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Mode of delivery and birth complications in fetal macrosomia: a simple cost-effectiveness analysis

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Aim: To evaluate the effect of delivery route on birth complications and related costs in fetal macrosomia (>4000 g).

Materials and methods: Patient and newborn hospital records of 365 macrosomic deliveries (≥ 4000 g) were retrospectively analyzed. Of these deliveries, 189 newborns weighed between 4000 and 4249 g (Group I), and 176 were between 4250 and 4500 g (Group II). The effects of mode of delivery on birth complications were evaluated and a simple cost-effectiveness analysis was performed.

Results: There was no statistical difference between the 2 groups concerning birth complications, except dystocia and episiotomy hematoma. The rate of dystocia was found to be significantly higher in Group II than in Group I (14.1% versus 3.8%, respectively; $P = 0.040$). Similarly, episiotomy hematoma was found to be significantly higher in Group II than in Group I (18.8% versus 3.8%, respectively; $P = 0.004$). As opposed to similar rates of serious and permanent complications, mild or moderate temporary maternal and fetal complications were seen to be higher in vaginal births of infants weighing more than 4250 g ($P = 0.001$ and $P = 0.024$, respectively). In macrosomia, the total cost of a cesarean section (C/S) was almost 2 times higher than the cost of a vaginal delivery per patient (937 Turkish liras versus 491 Turkish liras, respectively).

Conclusion: C/S was not related with favorable maternal or newborn outcomes, and it was not a cost-effective option in patients with fetal birth weights between 4250 and 4500 g.

Key words: Fetal macrosomia, brachial plexus injury, mode of delivery, cost effectiveness

Fetal makrozomide doğum şekli ve komplikasyonlar: Basit maliyet-etkinlik analizi

Amaç: Fetal makrozomide (>4000 g) doğum şeklinin komplikasyonlar ve bağıntılı maliyet üzerine etkisi araştırıldı.

Yöntem ve gereç: 365 makrozomik doğum (≥ 4000 g) bilgileri retrospektif olarak değerlendirilmiştir. Bu hastaların 189'unun 4000-4249 g arasında (Grup I) ve 176'sının ise 4250-4500 g arasında (Grup II) doğum yaptığı anlaşılmıştır. Doğum şeklinin doğum komplikasyonları üzerine olan etkileri değerlendirilmiş ve basit bir maliyet analizi yapılmıştır.

Bulgular: Komplikasyon oranları açısından, distosi ve epizyotomi hematomu haricinde her iki grup arasında istatistiksel anlamlı bir fark izlenmemiştir. Distosi oranı Grup II'de Grup I'e nazaran belirgin olarak daha yüksek saptanmıştır (% 14,1 ve % 3,8, $P = 0,040$). Benzer olarak, epizyotomi hematomu oranları da Grup II'de Grup I'e göre belirgin şekilde daha yüksek bulunmuştur (% 18,8 ve % 3,8, $P = 0,004$). Benzer kalıcı ve ciddi komplikasyon oranlarının aksine, 4250 gr üzerinde gerçekleşen doğumlarda hafif veya orta düzeydeki geçici maternal ve fetal komplikasyon oranları vajinal yolla doğumda yapan kadınlarda daha yüksek tespit edilmiştir ($P = 0,001$ ve $P = 0,024$). Hasta başına toplam maliyet, sezaryen operasyonunda vajinal doğumun neredeyse 2 katından daha yüksek olarak hesaplanmıştır (937 TL/hasta ve 491 TL/hasta).

Sonuç: Fötal doğum ağırlığı 4250-4500 g arasında bulunan hastalarda sezaryen maliyet-etkin bir doğum şekli olmayıp, daha olumlu maternal veya yenidoğan sonuçları ile ilişkili değildir.

Anahtar sözcükler: Fötal makrozomi, brakial pleksus hasarı, doğum şekli, maliyet etkinlik

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Introduction

Fetal macrosomia, frequently defined as a fetal birth weight >4000 g, has been reported in a wide range, from 1%-28% (1,2). Advanced age, diabetes mellitus, hypertension, and a previous history of a macrosomic infant or a pregnancy loss are common maternal risk factors (3). As the definite threshold is controversial, the American College of Obstetricians and Gynecologists (ACOG) recommended both 4000 and 4500 g in their 2 different previous guidelines as the threshold of fetal macrosomia, independent from the gestational week at birth (4).

Prolonged labor, increased rates of operative delivery, shoulder dystocia, and brachial plexus injuries, with increased perinatal asphyxia and fetal mortality, have been crucially associated with macrosomia-complicated pregnancies (5,6). The most common maternal complications have been reported to be operative delivery, prolonged labor, and third degree or fourth degree perineal lacerations due to cephalopelvic disproportion or a large infant (3,6). However, especially with brachial plexus injuries, those injuries that are permanent and are frequently observed due to operative delivery can often lead to litigation. Subsequent to fetal pulmonary maturation, delivery by either cesarean section (C/S) or the vaginal route have been recommended to avoid such complications in patients with an estimated fetal birth weight (EFBW) above the macrosomia thresholds (7,8). An accurate threshold of fetal weight is vitally important in the selection of the delivery route. More recent studies support the strict reevaluation of the macrosomia threshold at >4500 g to avoid unnecessary clinical applications and costs (9,10).

On the other hand, diagnosis of fetal macrosomia by either clinical examination or ultrasonography is challenging and can be inaccurate, leading to at least a 20% difference in fetal birth weights due to low sensitivity and specificity (9,10). According to previous studies, clinical management in fetal macrosomia varies highly, particularly at term and in cases in which the EFBW is >4250 and <4500 g, such as expectant management, induction of labor, or elective C/S, which all impose risks to the clinician as well as to the mother and newborn (9-12). In selected patients, one of these options might easily be chosen;

however, there is still not a paramount choice in most patients (13). For instance, elective C/S is robustly recommended for diabetic women with an EFBW of ≥ 4250 g due to previously described increased shoulder dystocia rates in such patients (11,12). On the other hand, such confusing recommendations might lead to a rapid increase in the rate of C/S, particularly in countries where litigations are highly debated and current guidelines are lacking. Turkey is such an example, wherein estimated fetal macrosomia seems to be one of the most popular indications for elective C/S.

The aim of the current study was to reevaluate the threshold of fetal macrosomia (>4000 g versus >4250 g) regarding maternal and fetal complications due to delivery routes and to compare the cost-effectiveness of delivery routes in the Turkish population.

Materials and methods

This is a retrospective case-control study of singleton pregnancies resulting in a birth weight of ≥ 4000 g. The hospital records of 365 macrosomia-complicated pregnancies between January 2006 and June 2010 in our hospital were examined. Data for vaginal and C/S deliveries in the study population were all included. Patients with any systemic disease or with other pregnancy-associated complications (hypertension, complicated gestational diabetes (classes A2-F), previous uterine surgery history, preterm delivery, premature rupture of membranes, and malpresentation) were then excluded. Maternal age, parity, previous history of a macrosomic infant, results of glucose screening tests (50 g), and gestational age at delivery were all evaluated in order to examine the effect of maternal risk factors.

All enrolled macrosomic deliveries were then divided into 2 groups according to fetal birth weight; Group I consisted of deliveries with fetal birth weights of between 4000 and 4249 g, whereas Group II consisted of deliveries with fetal birth weights of between 4250 and 4500 g. In each group, the patients were then divided into subgroups according to delivery routes, where complicated vaginal and C/S delivery rates were separately compared. The complications evaluated in the vaginal route were brachial plexus injury, cephalic and episiotomy

hematoma, clavicle fracture, perineal laceration, dystocia, and necessity of operative vaginal delivery (forceps usage). In both the vaginal and C/S routes, complications such as anemia due to blood loss, wound infection, urinary tract infection, and high fever were also compared between the groups.

A simple cost-effectiveness analysis was then performed regarding the expenses of social health security insurance based on a health application notification announced in 2009. The total healthcare costs of performed treatment strategies and managements related to mode of delivery in both groups, including the costs of associated complications to the delivery route, were evaluated. All expenses that arose from the selected delivery route and related complications were analyzed per patient in the currency of Turkish liras (TL).

Quantitative data were expressed as standard deviation \pm mean and categorical data were expressed as percentages. The chi-square test was used to compare the categorical data and Student's t-test was used to compare the continuous data between the groups. Data were analyzed using SPSS 13 (SPSS Inc., Chicago, IL, USA) and $P < 0.05$ was considered significant.

Results

Of the 365 enrolled pregnancies in the study, 189 resulted in birth weights of between 4000 and 4249 g (Group I), while 176 resulted in birth weights of between 4250 and 4500 g (Group II). There were

no significant differences between the groups in terms of demographic characteristics including age, parity, glucose screening test results, and gestational weeks at delivery (Table 1). On the contrary, history of a previous macrosomic infant (≥ 4000 g) was significantly higher in Group II than in Group I, respectively (21.6% versus 12.2%, $P = 0.016$, Table 1). In both of the main groups, the rates of delivery routes were similar, with C/S rates of 58.7% and 63.6% in Groups I and II, respectively ($P = 0.337$).

Table 2 summarizes the rates of complications regarding delivery route, either vaginally or via C/S, separately between the main groups. Total complication rates in terms of both fetal and maternal vaginal delivery-related complications were not different between Groups I and II (25.6% versus 40.6 %, respectively; $P = 0.058$). In detail, there was not any statistically significant difference between the main groups regarding brachial plexus injury, cephalic hematoma, fracture of clavicle, perineal laceration, and need for operative vaginal delivery (Table 2). However, the rate of dystocia and episiotomy hematoma were found to be significantly higher in Group II than in Group I (14.1% versus 3.8%, $P = 0.004$; and 18.8% versus 3.8%, $P = 0.040$, respectively; Table 2). Moreover, 21 (18.9%) out of 111 patients in Group I and 19 (17%) out of 112 patients in Group II who underwent C/S encountered maternal complications ($P = 0.705$). There were no statistically significant differences between the main groups regarding anemia due to blood loss, wound infection, urinary tract infection, or high fever (Table 2).

Table 1. Demographic characteristics of study populations.

	4000-4249 g (n = 189) (mean \pm SD)	4250-4500 g (n = 176) (mean \pm SD)	P
Age, years	29.1 \pm 5.2	30.2 \pm 5.7	0.064
Parity	0.84 \pm 1.26	1.34 \pm 3.49	0.277
Glucose screening test results	114.23 \pm 29.10	120.22 \pm 34.15	0.064
Gestational week at delivery	39.26 \pm 1.23	39.17 \pm 1.16	0.355
Previous macrosomic infant	23 (12.2%)	38 (21.6%)	0.016
Vaginal birth	78 (41.3%)	64 (36.4%)	0.337
C/S	111 (58.7%)	112 (63.6%)	

Table 2. Comparison of fetal and maternal complications between the study groups.

	Group I 4000-4249 g n (%)	Group II 4250-4500 g n (%)	P
Complicated vaginal births	20 (25.6)	26 (40.6)	0.058
Brachial plexus injury	3 (3.8)	7 (10.9)	0.102
Cephalic hematoma	2 (2.6)	2 (3.1)	0.844
Clavicle fracture	0 (0)	1 (1.6)	0.321
Episiotomy hematoma	3 (3.8)	12 (18.8)	0.004
Perineal laceration	10 (12.8)	12 (18.8)	0.342
Dystocia	3 (3.8)	9 (14.1)	0.040
Operative vaginal delivery	3 (3.8)	6 (9.4)	0.181
Complicated C/S births	21 (18.9)	19 (17)	0.705
Anemia due to blood loss	16 (14.4)	10 (8.9)	0.204
Wound infection	6 (5.4)	5 (4.5)	0.747
Urinary tract infection	3 (2.7)	2 (1.8)	0.646
High fever	6 (5.4)	9 (8)	0.435

The total cost of a birth or the separate costs of a birth and of the associated complications in deliveries via vaginal route per patient were all similar among the main groups (Table 3). The mean cost of an associated complication in vaginal delivery was 49 ± 112 TL and 68 ± 109 TL per patient in Groups I and II, respectively ($P = 0.071$). Likewise, the total cost of a C/S delivery or the separate costs of a delivery and of an associated complication in deliveries via C/S per patient were also similar between the main groups (Table 3). The mean cost of an associated complication in deliveries via the C/S route was 41 ± 99 TL and 30 ± 95 TL per patient in Groups I and II, respectively ($P = 0.278$).

When expenses and complications were separately analyzed according to delivery route in each group, there was no difference between vaginal delivery and C/S in either the rate of maternal and fetal complications or the cost of a complication in Group I (Table 4). However, both rates of maternal and fetal complications were found to be significantly higher in patients who delivered vaginally in Group II. The cost of a complication was also significantly higher in patients who delivered vaginally rather than in patients who delivered via C/S (68 ± 109 TL versus 30 ± 95 TL, $P = 0.017$). The total cost of a delivery by C/S was almost 2 times that of the cost of a delivery via vaginal route in both of the main groups, regardless of fetal birth weight ($P = 0.001$, Table 4).

Discussion

The present study clearly underlines a higher possibility of vaginal birth complications in patients with fetal birth weights above 4250 g when compared to patients with fetal birth weights below 4250 g, but reports statistically higher rates solely in episiotomy hematoma and dystocia. However, the rates of maternal or fetal complications all increased significantly in patients with an EFBW above 4250 g who delivered via the vaginal route in comparison to patients who delivered by C/S. Furthermore, although vaginal birth significantly increased the costs of complications when compared with delivery by C/S in patients with fetal birth weights above 4250 g, the total cost of a C/S was almost 2 times higher than that of vaginal birth in such patients. Thus, it can be assumed that the present study has limited power due to a small study population, and it seems safer to perform a C/S in patients with estimated fetal birth weights above 4250 g; however, the higher cost of such a delivery should be noted.

On the other hand, similar rates of maternal and fetal complications were observed in patients with estimated birth weights of between 4000 and 4249 g, regardless of the delivery route. The cost of an associated complication did not differ in terms of delivery route in patients with birth weight under a threshold value of 4250 g. Total cost of a delivery by

Table 3. Comparison of costs for vaginal and C/S deliveries and their complication between the study groups.

	Group I Cost (TL/patient) (mean ± SD)	Group II Cost (TL/patient) (mean ± SD)	P
Vaginal birth	427 ± 35	425 ± 31	0.830
Vaginal birth complications	49 ± 112	68 ± 109	0.071
Total for vaginal birth	476 ± 121	491 ± 117	0.313
C/S	910 ± 37	906 ± 34	0.357
C/S complications	41 ± 99	30 ± 95	0.278
Total for C/S	951 ± 113	937 ± 104	0.115

1 TL = US\$1.60

Table 4. Complication rates and cost analysis comparing vaginal birth and C/S in the groups, separately.

	Vaginal birth	C/S	P
Group I (n = 189)			
Maternal complications (%)	19 (24.4)	21 (18.9)	0.367
Fetal complications (%)	4 (5.1)	5 (4.5)	0.843
Cost for complications (TL/patient) ^a	49 ± 112	41 ± 99	0.517
Total cost (TL/patient) ^a	476 ± 121	951 ± 113	0.001
Group II (n = 176)			
Maternal complications (%)	26 (40.6)	18 (16.1)	0.001
Fetal complications (%)	8 (12.5)	4 (3.6)	0.024
Cost for complications (TL/patient) ^a	68 ± 109	30 ± 95	0.017
Total cost (TL/patient) ^a	491 ± 117	937 ± 104	0.001

^aData presented as mean ± SD

C/S was almost 2 times higher than by vaginal birth in patients with fetal weight below 4250 g. As expected, the rates of maternal and fetal complications were also lower than in patients with fetal weights above 4250 g. Therefore, performing a C/S in such patients with estimated fetal weights of between 4000 and 4250 g is a critical medical decision on the basis of the current literature, especially in Turkey. However, a reevaluation of a strict fetal macrosomia threshold is urgently needed based on the social security and insurance system of each location.

Even though more recent studies have indicated 4500 g as the fetal macrosomia threshold value, it has also been previously advocated that infants of >4000 g have an increased chance of encountering abundant obstetric complications, such as adverse maternal and neonatal outcomes (14). However, it is not fair to claim that maternal and fetal outcomes are statistically significant between deliveries with an EFBW of <4000 g and EFBWs of 4000-4250 g, especially with regard to permanent complications. The ACOG notes that delivery via C/S may be considered if

the EFBW is >5000 g in the absence of maternal diabetes (15). The Royal College of Obstetricians and Gynaecologists (RCOG) specifically disagrees with this recommendation by the ACOG as not widely supported by the literature data; the RCOG suggests that larger infants are more likely to have permanent brachial plexus injury than transient. The current study also showed that permanent complications were found to be similar in nondiabetic patients with an EFBW of between 4000 and 4250 g and between 4250 and 4500 g, except dystocia and episiotomy hematomas. Thus, an EFBW of >4500 g should be the optimal threshold for elective C/S delivery according to the RCOG in patients without diabetes (16). Nevertheless, both guidelines agree that among diabetic women, 4500 g is a sufficient threshold for C/S delivery in fetal macrosomia.

The birth weight increase predisposes to augmented rates of dystocia and neonatal injury, mainly including clavicle fractures and brachial plexus injuries, where the risk is maximized for infants weighing >4500 g (10). However, it is still obscure and controversial as to at which macrosomia threshold value the neonatal complications will increase. Fetal mortality rates increase for infants weighing >5000 g in vaginal deliveries. Boulet et al. used a proportional hazards model to analyze the risk of neonatal mortality associated with C/S among 3 macrosomic infant categories and noted that C/S may reduce the risk of neonatal deaths by 15% for infants weighing >5000 g (14). Even though a consensus on the clinical threshold value for C/S in macrosomia is still lacking and controversial between the 2 values, 4000 g and 4500 g, the majority of studies recommend an EFBW of >5000 g as the threshold for elective C/S (17,18), whereas >4500 g is usually referred to as the critical threshold in clinical practice (9,10,19). According to the studies of Langer et al. and Saleh et al., dystocia risk in diabetic patients increases with birth weights of >4250 g (12,13). On the other hand, the incidence of brachial plexus injury and Erb's palsy is widely estimated to be 4%-8% in fetal macrosomia (20). According to the results of the current study, fetal and maternal complications tended to increase in vaginal births; however, the most serious encountered complication in the above infant weight ranges was brachial plexus injury (10.9%). Only the rates of dystocia and episiotomy hematoma were increased

significantly. Therefore, as the general threshold for macrosomia is >4500 g, a fetus with an EFBW of between 4250 and 4500 g could be delivered, in most cases, via the vaginal route with only an increased risk of temporary brachial plexus injury (not statistically significant). In this situation, only the risks of dystocia and episiotomy hematoma would increase.

The increasing rates of C/S in Turkey, especially in patients with increased EFBWs, clearly indicate the vital importance of careful management in such cases with an infant weighing >4250 but <4500 g, especially due to fear from plausible litigations of the clinician, wherein other indications such as prolonged labor, as well as macrosomia, may be the widely mismanaged C/S indications.

While performing a cost analysis between delivery routes, we saw that with birth weights of <4250 g, the costs for complications were similar between vaginal births and C/S. It is therefore logical to suggest a vaginal birth for weights under 4250 g. However, according to the results of the current study, costs for complications were significantly higher in vaginal births than in C/S births for EFBWs between 4250 and 4500 g, as well as the general complication rates. However, the rate of serious complications is very low and the costs for complications are almost half that of the costs for performing routine C/S deliveries for all pregnancies at this EFBW range. Therefore, vaginal birth may be the proper first choice for EFBWs of 4250-4500 g in the absence of contraindications.

According to the 2008 national data of the Turkish Statistical Institute (Türkiye İstatistik Kurumu, TÜİK), 1,262,333 deliveries annually take place in Turkey (21). It has also been indicated that 6.21% of delivered newborns had a weight above 4000 g (22). Therefore, it can be speculated that 78,391 macrosomic deliveries would be expected annually in Turkey. Particularly, in 1 year, 22,397 newborns might have a birth weight above 4250 g in Turkey. Even with these speculations, performing a C/S instead of a vaginal delivery for infants weighing >4250 g would bring an extra cost of 10 million TL/year for the country ((937 - 491) × 22,397 TL).

In conclusion, the rates of fetal and maternal complications, such as brachial plexus injury, dystocia, or episiotomy hematomas, may increase with vaginal delivery in infants weighing >4250 g.

However, the majority of these complicated cases are likely to be not serious or permanent at weights <4500 g. Therefore, it is not rational or cost-effective to perform a C/S for an infant with an EFBW of 4250-4500 g. Nevertheless, the plausibility of a serious fetal complication such as permanent brachial plexus injury may cause critical litigation problems for the clinicians who referred to such a threshold value in macrosomic deliveries. Professional compulsory insurance, which will be legally official in the near future, will bring many lawsuits against obstetricians

aiming to reduce C/S rates. Therefore, a strict guideline regarding a pivotal threshold value and an associated notification of fetal macrosomia should be officially declared by the national health ministry in order to prevent augmented obstetrical costs and to defend self-respecting obstetricians. On the other hand, patients and/or spouses who do not accept the plausible increased risk of mild and temporary neonatal complications should have the right to decide the mode of delivery in such critical cases by self-compensating the health-related costs.

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