, drugs used for the treatment/prevention of threatened abortion/preterm delivery and clotrimazole were considered as confounder at the calculation of adjusted OR for the risk of preterm birth. The healthier lifestyle of pregnant women with vitamin E treatment was connected with a previous miscarriages and/or preterm delivery. The better prenatal care was indicated by the higher use of folic acid and other pregnancy supplements in these pregnant women.

Vitamin E is a well-known antioxidant and its possible beneficial effect for placenta function was shown in some studies and placental dysfunction may have a role in the origin of preterm birth.

In the basic of our result the vitamin E treatment has no effect for incidence of preeclampsia. Vitamin E treatment was able to reduce the (generally higher rate) of preterm birth in preeclamptic pregnant women with threatened abortion and preterm (8,6% vs. 10,4%) but beneficial effect for the higher rate of low birth weight in newborn infants born to mothers with preeclampsia was not found.

When we examined the congenital abnormalities, we had to understand for the correct result, that the birth of an infant with a congenital abnormalities is a traumatic event for mothers, who will try to find a causal explanation, such as illness or drug use during pregnancy. Of course, this does not happen after the birth of a healthy newborn infant. It is the reason, that „mother dusk” can modify the result, because the mother with baby with congenital abnormalities remember for every little moments, but mother with healthy baby does not remember a possible important explosion. It was

the reason, that tries to clear every data, concentrated the critical periods for congenital abnormalities and used like gold standard the medical source documents.

After the maximal cleared data I did not find any correlation between vitamin E treatment and congenital abnormalities, including cardiovascular malformations, despite of very high, about 450 mg per day vitamin E dose in pregnancy. Therefore the vitamin E treatment does not increase the risk of congenital abnormalities, including cardiovascular malformations.

Our result answered every assumptive question. We know, that in spite of worldwide unique dataset and scientific method we have to examine the results very critical. But nowadays we do not know better possibility for this type of analysis, and we have to want to continue this work with other vitamins and minerals.

5. NEW SCIENTIFIC RESULTS

1. The rate of preterm birth was lower, and the gestational age at delivery was 0,2 week longer in the newborns of pregnant women with vitamin E treatment.
2. The vitamin E treatment has got no protective effect for the incidence of pre-eclampsia.
3. The vitamin E treatment reduce the rate of preterm birth in pregnant women with pre-eclampsia.
4. The vitamin E treatment do not reduce the rate of low birth weight newborn in pregnant women with pre-eclampsia.
5. The vitamin E treatment dos not increase the rate of congenital abnormalities
6. The vitamin E treatment dos not increase the rate of cardiovascular malformations.

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