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ANTENATAL CHARACTERISTICS OF ROMA FEMALE POPULATION IN VIROVITICA-PODRAVINA COUNTY, CROATIA

ANTENATALNE ZNAČILNOSTI POPULACIJE ROMSKIH ŽENSK V REGIJI VIROVITICA-PODRAVJE NA HRVAŠKEM

Jadranko ŠEGREGUR1*, Domagoj ŠEGREGUR2

¹General Hospital Virovitica, Department of Gynecology and Obsterics, Gajeva 21, 33000 Virovitica, Croatia ²Johann Wolfgang Goethe-University, Frankfurt am Main, Altenhöferallee 30, 60438 Frankfurt am Main, Germany

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ABSTRACT

Keywords: antenatal characteristics, Roma women, Croatia

Introduction. This study reports about antenatal characteristics of Roma minority population. The study was designed to investigate data about health behaviours known to be associated with reproductive outcomes of Roma women that have very good living conditions and relatively high resource availability.

Methods. A retrospective study included 204 Roma and 408 non-Roma hospitalised singleton births that occurred in the Maternity Ward of the General Hospital Virovitica in the period from 1991 to 2010. Data about women's age, marital status, smoking, reproductive health (abortions, delivery), antenatal care, perinatal complications and gestational age were taken from hospital records and analysed.

Results. Roma women were averagely more than three years younger than non-Roma women, only 10.8% were married. Smoking was more frequent. The average number of births of Roma and non-Roma women was similar, averagely two children per woman. The rate of induced abortions in the Roma women was higher, while the frequency of spontaneous abortions was equal. Inadequate antenatal care of Roma women was associated with two times higher incidence of perinatal complications. A higher frequency of deliveries at home without professional assistance in Roma pregnancy resulted in lower perinatal outcomes. It was confirmed that Roma mothers give birth earlier (38+6 vs. 39+4 weeks) and have a higher incidence of premature births (9.3% vs. 2.2%).

Conclusions. In the comparison of antenatal parameters between the two researched groups, poorer prenatal outcomes in the Roma population were found, despite full integration and considerable improvement in living standards of this ethnic Roma population.

IZVLEČEK

Ključne besede: antenatalne značilnosti. romske ženske, Hrvaška

Namen. Raziskava prikazuje antenatalne značilnosti romske manjšinske populacije v hrvaški regiji Virovitica-Podravje. Analizira podatke o zdravstvenem stanju, povezanem z reproduktivnimi značilnostmi romskih žensk, ki živijo v relativno dobrih življenjskih razmerah.

Metode. V retrospektivno raziskavo so bile vključene 204 romske ženske ter 408 neromskih žensk, ki so rodile v porodnišnici Splošne bolnišnice Virovitica v obdobju od leta 1991 do leta 2010. Iz zgodovine bolezni porodnic so zbrani podatki o starosti žensk, njihovem zakonskem stanu, kajenju, reprodukcijskih značilnostih (splavi, porodi), atenatalni skrbi, perinatalnih zapletih in gestacijski dobi žensk.

Rezultati. Romske ženske so, ko rodijo, v povprečju več kot tri leta mlajše od neromskih žensk, le 10,8% romskih žensk je poročenih. Kajenje kot del tradicionalnega romskega življenja je pri romskih ženskah znatno pogostejše. Število porodov v obeh skupinah je podobno: vsaka ženska rodi povprečno dvakrat. Pogostost namernih splavov je pri romskih ženskah višja, medtem ko je pogostost spontanih splavov v obeh skupinah enaka. Neustrezna antenatalna skrb romskih žensk je povezana z dvakrat večjo pogostostjo perinatalnih zapletov. Pogostejše rojevanje romskih žensk doma, brez strokovne pomoči, prinaša slabše perinatalne rezultate. Potrjeno je, da romske ženske rojevajo prej (38+6 proti 39+4 tednov). Pri romskih ženskah je porod prezgoden v 9,3%, pri neromskih pa v 2,2%.

Zaključek. Primerjava antenatalnih značilnosti preučevanih skupin žensk je pokazala slabši perinatalni rezultat pri romskih ženskah kljub popolni integraciji in dobrim življenjskim razmeram te etnične populacije.

*Corresponding author: Tel: ++ 385 3 372 14 23; E-mail: segregur@vt.t-com.hr
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Angemeldet

1 INTRODUCTION

The Roma people are a widely dispersed transnational ethnic minority of northern Indian origin, located in Central and Eastern Europe. Throughout their history and migration the Roma have been politically, economically and culturally marginalized, ethnically stigmatized and discriminated against (1, 2). The Roma migrating in the area of today's Croatia settled down more than six centuries ago (3). The Roma represent a national minority in Croatia, the exact size of which is uncertain. The census of 2011 revealed that 9463 (0.4% of the total population of Croatia) claimed themselves to belong to the Roma nationality (4). However, estimates suggest a significantly larger number of the Roma in Croatia, between 30 000 - 40 000, or up to between 60 000 - 150 000 persons (5).

Etnomimicry, as a result of assimilation pressure of the local population on Roma in Podravina, led to difficulty in determining their number. The census of 1991 revealed 59 Roma (6), while according to the 2001 census, there are only 4 persons declared as Roma in that area (7). The census of 2011 reported that 14 (0.02%) persons in the Virovitica-Podravina County declared themselves as Roma, of which 6 (0.06%) persons were from Pitomača (4). According to the Centre for Social Work, the real number of Roma in a relatively small area of Podravina can be estimated at 1 500, which is disproportionately in relation to the data from the Census (8).

A higher share of Roma is more likely to be occasionally employed in seasonal agricultural jobs, trading in consumer goods, or collecting and trading with secondary processed materials (9, 10). A specific case is the Virovitica-Podravina County, where the Roma population is natively inhabited. Successfully integrated and adapted to the new environment, the completely assimilated Roma group speaks Croatian language, has better economic position than other Roma in Croatia and is engaged in private business affairs; however, it has therefore lost its national identity (11, 12).

Although a growing number of publications have dealt with the health and social situation of Roma in recent years, published researches on reproductive health of the Roma are limited and difficult to access. Virtually all studies so far were of a small size and most were conducted in non-representative population samples. The largest number of published studies on Roma comes from Slovakia, Czech Republic, Hungary, Romania and Spain (13-17). There are several recent reports dealing with the Roma in Croatia, but they are fragmentary, sparse and incomplete, especially the ones of reproductive health and antenatal care (18-21). The available data suggests that the health of the Roma people is poorer than that of the majority of population (13-17). Similarly, to ethnic differences in Croatia and elsewhere in Central and Eastern Europe,

the contributions of different factors, such as poverty, abject housing conditions, low educational status, high unemployment rate, short life expectancy and long term problematic relations to the majority of population, are emphasized as the most important problems of the Roma population (18-21). Several reports indicate that abortions, lower levels of antenatal care, and more perinatal complications and premature births are more common in Roma than non-Roma population (14, 16, 19, 22, 23).

The objectives of this perinatal research are focused on further and more thorough identification of similarities and differences between this completely assimilated Roma population and non-Roma population in Virovitica-Podravina County, and on the improvement of their health conditions, particularly their perinatal events, associated with Roma pregnant women, both in Virovitica-Podravina County, as well as in the whole Croatia.

2 METHODS

A retrospective study was performed on deliveries at the Maternity Ward of the General Hospital Virovitica, Croatia, in the period of 20 years, from January 1991 to December 2010. The sample for this study included 612 deliveries, of which 204 were of Roma women and 408 of non-Roma women, the second ones being the control group with singleton pregnancies and gestational age from 28 to 43 weeks. Women for the control group were selected in a 2:1 ratio, which means that our research includes the first delivery by two non-Roma women: one that gave birth before and one that gave birth after the birth of each Roma woman included in the study.

Descriptive statistical parameters for women's age are presented in Table 1.

Table 1. Descriptive statistics for age structure of Roma and non-Roma women.

	Roma (n=204)	Non-Roma (n=408)	p-value
Maternal age (years; mean±SD)	23.12±5.59	26.23±5.79	<0.001
Maternal age group (years)			<0.001
≤19	29.4%	10.5%	
20-24	35.8%	35.8%	
25-29	22.1%	25.2%	
30-34	7.8%	17.2%	
≥35	4.9%	11.3%	
Adolescents (<18 years)	19.6%	4.7%	<0.001

Ethnicity was based on their usual residential address at which the Roma population lives (Pitomača, Kloštar Podravski, Kladare - Figure 1), as well as on their specific names (Radelić, Ivanović, Đanić, Šajn, Špoljarić). The accuracy of the data is confirmed via inspection of the birth register.

Gestational age was determined by the duration of amenorrhea, calculated on the basis of the use of Naegle's rule (24), to align dates of the last menstrual period with the corresponding expected dates of delivery that was confirmed or corrected by the fetal ultrasonic biometry during pregnancy. After delivery, the gestational age was estimated using the method of Farr (25).

The data on women's age, marital status, smoking, reproductive health (abortions, delivery), antenatal care, perinatal complications and gestational age were taken from hospital records.



Figure 1. A map of Croatia with the location of the Virovitica-Podravina County.

The data on socio-economic characteristics was not registered in hospital records, and it was not surveyed in this retrospective study.

Descriptive statistics was shown in absolute numbers and frequencies for the qualitative variables, and means and standard deviations for the quantitative ones. Differences in qualitative variables were tested using x2-test and Mann-Whitney test, and differences in quantitative variables by t-test. All analyses were performed by IBM SPSS Statistics 19 package for Windows, with statistical significance set on p<0.05.

3 RESULTS

In the investigated period, there were 19318 births, of which 204 (1.06%) occurred among Roma women.

Significant differences were found in the age of Roma and non-Roma women (Table 1). Roma women were, on average, more than three years younger than non-Roma women. The incidence of adolescent women was four times higher in the group of Roma women; moreover, Roma women predominated in the younger age groups. In the youngest age group (13-19 years), their share was three times larger, the frequency decreasing gradually with increased age class, and in the oldest age group (35-43 years), the share of Roma women was two times lower than the one of the non-Roma women.

Only 56 Roma women declared their marital status, of which 22 (10.8%) were married, significantly less than non-Roma women (95.8%).

Smoking during pregnancy was considerably more common for Roma women (26.5% vs. 16.3%).

Table 2. Reproductive characteristics of Roma and non-Roma women

	Roma (n=204)	Non-Roma (n=408)	p-value
Number of induced abortions (mean±SD)	0.36±0.90	0.11±0.43	<0.001
1	7.5%	5.1%	
2	5.5%	2.0%	<0.001
≥3	5.0%	0.7%	
Number of spontaneous	0.11±0.35	0.18±0.50	0.194
abortions (mean±SD) 1	9.5%	10.0%	
2	1.0%	2.7%	0.302
≥3	0.0%	0.7%	
Sequence of births	2.29±1.67	1.97±1.22	0.140
(mean±SD)	44 20/	44 70/	
1st	41.2%	41.7%	
2nd	28.4%	36.3%	0.030
≥3rd	30.4%	22.0%	

While talking about perinatal parameters, one should mention reproductive characteristics of women. Table 2 shows differences of reproductive characteristics between Roma and non-Roma women. The rate of induced abortions in the Roma women was more than three times higher compared to non-Roma women. The frequency of women with one or more induced abortions was two times higher in the group of Roma women (17.9% vs. 7.8%), and this difference was significantly higher for women with three or more induced abortions. Hereby

presented results showed no differences in the frequency of spontaneous abortions between the studied groups.

One or more spontaneous abortions were more common for non-Roma women in relation to the Roma (10.4% vs. 14.0%), but the difference was not significant. The mean difference according to the ordinal number of deliveries between Roma and non-Roma women was not significant; in both groups, the average number of births was similar, meaning two children per woman. There is a marked dominance of nulliparous and secundiparous, more often among the non-Roma women, but with higher birth rates the frequency of Roma women in the group increased significantly. The frequency of Roma women with five or more births was higher than the one of non-Roma women (10.3% vs. 3.9%).

Table 3. The distribution of antenatal visits of Roma and non-Roma women.

	Roma (n=204)	Non-Roma (n=408)	p-value
Number of antenatal	4.01±3.29	6.25±2.65	<0.001
visits (mean±SD)			
0	18.4%	2.2%	
1-2	20.4%	6.9%	
3-5	29.4%	27.9%	<0.001
6-8	20.4%	45.6%	
≥9 (optimal)	11.4%	17.4%	

The distribution of antenatal visits is presented in Table 3. According to the number of antenatal visits, non-Roma women are in a better position, as they visit the gynaecologist during pregnancy averagely more than six times, while Roma women visit the gynaecologist during pregnancy averagely only four times. The difference was also significant in the distribution of the number of antenatal visits grouped into categories. Almost every fifth Roma woman during pregnancy did not make any gynaecological visit or was not optimally examined. Their optimal number of gynaecological controls was approximately two times lower than the one of (significantly better controlled) non-Roma women.

The prevalence of perinatal complications in the group of Roma women was almost two times higher, as well as a large variety of certain types of complications (Table 4).

Table 4. Perinatal characteristics of Roma and non-Roma women.

	Roma (n=204)	Non-Roma (n=408)	p-value
Perinatal complications (mean±SD)	1.05±0.96	0.63±0.75	<0.001
Narrow pelvis	19.1%	4.2%	<0.001
Fetopelvine disproportions	9.8%	4.2%	<0.001
Breech presentation	5.4%	1.5%	0.007
Urinary infections	7.4%	7.4%	0.042
Fetal asphyxia	10.8%	5.4%	0.020
Pathological cardiotocography	3.3%	0.6%	0.048
Deliveries at home	6.5%	0.0%	<0.001
Duration of labor (hours; mean±SD)	6.08±3.43	6.53±3.56	0.140
Gestational age (weeks; mean±SD)	38.88±1.73	39.52±1.21	<0.001
Premature births	9.3%	2.2%	<0.001

The diagnosis of narrow pelvis was found to be five times more common in Roma women, which is linked to two times higher frequency of fetopelvine disproportions, and four times higher frequency of breech presentation. The incidence of urinary infections was two times higher, and fetal asphyxia (Apgar score of 0 to 6 at 1 minute) was also two times more frequent, as confirmed by a significantly higher frequency of pathological cardiotocography (late and prolonged deceleration, bradycardic and sinusoidal fetal heart rate) recordings in Roma women. The frequency of deliveries at home without a medical or midwifery professional assistance, which is for Roma women traditionally still high, should be pointed out.

The duration of labour in the Roma women was averagely half an hour shorter, but not significantly different in the studied groups. Roma women gave birth significantly earlier, and their gestational age was, on average, five days shorter compared to non-Roma (38+6 vs. 39+4 weeks). Premature births were more common for Roma women than for non-Roma. A significantly higher incidence of early premature birth of gestational age 28-34+6 weeks (2.5% vs. 0.2%), as well as late premature births of gestational age 35-36+6 weeks (6.9% vs. 2.0%) are found in Roma women. There was no difference in the

frequency of male and female newborns between Roma and non-Roma mothers. Roma mothers gave birth to male newborns (52.0%) more often than to female, while non-Roma women often gave birth to female (52.5%) newborns.

4 DISCUSSION

The aim of this study was to compare antenatal parameters of this completely assimilated Roma population with the majority of the population living in the same geographical area. Perinatal outcomes of the Roma pregnant women were poorer despite their full integration and a considerable improvement in living standards of this ethnic Roma population in Virovitica-Podravina County.

The reproductive health of the Roma population presents a major challenge to public health professionals, especially where they are a significant minority.

By virtue of the national program for Roma and participation in the Decade of Roma Inclusion 2005-2015, Croatia has chosen its strategic standpoint toward programs of social inclusion of Roma; in the health area, the focus is on raising health awareness and care in terms of safe motherhood, reproductive health, prenatal and pregnancy health care in Roma women, and family planning. Indicators that are being tracked are the number of antenatal visits per woman, the number and share of births accompanied with professional help, the number and share of women included in the education for family planning, the use of contraceptives and contraceptive methods, the rate of deliveries of Roma women under the age of 16, and the rate of abortions. Most of those indicators are only obtainable through special studies, while routinely monitored indicators do not satisfy quantitative needs. Another problem is Roma not stating their ethnic denomination. The data about the number of Roma in Croatia and their age-sex-structure was neither accessible nor collected during the past years, while the research was being conducted. Thus, this kind of data, on the state level, stays unknown (21).

There are other studies suggesting that perinatal outcomes and reproductive health were poor, and perinatal death rate among Roma women was higher than among non-Roma. More of the data provided in the article is incomplete and suggests that reporting may not have been entirely reliable. The exact number of Roma in Slovakia is also unclear (17). Results of Jarcuska et al. suggest that worse health among Roma compared with non-Roma in Slovakia is mediated by worse access to health services, apart from a large educational gap between Roma and non-Roma. Another important factor is cultural divergence regarding health belief and attitudes of Roma or their distrust of health care system arising from previous experiences (26). The main determinants of inequities in the health status of Roma population in Hungary, Bulgaria and Romania are

education and wealth. Authors suggest broad multisectoral policies to reduce poverty, improve housing and education, as well as specific health-related policies targeting Roma and other ethnic minorities (27). Socioeconomic status is a strong clue of health of people living in Roma settlements in Hungary (28). Although socio-economic factors were not investigated in this study, compared to other groups of Roma in Croatia, Roma population in Virovitica-Podravina County lives in very good conditions with relatively high resource availability (9, 10).

At the time when the national population becomes older and smaller, the birth rate of Roma population increases and exceeds the national average with a high proportion of younger children (23). Rasevic found increased fertility in less developed regions of Serbia and by women with lower education, especially in groups of Albanian, Muslim and Roma women (29). In contrast to Roma in this study, whose population is small, integrated and similar to the majority of non-Roma population, the Roma population in Medimurje county, Croatia, is numerous and more specific. A study on deliveries for the period from 1998 to 2006 reports about 1767 Roma infants, which makes an average of 15.7% of the total number of births in Međimurje with a rising frequency of their respective births from 12.0% to 18.4% (30). The indicators of the reproductive status reported by the Roma women reflect their traditional life-style, the existence of very young mothers and the multi-children family model (19).

Especially traditional are Roma marriages. Wedding is characterized by celebration and ritual, while registering of the marriage at a register office or church is not a rule. The Roma in Central Europe have maintained their traditions and culture and tend to marry other Roma (17). The phenomenon of endogamy of Roma, which was found generally in all of Roma women in this research, is determined with strict and often complicated rules. They are rarely married, in contrast to non-Roma women that are generally married. Traditional rules do not apply to all of the Roma population. Bereczkei and Dunbar report that in Hungary Roma women were supposed to engage in exogamous marriages; 2.8% of rural Roma women married Hungarian men and 26.7% of women in the urban Roma population did so. One reason why those exogamous marriages exist, in contrast to endogamous ones, might be the benefit of social status improvement and survival chances for the Roma children (31). Roma girls in Serbia were found to be at very high risk of being married as children; 50.4% of women from 20 to 24 years of age reported being first married before the age of 18, and 13.2% were first married before the age of 15. This is considerably higher than the rates among females of the same age in the general population (32). The Bayash Roma women in Croatia marry averagely at the age of 16.8 (19). Cook et al. in a systematic review reported about multiple studies of Roma and non-Roma disparities in prenatal care

and pregnancy outcomes (33). Roma women had their first pregnancy earlier than non-Roma women. A study of the sexual culture of Roma women in Bulgaria found that nearly half of pregnancies, where the mother's age is 13-16, were among Roma women (22). A high share of children in the Bayash Roma population in Croatia is characterised by the average birth rate of four children per woman. The rate is markedly higher in Medimurje, with more than five children per woman (19). Roma women in Serbia and Macedonia had an average of 2.5 children (34), while in Hungary, they had 3-13 children (35). In our research, regarding childbirth, one fifth of the Roma women were adolescents and averagely more than three years younger than non-Roma women. Roma women predominated in the younger age groups, but in both groups the average number of births was similar - two children per woman.

In addition, the rate of induced abortions in Roma women in our research was high, more frequent than in non-Roma women. Results showed no differences in the frequency of spontaneous abortions between the studied groups. In the Bayash Roma population in Croatia, the number of induced abortions is equal to the number of born infants. The mean number of induced abortions per Roma woman was higher than in the majority of population (19).

Smoking, as a part of traditional Roma life-style and one of perinatal risk factors is more frequent in Roma than in non-Roma mothers. According to Dejmek et al., in the Czech Republic, the habit of smoking was recorded in approximately 78% of Roma mothers, compared to 31% of non-Roma mothers (36). In the Bayash Roma population in Croatia, smoking was recorded in 69.4% of the examined women (20), as opposed to 26.6% in the general population (37). In our case, smoking during pregnancy is somewhat less often, but nevertheless, almost two times more frequent in Roma women than in non-Roma women.

There is a research study about the reproductive health of Roma women that was carried out in Slovenia. Numerous Roma people in the area of the Dolenjska region are situated and live in residential conditions that have improved only in the last decade. The progress with regard to the improvement of social circumstances, education and the accessibility of healthcare is noticeable. The weaknesses of reproductive health arise from poor health awareness and unhealthy lifestyle, the lack of participation in preventive programmes, the inappropriate use of healthcare services and the inappropriate approaches to providing healthcare services to Roma women. During pregnancy, young Roma women regularly come to the clinic for examinations, whereas after delivery, they visit a gynaecologist less frequently and rarely take part in preventive programmes (38).

Good antenatal care is an important factor for a successful outcome of pregnancy. According to The Plan and Program

of the Health Care, there are standards of ≥9 prenatal examinations during pregnancy, and the optimal number of ultrasound examinations within antenatal care that should provide a successful perinatal outcome (39). One of the problems of health care of Roma is non-realization of the right to free health care on the part of the Roma population. According to UNICEF, perinatal care of Roma pregnant women is poor; in Macedonia, there were 38% of women without examining during pregnancy, and in Kosovo, as much as 60%, with a high percentage of births at home without a medical professional assistance (40). Newer data indicates that 9% of Roma women in Serbia, compared to 1% in the overall population, and 21% in Macedonia, compared to 2% in the overall population, did not attend any prenatal care visits (34). Our data suggests that a high percentage of Roma women did not have any prenatal care visits, only one third of Roma women had more than 5 visits, in comparison to two thirds of non-Roma women with more than 5 visits during pregnancy.

Inadequate antenatal care of Roma mothers included in our research is associated with a higher incidence of perinatal complications. More frequent abnormal cardiotocographic records in Roma mothers from this research are associated with two times higher fetal asphyxia and neonatal complications as well as the high incidence of deliveries at home without a medical or midwifery assistance, which has resulted in poor perinatal outcomes. The incidence of adolescent Roma mothers in our case is high, and pregnancy and childbirth can be associated with perinatal complications. Authors from Canada found a higher incidence of neonatal complications and an increased incidence of fetal asphyxia in adolescent mothers, which they attribute to a lower socioeconomic status, inadequate prenatal care and inadequate gestational weight gain in adolescent pregnant women (41).

The duration of pregnancy is an important factor that has an impact on the size of the infant and neonatal complications. Roma women in our research gave birth significantly earlier, and their gestational age was averagely five days shorter, compared to non-Roma women. The data from Bulgaria, Hungary, Czech Republic and Slovakia indicates that low birth weight and premature births are more common in Roma than in non-Roma women (14, 22, 42). In Hungary, the incidence of premature birth was higher among Roma women (9.9%) than among non-Roma women (7.1%), and the gestational age of Roma newborns was lower (0.4 weeks) than that of non-Roma newborns (42). We also found a similar incidence of preterm births, which are significantly more frequent in Roma women than in non-Roma women, especially late premature births of gestational age 35-36+6 weeks.

In our case, the sex ratio at birth shows a male surplus, but the difference was not significant between Roma and

non-Roma women. Similar results were found in studies of Hungarian (31) and Czech Roma mothers (14).

The present study suffers the limitation that it is not representative of the overall Croatian Roma population, and it did not include those Roma that are not assimilated to the majority of population to a certain degree. Given the unwillingness of many people to self-define their ethnicity as Roma, this is a constraint that will be very difficult to overcome. Several limitations of the study should be considered when interpreting the results. More detailed data of a family environment, economic and material conditions as well as maternal education would provide a more complete picture for the explanation of ethnic differences of perinatal indicators. In addition, mothers may have misreported some of the information.

Roma are a very heterogeneous group in terms of living conditions and levels of integration, and results can be generalized only to the Roma population living in Roma settlements. Further research into the health of Roma people is needed, with a particular emphasis on the reproductive health and interventions that would improve their health. It would be necessary to conduct research at the level of the entire country, which would include all Croatian regions where Roma people live. Such a national research study would enable the comparison of Roma women's reproductive health between individual regions, and represent guidelines for research on these problems in other countries with Roma populations or other ethnic minorities.

6 CONCLUSIONS

Comprehensive and comparative studies of the health status and perinatal parameters of Roma in Croatia are rare and fragmentary. The objectives of this perinatal research are focused on the reproductive health of Roma population in Virovitica-Podravina County, especially in relation to perinatal events of Roma pregnant women, mothers and newborns. In the comparison of antenatal parameters between the two researched groups, despite full integration and considerable improvement in living standards of this ethnic Roma population, poorer prenatal outcome was found in the Roma population.

CONFLICTS OF INTEREST

The authors declared that they have no financial, professional or personal conflicting interests related to this article.

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ETHICAL APPROVAL

The research protocol was approved by the Commission of the General Hospital Virovitica for Medical Ethics.

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