ORIGINAL ARTICLE

Review of socioeconomic risk factors for cesarean births: a population-based study

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Abstract. Objectives: The reasons for increased cesarean section (CS) rates are complex and multifactorial. The goal of this study was to look at different social and economic factors that might be causing more cases of CS in the population. Study design: A retrospective population-based cohort study. Data was taken from the Perinatal Neonatal Outcomes Research study in the Arabian Gulf (PEARL study) registry. Data from 60,728 live births ≥ 24 weeks of gestation were analyzed. In this study, various socioeconomic factors, such as maternal nationality, religion, educational level, employment status, parental income, consanguinity, housing, preterm birth, and tall stature, were examined for women undergoing cesarean section (CS) and their economic outcomes. Women who underwent vaginal delivery (VD) were compared. There are risks associated with pregnancy, smoking, assisted conception, and prenatal care. Results: 60,728 births ≥ 24 weeks gestation were included in the analysis. 17,535 women delivered by CS (28.9%). Women with university-level education and above were more likely to deliver by CS (61%), as compared to illiterate women or women with basic education at elementary or secondary levels (OR 0.73, CI 95%: P: <0.0001). Working women were more likely to deliver by CS (OR 1.40, CI 95%, P value <0.0001). Women living in rented houses were less likely to achieve a normal delivery (71.8%) (OR 1.40, CI 95%; P: <0.0001) as compared to women living in owned houses (74.7%). Women over 20 years old tended to achieve more VD compared to women less than 20 years old. P value <0.0001. Smoking was associated with lower chances of VD, with 42.4% of smokers delivered by CS compared to 28.3% of non-smokers (OR 1.87, CI 95%; P: <0.0001). Assisted conception was associated with higher CS rates as compared to spontaneous conceptions (OR 0.39; P: <0.0001). We found no statistically significant differences in how babies were born based on the mother's nationality, the father's job, or the mother's income. Conclusions: Higher education, employed mothers, smoking, and living in rented houses were socioeconomic factors associated with a higher rate of CS in our population. Furthermore, women who had regular antenatal care were more at risk for delivery by cesarean section, which could be related to other comorbidities increasing the likelihood of cesarean birth rather than antenatal care itself. In our population, assisted reproduction was associated with a higher probability of cesarean delivery. (www.actabiomedica.it)

Key words: Cesarean section, population-based study, risk factors, socioeconomic factors, vaginal delivery

Introduction

A cesarean section (CS) is a life-saving procedure when pregnancy or labor complications arise. However,

the incidence of CS has increased significantly and steadily over the past two decades, causing concern among various health professionals, institutions, and nations (1). Although CS is considered a routine 2 Acta Biomed 2023; Vol. 94, N. 3: e2023082

surgical procedure, there are risks involved. Numerous immediate, short-term, and long-term health effects and complications have been documented. These may also have long-term effects on future pregnancies, in addition to their effects on women and their children. Compared to women who deliver vaginally, women with CS experience higher rates of morbidity and mortality (VD). Women who undergo CS are at risk for a variety of adverse outcomes, including mortality, ICU admission, hysterectomy, anemia, blood transfusions, uterine rupture, placental abnormalities, and long-term effects on their fertility (2,3). Newborns with CS are more likely to develop allergies, asthma, and type 1 diabetes, and they are at risk for developing shortness of breath (4,5).

Consequently, reducing the number of CS is gaining popularity among healthcare planners. This objective can be attained by understanding the causes of the rise in CS. In addition to medical factors, non-medical factors, such as the varied changes in maternal features over the past few decades, as well as social and cultural factors, may also be to blame (6). The goal of our study was to find out how different mother characteristics and socioeconomic factors affect CS rates.

Methods

This is a retrospective longitudinal study in Qatari government hospital facilities utilizing maternal and neonatal registries with data bridging the perinatalpostnatal period. Data for this study were taken from the Qatar Perinatal Registry, which was developed in 2011 and resumed as the Qatar Pearl Peristat Registry in 2016 funded by the Qatar National Research Fund [QNRF] and sponsored by the Hamad Medical Corporation Medical Research Center. The registry includes information from all Qatari provincial hospitals with obstetric units covering both the prenatal and postnatal phases. To investigate the short- and longterm health condition of both mothers and neonates, the registry seeks to use patient records. To improve the outcomes for the Qatari population's reproductive health, this study also aims to look at the development of particular sub-cohorts. The first part of the register covers the birth cohort from 2011-2012, with 35,000 births, and the second phase covers the birth cohort from 2017-2019, with 35,000 births nationwide. Because the register only represents less than 10% of all deliveries in Qatar and does not make use of the same electronic health record system, we omitted instances from the private sector. A common electronic medical record (EMR Cerner®) that links all state hospitals serves as the source of the first registration data collection. To address the social status of pregnant women, social data questionnaires given out after birth are also utilized to gather socioeconomic and demographic health data. The research team for the registry is made up of 12 skilled research assistants who are responsible for gathering patient data from families (social data) or EMRs (electronic clinical data Cerner®), under the direction of a full-time qualified researcher. It has been constructed. Each factor was divided into optimal socioeconomic settings (control) and less optimal settings (risk factors). Socioeconomic factors include the mother's nationality (national vs. resident), religion (Muslim vs. non-Muslim), educational level (high vs. non-Muslim), mother's occupation (housewife vs. employed), and family income (high vs. employed). low), placement (separate vs. shared), consanguinity (none vs. yes), preterm birth (≥ 20 years vs. <20 years), highrisk pregnancy (none vs. yes), smoking (none vs. yes), Assisted conception (no vs. yes), prenatal care (yes vs. no), and place of birth (Level 3 referral hospitals vs. Level 1 and 2 hospitals).

Statistical analysis

Collected data is analyzed and stored in a specially designed program created by Dendrite® database solutions. The analysis is performed in both Dendrite® and SPSS® version 22. Records for the cesarean section are retrieved from the PEARL-Peristat Registry in Excel format. Data for a total of 60,728 births are recovered following which extreme or aberrant maternal age, birth weight, or gestational ages are removed from the dataset. Test cases from some years and additional records are also removed for various reasons. There are a total of 60,728 births used finally; (19166 preterm and 41,562 term newborns). Mode of delivery is examined within the following cohorts: year of delivery, nativity (Native vs.

Expatriates), maternal age at delivery, newborn gender, and the duration of pregnancy. For each group examined, frequencies and percentages or percentiles are calculated. Differences in proportion are tested using Pearson's Chisquare test with statistical significance set at P value < 0.05. Results are presented in the table. Confidence interval (CI) and odds ratio (OR) (7). The rate centile was calculated as the number of LBW divided by the number of LBW plus NBW expressed as 100%.

Results

60,728 births ≥ 24 weeks' gestation were included in the analysis. 11,444 were labelled as high risk pregnancies. Most women (51,782) delivered in Women's Wellness and Research Centre. Few women (3,773) had no antenatal care. 17,535 women delivered by CS (28.9%). Women with university-level education and above were more likely to deliver by CS (61%) as compared to illiterate women or women with basic education at elementary or secondary levels (OR 0.73, CI 95%; P: <0.0001). Working women were likely to deliver by CS (OR 1.40, CI 95%, P: <0.0001). Women living in rented houses were less likely to achieve a normal delivery (71.8%) (OR 1.40, CI 95%, P: <0.0001) as compared to women living in owned houses (74.7%). Women more than 20 years old tended to achieve more VD as compared to women > 20 years old (P; <0.0001). Smoking was associated with lower chances of VD, 42.4% of smokers delivered by CS as compared to 28.3% of non-smokers (OR 1.87, CI 95%, P value < 0.0001). Assisted conception was associated with higher CS rates as compared to spontaneous conceptions (OR 0.39; P: <0.0001). We found no statistically significant differences in the mode of delivery regarding nationality, paternal occupation, and maternal income. We found no statistically significant differences concerning nationality, paternal occupation, marital status, and maternal income (Table 1).

Discussion

Globally, the CS rate nearly tripled between 1990 and 2014, from 6.7% to 19.4%. However, rates

vary from country to country and even between hospitals within the same nation. Compared to others, the growth rates of some nations were exceptionally high. In Egypt, the prevalence of CS increased dramatically from 4.6% in the 1990s to 51.8% in 2014. Romania had the largest increase in Europe. In Latin America, from 7.2% to 36.3%. Mexico, Colombia, and the Dominican Republic experienced the greatest increases in CS incidence rates (1,8). Multiple variables have contributed to the rise in CS rates. Providers of healthcare must comprehend the underlying causes of the CS increase in their patient population and make every effort to optimize these rates (9). Multiple medical explanations have been proposed for this increase. However, medical and health-related factors cannot fully account for the vast variation in rates across nations (1,9,10).

Social, economic, religious, and cultural factors may play a larger role than previously believed. Considering this, the purpose of the study was to examine the effect of various socioeconomic factors on CS rates among 60,728 births ≥ 24 weeks gestation. In our study, 17,535 women gave birth via caesarean section, while 43,193 delivered normally. The prevalence of CS was 28.9% in our study population. In our study, women with a bachelor's degree or higher and women who were employed were more likely to deliver by cesarean section than illiterate women or women with elementary or secondary education. The prevalence of CS among women with a higher level of education and employment was 30.4% and 32.8%, respectively. This was statistically significant in comparison to the CS rates of women with less education (23%) and housewives (25.9%).

This finding supports the work of other studies in this area where increased cesarean section rates are associated with the mothers' higher education (11,12). It is plausible that more educated women feel more empowered to choose a CS that they will confidently stand by. Moreover, by being more aware of the potential risks, they may select a CS for better safety for the baby and less pelvic floor trauma (13). However, what still needs to be defined is the proportion of that increase related to other factors such as wealth, inherent differences in risk in these women, ease of access to health services, and physician biases (11,12). One

 Table 1. Socioeconomic factors data analysis.

Number % n %		Me	ode of delive	OR (95% CI)	P value		
Nationality Non-Qatari 12464 28.9 30606 71.1 1.01 (0.97-1.05) 0.585.	Risk factors	CS				Vaginal	
Non-Qatari 12464 28.9 30606 71.1 1.01 (0.97-1.05) 0.585		Number	%	n	%		
Qatari 5071 28.7 12587 71.3 Control Religion Other 358 33.9 698 66.1 1.35 (1.19-1.54) <0.000°	Nationality						
Religion State	Non-Qatari	12464	28.9	30606	71.1	1.01 (0.97-1.05)	0.5851
Other 358 33.9 698 66.1 1.35 (1.19-1.54) <0.000° Muslim 8050 27.5 21258 72.5 Control Marital status Single/divorced/separated/unknown Married 1267 29.2 3066 70.8 1.01 (0.95-1.09) 0.6946 Father's education Illiterate/elementary/secondary 4345 23.4 14193 76.6 0.73 (0.7-0.76) <0.000° Mother's education University and above 7447 29.6 17682 70.4 Control Control Mother's education University and above 7447 29.6 17682 70.4 Control Mother's education University and above 7253 30.4 16588 69.6 Control Mother's education University and above 7253 30.4 16588 69.6 Control Tather's occupation	Qatari	5071	28.7	12587	71.3	Control	
Muslim 8050 27.5 21258 72.5 Control Marital status Single/divorced/ separated/unknown 1267 29.2 3066 70.8 1.01 (0.95-1.09) 0.6946 Married 14185 29.0 34799 71.0 Control 7.0000 0.000 Father's education Illiterate/elementary/ secondary 4345 23.4 14193 76.6 0.73 (0.7-0.76) <0.000	Religion						
Marital status Single/divorced/separated/unknown 1267 29.2 3066 70.8 1.01 (0.95-1.09) 0.6946 Married 14185 29.0 34799 71.0 Control Father's education Illiterate/elementary/secondary 4345 23.4 14193 76.6 0.73 (0.7-0.76) <0.000* Mother's education University and above 7447 29.6 17682 70.4 Control Mother's education University and above 7447 29.6 17682 70.4 Control Mother's education University or above 7253 30.4 16588 69.6 Control Father's occupation Unemployed 282 27.9 727 72.1 1.05 (0.91-1.21) 0.507: Employed 11469 27.0 30993 73.0 Control Mother's occupation Worker 5866 <td>Other</td> <td>358</td> <td>33.9</td> <td>698</td> <td>66.1</td> <td>1.35 (1.19-1.54)</td> <td>< 0.0001</td>	Other	358	33.9	698	66.1	1.35 (1.19-1.54)	< 0.0001
Single/divorced/separated/unknown	Muslim	8050	27.5	21258	72.5	Control	7
Separated Married 14185 29.0 34799 71.0 Control	Marital status						•
Father's education Control Con	Single/divorced/ separated/unknown	1267	29.2	3066	70.8	1.01 (0.95-1.09)	0.6946
Hilterate/elementary/secondary	Married	14185	29.0	34799	71.0	Control	
University and above 7447 29.6 17682 70.4 Control	Father's education						•
Mother's education Illiterate/elementary/ secondary 4633 23.0 15509 77.0 0.68 (0.65-0.71) <0.0003 Father's occupation University or above 7253 30.4 16588 69.6 Control Father's occupation Unemployed 282 27.9 727 72.1 1.05 (0.91-1.21) 0.507 Employed 11469 27.0 30993 73.0 Control 0.507 Mother's occupation Worker 5866 32.8 12037 67.2 Control <0.0003	Illiterate/elementary/ secondary	4345	23.4	14193	76.6	0.73 (0.7-0.76)	<0.0001
Hilterate/elementary/secondary	University and above	7447	29.6	17682	70.4	Control	
secondary University or above 7253 30.4 16588 69.6 Control Father's occupation Unemployed 282 27.9 727 72.1 1.05 (0.91-1.21) 0.507 Employed 11469 27.0 30993 73.0 Control Mother's occupation Worker 5866 32.8 12037 67.2 Control <0.0003	Mother's education				'		1
Father's occupation Unemployed 282 27.9 727 72.1 1.05 (0.91-1.21) 0.507 Employed 11469 27.0 30993 73.0 Control Cont	Illiterate/elementary/ secondary	4633	23.0	15509	77.0	0.68 (0.65-0.71)	<0.0003
Unemployed 282 27.9 727 72.1 1.05 (0.91-1.21) 0.507 Employed 11469 27.0 30993 73.0 Control 0.507 Mother's occupation Worker 5866 32.8 12037 67.2 Control <0.000 Housewife 8439 25.8 24240 74.2 1.40 (1.35-1.46) 7.40 0.92 (0.88-0.97) 0.000 Father's income 4453 26.0 12649 74.0 0.92 (0.88-0.97) 0.000 0.000 Mother's income 40 thousand 5843 27.6 15335 72.4 Control 0.0468 0.93 (0.87-1) 0.0468 0.000	University or above	7253	30.4	16588	69.6	Control	1
Employed 11469 27.0 30993 73.0 Control Mother's occupation Worker 5866 32.8 12037 67.2 Control <0.0003 Housewife 8439 25.8 24240 74.2 1.40 (1.35-1.46) 7.2 Control Pather's income < 10 thousand 4453 26.0 12649 74.0 0.92 (0.88-0.97) 0.0003 ≥10 thousand 5843 27.6 15335 72.4 Control Control Mother's income 30.2 5152 69.8 0.93 (0.87-1) 0.0468 ≥10 Thousand 2115 31.7 4550 68.3 Control Control Housing Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0003 Owned 3765 25.3 11100 74.7 Control Type of house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0003	Father's occupation						•
Mother's occupation Worker 5866 32.8 12037 67.2 Control <0.0003	Unemployed	282	27.9	727	72.1	1.05 (0.91-1.21)	0.507
Worker 5866 32.8 12037 67.2 Control <0.0007 Housewife 8439 25.8 24240 74.2 1.40 (1.35-1.46) 74.0 1.40 (1.35-1.46) 74.0 0.92 (0.88-0.97) 0.0007	Employed	11469	27.0	30993	73.0	Control	
Housewife 8439 25.8 24240 74.2 1.40 (1.35-1.46) Father's income < 10 thousand 4453 26.0 12649 74.0 0.92 (0.88-0.97) 0.0007 ≥10 thousand 5843 27.6 15335 72.4 Control Mother's income <10 thousand 2227 30.2 5152 69.8 0.93 (0.87-1) 0.0468 ≥10 Thousand 2115 31.7 4550 68.3 Control Housing Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0007 Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0007	Mother's occupation						
Father's income < 10 thousand	Worker	5866	32.8	12037	67.2	Control	<0.0001
< 10 thousand	Housewife	8439	25.8	24240	74.2	1.40 (1.35-1.46)	
≥10 thousand 5843 27.6 15335 72.4 Control Mother's income <10 thousand 2227 30.2 5152 69.8 0.93 (0.87-1) 0.0468 ≥10 Thousand 2115 31.7 4550 68.3 Control Housing Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0003 Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0003	Father's income						•
Mother's income <10 thousand	< 10 thousand	4453	26.0	12649	74.0	0.92 (0.88-0.97)	0.0007
<10 thousand	≥10 thousand	5843	27.6	15335	72.4	Control	7
≥10 Thousand 2115 31.7 4550 68.3 Control Housing Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0007 Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0007	Mother's income						
Housing Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0003 Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0003	<10 thousand	2227	30.2	5152	69.8	0.93 (0.87-1)	0.0468
Rented house 7936 28.2 20180 71.8 1.16 (1.11-1.21) <0.0007 Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0007	≥10 Thousand	2115	31.7	4550	68.3	Control	7
Owned 3765 25.3 11100 74.7 Control Type of house popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0003	Housing						
Type of house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0007	Rented house	7936	28.2	20180	71.8	1.16 (1.11-1.21)	<0.0001
popular house 1978 21.6 7171 78.4 0.7697 (0.73-0.81) <0.0003	Owned	3765	25.3	11100	74.7	Control	1
	Type of house						
Apartment/villa 9825 28.5 24630 71.5 Control	popular house	1978	21.6	7171	78.4	0.7697 (0.73-0.81)	<0.000
	Apartment/villa	9825	28.5	24630	71.5	Control	7

	M	ode of delive	OR (95% CI)	P value		
	CS				Vaginal	
Risk factors	Number	%	n	%		
Consanguinity						
Yes	3231	23.6	10488	76.4	0.77 (0.73-0.81)	<0.0001
No	8506	28.6	21252	71.4	Control	
Maternal age						
Mother < 20 years	193	13.4	1251	86.6	0.37 (0.32-0.43)	<0.0001
Mother 20+ years	17387	29.3	42037	70.7	Control	
Gravidity						
High gravidity (>3)	6184	29.4	14820	70.6	1.04 (1.01-1.08)	0.0262
0-3	11386	28.6	28449	71.4	Control	
Smoking						
Yes	126	42.4	171	57.6	1.87 (1.48-2.35)	<0.0001
No	14642	28.3	37070	71.7	Control	

of the strengths of our study is that access to health-care services is nearly free for all, limiting the bias from other factors such as wealth and physician economic considerations. In our study, the rate of CS was nearly double in women > 20 years old (29.3%) as compared to those < 20 years old (13.4%). The OR for a VD was 0.37 (0.32-0.43). This is statistically significant. Although the reasons for this can be multifactorial, older women tend to have more comorbidities, which can contribute to a CS. This finding agrees with other studies, where the overall CS increased with increasing maternal age (14,15).

In our study, women who smoke tended to achieve lower chances of VD and statistically more CS rates. 42.4% of smokers delivered by CS compared to 28.3% of non-smokers (OR 1.87, CI 95%, P: <0.0001). Smoking increases the risk of intrauterine growth restriction, low birth weight babies, and preterm delivery. All can complicate a normally going pregnancy and increase CS rates (16,17) and the risk of fetal compromise during labor leading to increased operative delivery rates via instrumental delivery and CS (18).

In our study, women with a high-risk pregnancy and having routine antenatal care were more likely to deliver by a CS as compared to women with low-risk pregnancies and those with limited antenatal care. One step to decrease CS rates is to limit CS in low-risk pregnancies (19).

Women living in rented houses were less likely to achieve a normal delivery (71.8%) as compared to women living in owned houses (74.7%; P: <0.0001. The rate of CS in rented houses was 28.2% compared to owned houses (25.3%), which was statistically significant. Living in an apartment or villa was associated with more CS rates (28.5%) than living in a 'popular house' (21.6%), which sometimes refers to a house where many families live. Higher socioeconomic status may perceive CS as a more prestigious option (11).

In our study, assisted conception was associated with higher CS rates as compared to spontaneous conceptions (OR 39; P: <0.0001). The CS rate among women who achieved pregnancy via assisted conception was only 13.2% compared to women who spontaneously conceived (27.8%). This finding is broadly consistent with other studies. These women are usually older and have comorbidities such as endometriosis, obesity, diabetes, hypertension, and previous surgeries, complicating the pregnancy and contributing to the higher CS rates (20– 23).

We found no statistically significant differences in the mode of delivery concerning nationality or paternal occupation and maternal income. This is in contrast to other studies which have linked the increased CS rate with higher family income, insured mothers and delivery in private health care facilities, and increased profitability (24-26). Many of these factors do not apply to 6 Acta Biomed 2023; Vol. 94, N. 3: e2023082

our institution, where delivery is at low cost or free for all, irrespective of socioeconomic status or nationality. This can also be one of the strengths of our study, as cost and lack of resources probably contribute very little to the increased CS in our widely diverse population.

Strengths and limitations of our study

Our population sample is large (60,728 women) and diverse, with ex-patriots of various nationalities (12,464 women), more than double the number of Qatari people (5,071 women). This sample is also representative of the majority of the total population.

Cost as a contributing factor to the highly complex socioeconomic equation is largely eliminated in our study. This is because health care at our facilities is almost free or very low cost for everyone regardless of nationality. This variable may confound other socioeconomic variables in many other studies.

The combination of the above in medical facilities with the same HCP helps reduce differences in expertise when studies are conducted in different hospitals or geographies. Since we operate an on-call system and do not have specific physicians available for patients, physician availability has little impact on the facility. These factors strengthen our study with many of the confounding factors of other studies, such as: For example, differences in physician expertise, maternal costs, accessibility to health care, and convenience of physicians do not apply to our study.

Some limitations need to be noted regarding our study. It would have been more useful to stratify CS rates with different age groups. To analyze elective versus emergency section. Another is further analysis of assisted reproductive technologies (ART) into multiple sections ranging from mere ovulation induction to in-vitro fertilization.

Conclusions

Higher education, women who were employed, smoking, and living in rented houses were some of the socioeconomic factors associated with the women who were delivered by CS in our population. Furthermore, women who had regular antenatal care were more at

risk for delivery by a cesarean section which could be related to other comorbidities increasing the likelihood of cesarean birth rather than the antenatal care itself. Unlike previously published reports, assisted reproduction did not seem to contribute to cesarean delivery in our population.

There is considerable evidence to suggest an increased role of socioeconomic factors in the rise of CS rates, which appear independent of medical indications. More in-depth studies are needed to quantify this role. These factors can differ from one healthcare system to another. Tailoring health services to target the factors for a particular population cohort is essential in counselling and optimizing CS rates.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Author Contributions: G.S wrote the manuscript. HS is the lead principal investigator of PEARL, data analysis, data verification, participated in writing manuscript and manuscript submission. SA is a research fellow participated in the data collection. HS, SA, MA, HA are the research collaboration group, data analysis and manuscript revision.

Ethic Committee: The study has been granted an exemption from requiring ethics approval because it was retrospective and "non-interventional". All procedures were in accordance with the 1964 Helsinki declaration and its later amendments.

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