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CME ARTICLE

No increased risk of adverse pregnancy outcomes for women with myasthenia gravis: a nationwide population-based study

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Background: This study aims to examine the risk of adverse pregnancy outcomes [low birthweight (LBW), preterm birth, cesarean sections (CS) and babies born small for gestational age (SGA)] in pregnant women with myasthenia gravis (MG), using a 3-year population-based database, taking characteristics of infant and mother into consideration.

Methods: This study used two nationwide population-based datasets: the Taiwan National Health Insurance Research Dataset and the Taiwan birth certificate registry. We identified 163 pregnant women with MG during 2001–2003 as the study cohort and 815 randomly selected pregnant women as a comparison cohort. Conditional logistic regression analyses were performed.

Results: The results showed that, although these patterns did not reach a statistically significant level, mothers with MG had higher percentages of LBW (6.8%, vs. 5.6%), SGA (17.8%, vs. 14.1%) and cesarean deliveries (44.8%, vs. 37.4%), except for preterm births (8.1%, vs. 8.1%). After adjusting for highest maternal education level, marital status, family monthly income and infant gender and parity, the odds ratios (OR) of LBW, preterm birth, SGA infants, and cesarean delivery for mothers with MG were 1.19 (95% CI = 0.60–2.38), 1.00 (95% CI = 0.54–1.87), 1.30 (95% CI = 0.83–2.04), and 1.33 (95% CI = 0.94–1.88), respectively, as compared to unaffected mothers.

Conclusions: We conclude that there were no statistically significant differences in the risk of having preterm, LBW, SGA infants and cesarean deliveries between women with and without MG.

Introduction

Myasthenia gravis (MG) is a chronic autoimmune disorder of neuromuscular transmission characterized by varying degrees of weakness and easy fatigability of the skeletal muscles. The disease is twice as common in females; it frequently affects young women of childbearing age and is diagnosed in an estimated 1 in 20 000 pregnancies [1–3]. Pregnancy has a variable effect on disease relapse and the course of MG during pregnancy is unpredictable; it is equally likely that MG will remain stable, improve, or worsen during pregnancy [2,4–6].

Despite long concern about the relationship between MG and pregnancy, the existing literature on MG and pregnancy outcomes and has yielded contradictory findings. For example, some studies found that women with MG had a higher prevalence of premature births and/or low birthweight (LBW) [3,6,7] compared to the general population, whereas an equal number of studies failed to prove such associations [8–10]. Furthermore, the findings regarding whether there was an increased risk of cesarean sections among women with MG was still controversial [8–10]. Since prior studies dealing with this topic have generally relied on a small number of cases from one hospital [3,6–9] or in population subgroups [10], inconsistent results could be due to the use of selective data, limited sample sizes and inadequate control of confounders. Furthermore, the non-representative nature of their data means these studies lack statistical rigor for attempting to detect differences from

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the population as a whole or for generalizing from their findings to the entire population.

This study aims to examine the risk of adverse pregnancy outcomes [LBW, preterm birth, infants born small for gestational age (SGA) and cesarean sections (CS)] among women with MG, using a 3-year nationwide population-based database. Taiwan initiated its National Health Insurance program in 1995 to finance healthcare for all of the island's 22 million citizens. The data now available from Taiwan presents a unique opportunity to clarify the relationship between MG and adverse pregnancy outcomes.

Methods

Database

This study used two nationwide population-based datasets. The first dataset was the Taiwan National Health Insurance Research Dataset (NHIRD), released by Taiwan National Health Research Institutes. The NHIRD includes all medical claims data (inpatient and ambulatory care visits) and registration files (contracted medical facilities, board-certified specialists, medical personnel and beneficiaries) under the NHI, for over 22 million enrollees, representing over 98% of the Taiwanese population. The NHIRD data are quite accurate because the Bureau of the NHI audits claims regularly. Fines for fraud are 100 times the amount of the false claim charged to the NHI.

The second dataset was the Taiwan birth certificate registry. The birth certificate registry includes birthdates for both infants and their parents, gestational week at birth, birthweight, gender, parity, place of birth, parental educational levels and maternal marital status. The government in Taiwan mandates all births and deaths be registered, so the birth certificate data are considered to be accurate.

The two datasets were linked by the mother's and infant's unique personal identification numbers, with assistance from the Bureau of the NHI. All personal identifiers were encrypted by the Bureau of NHI before release to the researchers. Confidentiality assurances were addressed by abiding by the data regulations of the Bureau of NHI. Since the NHIRD consists of de-identified secondary data released to the public for research purposes, this study was exempt from full review by the Internal Review Board.

Study sample

The study group was selected from a total of 473 529 pregnant women, identified as having had singleton live births in Taiwan between 1 January 2001 and 31 December 2003. If a mother had more than one singleton birth during 2001–2003, we only selected the first one for inclusion in the study sample. Of these women, 163 were identified as having visited ambulatory care centers for the treatment of myasthenia gravis (ICD-9-CM code 358.0) within the 2 years prior to their index deliveries.

The comparison group was extracted from the remaining 473 361 mothers. We randomly selected 815 women (five for every woman with MG) matched with the study group in terms of age (<20, 20–24, 25–29, 30–34 and ≥ 35 years), the year of delivery and whether a woman had diabetes, hypertension, anemia, coronary heart disease (CHD) or hyperlipidemia. Ultimately, 978 patients were included in our sample.

Variables of interest

The outcome variables of this study were all dichotomous, including low birthweight (LBW) (<2500 g), preterm birth (<37 weeks), infants born small for gestational age (SGA) (birthweight below the tenth percentile for gestational age), and cesarean delivery. The key independent variable was whether or not a mother had visited an ambulatory care center for the treatment of MG in the 2 years prior to their index deliveries.

This study also took potential confounding factors into consideration in the regression modeling. Such factors included characteristics of the mother (age, the highest educational level and marital status), infant (gender and parity) and monthly family income. Maternal education was grouped into four levels: elementary school or lower, junior high school, senior high school, college or above. Monthly income was divided into four categories: $<$NT\$15,000, NT15,000-NT30,000, NT30,001-NT50,000, $\geq$NT50,001 (US\$1.00 = NT\$ 33.00 in 2003).

Statistical analysis

The SAS statistical package (SAS System for Windows, Version 8.2) was used to perform the analyses. The chi-squared tests were carried out to examine differences in the characteristics of mother and infant, comparing mothers with MG and unaffected mothers. Conditional logistic regression analyses, which were conditioned on maternal age, the year of delivery, diabetes, hypertension, anemia, CHD and hyperlipidemia, were also performed to compare the risk of LBW, preterm birth, SGA, and cesarean delivery between these two groups, after adjusting for the potential confounders. A two-sided P-value of <0.05 was considered statistically significant for this study.

Table 1 Comparisons of mothers with myasthenia gravis and unaffected mothers in relation to maternal and infant characteristics in Taiwan, 2001–2003 (n = 978)

Variable	Mothers with myasthenia gravis (n = 163)		Mothers in comparison group (n = 815)		P value
	Total No.	%	Total No.	%	
Maternal characteristics					
Age (years)					
<20	6	3.7	30	3.7	1.000
20–24	16	9.8	80	9.8	
25–29	65	39.9	325	39.9	
30–34	49	30.1	245	30.1	
>34	27	16.6	135	16.6	
Education level					
Elementary school or lower	3	1.8	13	1.6	0.829
Junior high school	26	16.0	133	16.3	
Senior high school	104	63.8	542	66.5	
College or above	30	18.4	127	15.6	
Marital status					
Married	155	95.1	797	97.8	0.051
Others	8	4.9	18	2.2	
Family monthly income					
NT$15 000	46	28.2	243	29.8	0.856
NT$15 000–30 000	43	26.4	203	24.9	
NT$30 001–50 000	44	27.0	236	29.0	
>NT$50 000	30	18.4	133	16.3	
Gestational diabetes					
Yes	9	5.5	45	5.5	1.000
No	154	94.5	770	94.5	
Hypertension					
Yes	6	3.7	30	3.7	1.000
No	157	96.3	785	96.3	
Anemia					
Yes	18	11.0	90	11.0	1.000
No	145	89.0	725	89.0	
Coronary heart disease					
Yes	4	2.5	20	2.5	1.000
No	159	97.5	795	97.5	
Hyperlipidemia					
Yes	3	1.8	15	1.8	
No	160	98.2	800	98.2	
Infant characteristics					
Gender					
Male	89	54.6	446	54.7	0.977
Female	74	45.4	369	45.3	
Parity					
1	80	49.1	385	47.2	0.856
2	62	38.0	313	38.4	
3 or more	21	12.9	117	14.4	

Results

Table 1 presents the distribution of characteristics of mothers and infants among mothers with MG and unaffected mothers. After matching for maternal age, the year of delivery and whether the woman had diabetes, hypertension, anemia, CHD and hyperlipidemia, no significant differences in maternal educational level, marital status, infant gender and parity or family monthly income were observed.

Table 2 illustrates the distributions of LBW, preterm birth, SGA, and cesarean deliveries among women with MG and unaffected women. Although they did not reach a statistically significant level, Table 2 consistently shows that women with MG had higher percentages of LBW (6.8% vs. 5.6%) and SGA infants (17.8% vs. 14.1%) and cesarean deliveries (44.8% vs. 37.4%), but not preterm births (8.1% vs. 8.1%). Further of those having cesarean deliveries, six (out of 73 = 8.2%) and 21 (out of 305 = 6.9%) patients with and without MG, respectively, had elective surgeries (P = 0.69; data not shown in table). Conditional logistic regressions showed that the crude ORs of LBW, preterm birth, SGA infants, and cesarean deliveries for women with MG were 1.21 (95% CI = 0.61–2.39), 0.98 (95% CI = 0.53–1.83), 1.32 (95% CI = 0.84–2.61) and 1.36 (95% CI = 0.97–1.91), respectively, compared to unaffected women.

Table 3 shows the adjusted ORs of LBW, preterm birth, SGA infants, and cesarean delivery between these two groups by conditional logistic regression. After adjusting for maternal education level, marital status and family monthly income, infant gender and parity, the ORs of LBW, preterm births, SGA infants, and cesarean delivery for women with MG were 1.19 (95% CI = 0.60–2.38), 1.00 (95% CI = 0.54–1.87), 1.30 (95% CI = 0.83–2.04), and 1.33 (95% CI = 0.94–1.88), respectively, as compared to unaffected women.

Discussion

As far as we know, this is the first report of pregnancy outcomes among women with MG in Asia. Our nationwide population-based study clearly demonstrated that after adjusting for potential confounders, women with MG were not at increased risk of having preterm, LBW and SGA infants. Similarly, women with MG did not have a higher risk of cesarean delivery compared to unaffected women.

Myasthenia gravis commonly affects women who are in their child-bearing years [1,3]. Therefore, it is important to evaluate the effects of pre-existing MG on delivery and outcomes for newborns. As MG is a rare disease, the bulk of scholarship in this area has been largely observational in nature, and, particularly in older studies, derives from relatively small study cohorts [3,5–9,11] producing contradictory results in the literature. Only recently has interest fueled the organization of multicenter prospective cohorts of pregnant MG patients and analysis of nationwide administrative claims datasets with adequate numbers of patients for

Table 2 The distribution of LBW, preterm birth, infants small for gestational age and cesarean deliveries among mothers with myasthenia gravis and unaffected mothers, 2001–2003 (n = 978)

Variable	Mothers with myasthenia gravis (n = 163)		Mothers in comparison group (n = 815)		P value
	No.	%	No.	%	
Low birthweight					
Yes	11	6.8	46	5.6	0.583
No	152	93.2	769	94.4	
Crude OR, 95% CI	1.21 (0.61–2.39)		1.00		
Preterm birth					
Yes	13	8.1	66	8.1	0.958
No	150	91.9	749	91.9	
Crude OR, 95% CI	0.98 (0.53–1.83)		1.00		
Small for gestational age					
Yes	29	17.8	115	14.1	0.226
No	134	82.2	700	85.9	
Crude OR, 95% CI	1.32 (0.84–2.61)		1.00		
Cesarean delivery					
Yes	73	44.8	305	37.4	0.078
No	90	55.2	510	62.6	
Crude OR, 95% CI	1.36 (0.97–1.91)		1.00		

Crude ORs were calculated by conditional logistic regressions which were conditioned on maternal age, the year of delivery and whether a woman's condition was complicated by diabetes, hypertension, anemia, coronary heart disease and hyperlipidemia.

Table 3 Adjusted Odds ratios of LBW, preterm birth, infants small for gestational age and cesarean deliveries for women with myasthenia gravis and unaffected mothers, 2001–2003 (n = 978)

Variable	Low birthweight	Preterm birth	SGA	CS
	Adjusted OR 95% CI	Adjusted OR 95% CI	Adjusted OR 95% CI	Adjusted OR 95% CI
Cohort				
Myasthenia gravis	1.19 (0.60–2.38)	1.00 (0.54–1.87)	1.30 (0.83–2.04)	1.33 (0.94–1.87)
Comparison cohort	1.00	1.00	1.00	1.00
Maternal characteristics				
Education level				
Elementary school or lower	2.62 (0.56–12.30)	0.75 (0.10–5.85)	2.08 (0.65–6.67)	1.10 (0.39–3.10)
Junior high school	1.31 (0.66–2.61)	1.18 (0.65–2.14)	1.41 (0.89–2.24)	1.05 (0.73–1.51)
Senior high school	1.00	1.00	1.00	1.00
College or above	0.77 (0.33–1.80)	0.73 (0.35–1.53)	1.08 (0.64–1.80)	1.02 (0.70–1.47)
Marital status				
Married	0.58 (0.16–2.05)	0.69 (0.20–2.43)	0.63 (0.25–1.63)	0.81 (0.36–1.82)
Other	1.00	1.00	1.00	1.00
Monthly income				
< NT$15 000	1.00	1.00	1.00	1.00
NT$15 000–30 000	1.20 (0.56–2.56)	1.22 (0.62–2.40)	1.14 (0.70–1.84)	1.42 (0.99–2.04)
NT$30 001–50 000	1.42 (0.69–2.92)	1.65 (0.88–3.10)	1.03 (0.64–1.66)	1.32 (0.93–1.88)
> NT$50 000	1.49 (0.64–3.46)	1.34 (0.63–2.85)	0.99 (0.56–1.75)	2.12 (1.42–3.16)
Infant characteristics				
Gender				
Male	0.64 (0.37–1.10)	1.12 (0.70–1.79)	0.76 (0.53–1.08)	0.99 (0.76–1.29)
Female	1.00	1.00	1.00	1.00
Parity				
1	1.00	1.00	1.00	1.00
2	0.43* (0.22–0.83)	0.97 (0.57–1.64)	0.82 (0.55–1.22)	0.99 (0.75–1.33)
3 or more	0.78 (0.36–1.70)	1.58 (0.84–3.00)	1.11 (0.66–1.87)	0.72 (0.48–1.09)

*$P < 0.05$. Adjusted ORs were calculated 'y conditional logistic regressions which were conditioned on maternal age, the year of delivery and whether a mother's condition was complicated by diabetes, hypertension, anemia, coronary heart disease and hyperlipidemia.

reaching reliable conclusions [10]. In addition, some studies suffer from inadequate control of confounders, which could undermine the strength of their findings. For example, recent studies indicate that the most common complications during pregnancy are anemia and hypertensive disorders; anemia in particular was demonstrated to be associated with adverse pregnancy outcomes [12]. As a consequence, the extent of pregnancies affected by MG is not well established and assessments of the MG of pregnancy complications remain inconsistent.

To fill this gap in the literature, this report, based on a large-scale population-based dataset from Taiwan, provides enough statistical power to fully evaluate the association between MG in pregnant women and adverse pregnancy outcomes. Furthermore, our study has taken comorbidities and other potential confounders into consideration. On balance, the our results were largely consistent with prior studies conducted in different regions and documented no association between MG and LBW [8–10], preterm birth [8,10] and CS [8]. As previous studies investigating pregnancy outcomes for women with MG have been conducted in western countries, our findings not only add evidence that MG has no significant adverse effect on pregnancy outcomes, but also extend the literature to include the experiences of an Asian population.

The reported prevalence of MG has increased in every decade since the 1950s [13,14]. Our study likewise found that MG prevalence among pregnant women in Taiwan was much higher (3.4/10 000) than that documented by previous studies (1/20 000) [2]. The increase in the number of mothers with MG can be attributed to several factors, including improved recognition of the disease, the availability of diagnostic tests with higher sensitivity and specificity, and longer life spans in affected patients due to more effective treatment. For example, under Taiwan's NHI program, all pregnant women are allowed to have ten free scheduled prenatal care visits, which may increase the rate at which MG is diagnosed among them. By screening for and aggressively treating pregnant women with MG in Taiwan, it is possible to significantly decrease the incidence of adverse pregnancy outcomes.

Other issues also require further consideration. It has been proposed that due to the muscular fatigue, MG mothers have difficulty with vaginal delivery, especially during the second stage of labor. The use of forceps delivery and vacuum extraction was essential in these urgent situations [15]. However, we observed that a total of nine (out of 90 = 10.0%) and 52 (out of 510 = 10.2%) patients with and without MG, respectively, underwent forceps/vacuum vaginal delivery. This insignificant difference between groups ($P = 0.955$) does not indicate problems during vaginal delivery among patients with MG. Consistent with previous findings, caesarean delivery is recommended only in cases where there is obstetric need [15].

A wide variation in cesarean section rates among countries worldwide has been reported, ranging from 0.4 to 40 percent. The median cesarean section rates were 4.0%, 16.1% and 17% among the low-, medium-, and high-income countries respectively [16]. An upward trend over the past decades has been further identified. In the United States, cesarean delivery increased from 20.7% in 1996 to 31.1% in 2006 [17]. In Taiwan, a high cesarean section rate of 32.3% of all deliveries was reported [18]. With an older population, we observed a cesarean rate of 37.4% among women without MG, compared to 44.8% among those with MG ($P = 0.08$). The difference in the proportion of elective cesarean sections among patients with MG was not significant, compared to unaffected women. Despite these insignificant differences, it is worth noting that a relatively high cesarean rate in the general population can mask the possibility of an even higher rate of cesarean delivery among specific risk groups, compared to unaffected women.

Maternal MG might also contribute to neonatal complications. A 21% incidence of transient neonatal MG in infants born to mothers with MG was reported [19]. Sucking, swallowing, and respiratory difficulties are the most commonly observed signs. Although transient, and in most cases very mild, about eighty percent of patients may require supportive management and anticholinesterase agents prior to feedings. Thymectomy, usually recommended and performed on all early-onset MG patients, seemed to provide a protective effect against neonatal MG [9,20]. Although thymectomy may indicate the severity of the maternal MG, it was not associated with pregnancy outcomes in our study. Specifically, among MG patients, 6.7% had received thymectomy. No significant difference was identified in terms of the proportion of LBW (9.1% vs. 6.6%, $P = 0.75$), preterm births (9.1% vs. 7.9%, $P = 0.89$), SGA infants (18.2% vs. 17.8%, $P = 0.97$), and cesarean deliveries (63.6% vs. 43.4%, $P = 0.19$) among women who had thymectomies compared to those who did not. In addition, maternal MG might also cause a rare fetal condition, arthrogryposis multiplex congenita [21]. While some diseases are fatal early in life, early identification and appropriate treatment can be essential in prolonging survival into adulthood. Prior studies have proposed that it is not the clinical symptoms of the MG mother, but rather, her type of antibodies, which is a critical determinant of whether her newborn will develop neonatal MG, and in a few cases, arthrogryposis multiplex congenita [22]. More studies are needed that further investigate the connection between maternal MG and associated neonatal

complications in order to give more reliable genetic advice to parents, and to organize more effective and realistic management.

Despite the strengths of our study, findings must still be interpreted with caution due to the following limitations. First, the NHIRD database only represented patients who had sought treatment for MG. Certain factors, such as socioeconomic status, could affect healthcare utilization. For example, despite the existence of universal healthcare, individuals with lower incomes and education received a lower rate of physician services [23]. In addition, MG mothers were identified through having visited ambulatory care centers for treatment of MG within the 2 years prior to their index deliveries. As only symptomatic MG women were recruited as cases, our results would likely be biased towards the null. Second, the NHIRD lacks detailed clinical information and therefore did not allow us to differentiate study participants according to the severity of their MG. Third, NHIRD uses discharge diagnoses provided by treating physicians, and standardized criteria to define cases were not imposed, which could leave some room for bias due to case misclassification. Finally, because the NHIRD does not include complete information regarding medications taken during pregnancy, it is not possible for us to assess the confounding role of medications in the relationship between MG and pregnancy outcomes. Meanwhile, information on neonatal complications, including neonatal MG and arthrogryposis multiplex congenital, were also unavailable in our dataset.

This study using a large, unselected national dataset has demonstrated that women with MG are not at increased risk for having preterm, LBW and SGA babies, and for delivery by CS, compared to unaffected mothers. We suggest that although women with MG need not panic about adverse pregnancy outcomes, the management of MG should not be altered during pregnancy. Women with MG who choose to become pregnant should discuss their plan for pregnancy with their neurologist and their gynecologist and should get good prenatal care with doctors who are experienced in treating MG. Further large-scale studies in other regions or countries should also be carried out to confirm the findings of the present one.

Disclosure

No financial conflict of interest to declare.

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