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The effect of hospital acuity on severe maternal morbidity in high-risk patients

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Condensation, Short Title, Implications

Condensation: High-risk patients have a higher risk of severe maternal morbidity at low acuity hospitals compared to high acuity hospitals.

Short title: Hospital acuity and maternal morbidity

Implications and Contributions:

This study was conducted to understand the relationship between a hospital's level of obstetric acuity and a patient's risk for severe maternal morbidity. For this analysis, hospital acuity was defined using the percentage of delivering patients with high-risk maternal conditions. The results indicate that high-risk obstetric patients have a lower risk of severe maternal morbidity at high acuity centers compared to low acuity centers. These findings support the implementation of the levels of maternal care and the concept of regionalization for high-risk maternal conditions.

Abstract (word count: 501).

Background: In 2015, the Society for Maternal-Fetal Medicine and the American College of Obstetricians and Gynecologists published guidelines that established levels of maternal care. These guidelines outline the nursing, provider, and facility requirements for hospitals to be designated a birthing center or one of four levels of care. To-date, these levels of maternal care have not been widely adopted, and currently, no data exists on how these designations may affect maternal or neonatal outcomes.

Objective: As the levels of maternal care attempt to reflect a hospital's ability to manage patients with certain conditions associated with increased risk of complications, our objective was to compare outcomes among high- and low-risk patients between high and low acuity hospitals. We hypothesized that hospitals caring for a high rate of high-risk patients, which we considered "high acuity" centers, would have a lower risk of severe maternal morbidity among high-risk patients compared to low acuity centers.

Study Design: Deliveries were identified in the 2013 Nationwide Readmission Database. A patient's comorbidity index was assigned based on diagnosis and procedures codes using previously validated methods; a comorbidity index ≥3 has been associated with increased odds of severe maternal morbidity. Patients were classified as either low, intermediate, or high risk by their comorbidity index for analysis. Patients at hospitals with <100 deliveries per year and transferred patients were excluded. A hospital was defined as low or high acuity if it was in the bottom or top quartile, respectively, based on its percent of patients with comorbidity index ≥3. Log-binomial regression models were constructed to assess the effects of a patient's comorbidity index group on the risk of severe morbidity in high and low acuity hospitals. The models controlled for available patient and hospital factors. The regression used patient-level data with robust standard errors clustered at the level of the hospital. The Wald test was used to assess for the effect modification between comorbidity index group and hospital acuity.

Results: 1,656,659 delivering patients from 1,203 hospitals met the inclusion criteria. There were 58.7% low-risk, 39.0% intermediate-risk, and 2.3% high-risk patients in the overall sample, and the overall rate of severe maternal morbidity was 1.2%. Less than 3.7% of delivering patients in low acuity hospitals had a high-risk condition. In comparison, more than 7.1% patients in high acuity centers had a high-risk condition. In the adjusted analysis, intermediate-risk patients had slightly increased risk of morbidity in both low acuity and high acuity centers compared to low-risk patients (adjusted risk ratios 1.53 (95%

confidence interval 1.33-1.77) versus 1.57 (95% confidence interval 1.49-1.65)). However, there was a notable difference in the adjusted risk ratios for severe maternal morbidity in the high-risk population: the adjusted risk ratio was 9.55 (95% confidence interval 6.83-13.35) in low acuity hospitals compared to 6.50 (95% confidence interval 5.94-7.09) in high acuity hospitals.

Conclusions: High-risk patients have a higher risk of severe maternal morbidity at low acuity hospitals compared to high acuity centers. These findings support the concept of regionalization of maternity care to improve outcomes for high-risk patients.

Keywords: levels of maternal care, maternal morbidity, comorbidity index, acuity, high-risk, delivery, acute heart failure, acute renal failure, acute liver disease, acute myocardial infarction, acute respiratory distress syndrome, disseminated intravascular coagulation, coma, delirium, stroke, pulmonary edema, pulmonary embolism, sepsis, shock, status asthmaticus, status epilepticus.

Introduction

In 2015, the Society for Maternal-Fetal Medicine (SMFM) and the American College of Obstetricians and Gynecologists (ACOG) published guidelines establishing levels of maternal care.(1,2) Similar to the neonatal levels of care, the guidelines outline four levels of maternity care and the nursing, provider, and facility requirements to achieve each designation.(3) To date, these levels of maternal care have not been widely adopted, and currently, no data exists on how their implementation may affect maternal or neonatal outcomes. However, it is hypothesized that women, especially those with high-risk conditions, will have improved outcomes during labor and delivery if they receive care at a hospital equipped with the resources to provide timely and appropriate care relative to their anticipated needs.

There has been little research on how a hospital's capacity to care for certain types of patients ultimately corresponds to its obstetric outcomes. Most previous studies have focused on the relationship between hospital volume and outcomes. Kyser et al. reported lower rates of postpartum complications in women delivering at high-volume centers compared to low-volume centers.(4) However, Hehir et al. recently noted that the rates of severe maternal morbidity were increasing over time in both low (<1,000) and high-volume (≥1,000) hospitals, emphasizing the need to improve maternity care in all hospitals regardless of volume.(5) Similarly, Friedman et al. noted hospital factors other than volume may be associated with differences in outcomes as they reported an increased risk for severe maternal morbidity among both low- and high-volume centers.(6)

As the maternal levels of care attempt to reflect a hospital's ability to manage patients with certain diagnoses associated with increased risk of complications, our objective was to compare patient outcomes among high- and low-risk patients between high and low acuity hospitals. We hypothesized that hospitals caring for a high rate of high-risk patients, which we considered "high acuity" centers, would have a lower risk of severe maternal morbidity among high-risk patients compared to low acuity centers.

Materials and Methods

This project was conducted using the 2013 Nationwide Readmissions Database (NRD), which contains information from every hospital discharge in 21 states. In total, the database represents nearly 50% of the US population.(7) It was obtained with permission from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project. Although initially designed for readmission analyses, this database was selected for this project as it contains all discharges within a state (i.e., it does not sample hospitals or discharges) and contains a hospital identifier, both which allow for hospital-based analyses with rate data.

Deliveries were identified in the database using methods previously described.(8) The following patients were excluded from the analysis: patients with multiple deliveries in a calendar year; transferred patients; and patients delivering at very low volume hospitals (defined as less than 100 deliveries per year). To identify patient comorbidities and quantify their severity at the time of delivery, each patient was assigned a comorbidity index. In this previously validated method, the comorbidity index is calculated by summing the weights of the associated conditions listed in Figure 1. The International Classification of Disease, Ninth Revision, (ICD-9) codes for these conditions are published in the original description of this method.(9) A comorbidity index ≥ 3 has been associated with increased risk of severe maternal morbidity.(10) Therefore, patients were stratified into risk categories: "low risk" (comorbidity index = 0), "intermediate risk" (comorbidity index = 1-2), or "high risk" (comorbidity index ≥ 3).

To estimate a hospital's acuity level, we calculated the percent of high-risk patients delivering at each hospital. Hospitals in the lowest quartile based on their percent of high-risk patients were considered "low acuity," and those in the top quartile were considered "high acuity" centers. Hospitals in the middle two quartiles were considered "average acuity," though the focus of the analysis compared outcomes in low versus high acuity centers.

In addition, the following patient characteristics were available in the database and used in the analysis: patient primary insurer, quartile of the median income of the patient's zip code, urban-rural designation of the patient's county of residence (as defined per the National Center for Health Statistics). Hospital ownership (for profit, not-for-profit, or public) and hospital teaching status (metropolitan non-teaching, metropolitan teaching, or non-metropolitan) were defined in the database. Chi-squared tests

were used for all categorical variable comparisons. The incidence of the conditions contributing to maternal morbidity were compared in the low and high acuity hospital groups using chi-squared tests.

Log-binomial regression models with patient-level data were used to assess the effects of hospital acuity on severe maternal morbidity, as defined by Bateman et al.(9,11) Severe maternal morbidity was considered to be any one of fifteen conditions, many which represent significant end-organ damage: acute heart failure, acute renal failure, acute liver disease, acute myocardial infarction, acute respiratory distress syndrome and/or respiratory failure, disseminated intravascular coagulation, coma, delirium, puerperal cerebrovascular disorders, pulmonary edema, pulmonary embolism, sepsis, shock, status asthmaticus, status epilepticus. The ICD-9 codes for this designation were also previously published.(9) The models controlled for the available patient demographic and hospital characteristics, which were planned a priori. A patient's overall risk status (low, intermediate, or high) was also included as a means of adjusting for patient comorbidities. First, a model was constructed using these characteristics and an interaction term between acuity and risk group. The significance of the interaction was tested using the Wald test.

As this interaction was significant ($p<0.001$), separate log-binomial regression models were constructed for both low and high acuity hospitals to quantify the effect of acuity on a patient's risk of severe maternal morbidity. The estimated risk difference of maternal morbidity between low- and high-risk patients for both hospital groups and the partial population attributable risk (pPAR) of hospital acuity among high-risk patients were calculated, each with corresponding 95% confidence intervals.(12) The risk ratios were compared between the two hospital groups to determine the relative difference in risk of maternal morbidity between low-risk and high-risk patients. The confidence intervals for the all estimates were calculated using cluster robust standard errors to account for clustering at the hospital level. As a sensitivity analysis, E-values were calculated to test for the potential effects of unmeasured confounding.(13)

As a subgroup analysis, the same method was used to assess the effects of acuity in only urban hospitals, as the models may not accurately control for other factors that affect patient outcomes, such as access and availability of resources in rural areas. Rural hospitals were defined in the NRD as hospitals located in rural counties and designated by the American Hospital Association; they were excluded in this

subgroup analysis. Quartiles based on the percent of high-risk patients were reassigned for these urban hospitals, and those in the bottom and top quartile were considered “low acuity” and “high acuity,” as described above.

StataSE 14.1 (StataCorp, College Station, TX) was used for the analysis. P-values <0.05 were considered statistically significant. The Partners Healthcare Institution Review Board exempted this study from review.

Results

1,656,659 delivering patients in 1,203 hospitals met the inclusion criteria. There were 58.7% low-risk, 39.0% intermediate-risk, and 2.3% high-risk patients in the sample, and the overall rate of severe maternal morbidity was 1.2%. Figure 2 shows the distribution of hospitals based on their rates of delivering patients with comorbidity index ≥ 3. The median hospital rate of high-risk patients was 5.2% and the interquartile range was 3.7-7.1%. Hospitals with less than 3.7% of high-risk patients were considered low acuity (n=302), and hospitals with more than 7.1% of high-risk patients were considered high acuity (n=300).

Table 1 compares the baseline characteristics between the low and high acuity centers. 185,414 patients delivered at low acuity centers, and 702,920 patients delivered at high acuity centers. More patients had public insurance, lived in areas with lower median income, and were from micropolitan or rural areas in low acuity centers. Furthermore, there were more patients delivering at for-profit and metropolitan non-teaching hospitals in low acuity centers. Low acuity centers tended to have lower delivery volumes compared to high acuity centers; the median number of deliveries in the low acuity centers was 923 compared to 3,189 in the high acuity centers ($p<0.001$).

The overall rate of severe maternal morbidity was two times higher in the high acuity centers: 0.7% vs 1.6% ($p<0.001$). When stratified by comorbidity risk, low-risk patients had severe maternal morbidity rates of 0.6% and 1.1% among low and high acuity centers (<0.001), intermediate-risk patients had rates of 0.9% and 1.7% ($p<0.001$), and high-risk patients had rates of 5.2% and 7.5% ($p<0.001$). There was a significant interaction between hospital acuity and patient risk status ($p<0.001$).

The estimated absolute risk difference of maternal morbidity between low- and high-risk patients was 5.0% (95%CI 3.6-6.3%) in the low acuity centers and 5.9% (95%CI 5.5-6.3%) in high acuity centers. Table 2 presents the adjusted risk ratios for severe maternal morbidity based on a patient's risk status from the primary analysis. Compared to the low-risk group, intermediate-risk patients had a slightly increased risk of morbidity in both low acuity and high acuity centers (adjusted risk ratio (aRR) 1.53 (95% confidence interval (95%CI) 1.33-1.77) versus 1.57 (95%CI 1.49-1.65)). However, there were notable differences in the risk ratios for morbidity in the high-risk population: aRR 9.55 (95%CI 6.83-13.35) in the low acuity hospitals versus aRR 6.50 (95%CI 5.94-7.09). Among high-risk patients, there was no

196 significant partial population attributable risk for being at a low acuity center compared to a high acuity
197 center (pPAR 0.4% (95%CI -1.3-2.2%)).

198 E-values represent the minimum adjusted strength of an unobserved confounder that would be
199 necessary to potentially nullify the findings of the risk ratio estimates; these values were calculated as a
200 sensitivity analysis. For the intermediate risk patients, the E-values for these risk ratio estimates were
201 2.44 and 2.52 for the low and high acuity hospitals. For the high-risk patients, the E-values were 18.58
202 and 12.47 for the low and high acuity hospitals.

203 Similar findings were demonstrated in the subgroup of urban hospitals. The aRR was 1.59
204 (95%CI 1.40-1.80) and 1.56 (1.48-1.65) for the intermediate-risk group in low and high acuity urban
205 centers, respectively. For the high-risk patients, the aRR was 9.70 (95%CI 7.17-13.13) versus 6.45
206 (95%CI 5.89-7.06) for the low and high acuity urban centers.

207 Table 3 explores the distribution of specific diagnoses comprising severe maternal morbidity in
208 low and high acuity centers. The two most common diagnoses in both groups were acute liver disease
209 and disseminated intravascular coagulation (DIC). There was no difference in liver disease between the
210 two groups (41.4% vs. 39.9%, p=0.277), but there were more cases of DIC in the high acuity centers
211 (33.6% vs. 25.6%, p<0.001). However, the largest difference between low and high acuity centers was
212 the percent of patients with sepsis. Sepsis comprised 17.5% of patients with severe maternal morbidity in
213 low acuity centers compared to 5.9% of patients in high acuity centers (p<0.001).

Comment

The primary objective of this study was to compare the outcomes of high-risk patients among low acuity and high acuity centers and ultimately determine the potential benefit of maternity care designations or regionalization. There was a higher risk of severe maternal morbidity for high-risk patients at low acuity centers (aRR 9.55 (95%CI 6.83-13.35)) compared to high acuity centers (aRR 6.50 (95%CI 5.95-7.10)) in the adjusted model. The actual, unadjusted rates of severe maternal morbidity were higher in the high acuity centers (1.6% vs. 0.7%). However, there were notable differences in the patient and hospital characteristics between low and high acuity centers. After accounting for these differences, the risk ratio of experiencing severe maternal morbidity among high-risk patients was greater in low acuity hospitals compared to high acuity hospitals.

Research on maternal levels of care has been limited to-date as the levels were introduced recently and have not been universally adopted. In pediatrics, implementation studies of the levels of neonatal care revealed reduced mortality and morbidity among very low birth weight infants at Level III neonatal intensive care units compared to other levels.(14–17) Prior studies in obstetrics have primarily examined maternal outcomes by hospital volume.(4–6,18–20) However, a study by Sullivan et al. demonstrated lower maternal mortality ratios in areas with higher densities of maternal-fetal medicine specialists, suggesting that the type of available care or resources may also influence outcomes, in addition to volume.(21) In the absence of publicly reported or available levels for maternity care, we defined acuity based on the percent of high-risk patients delivering at a hospital. From our literature review, this study is the first to show improved maternal outcomes for high-risk obstetrics patients at high acuity centers.

We used a validated comorbidity index as a means of risk-stratifying patients to better understand the risk of morbidity at low and high acuity centers. This comorbidity index, as defined and proposed by Bateman et al., could be used as tool to risk stratify patients during the prenatal period and on presentation to labor and delivery to determine the appropriate hospital level of care needed to reduce the risk of maternal morbidity and mortality.(9) When examining the diagnoses comprising severe maternal morbidity, the most notable difference between the hospital groups was the rate of sepsis, which was three times higher in low acuity hospitals (17.5% vs. 5.9%). This difference is not surprising as sepsis is

more likely to affect otherwise healthy women compared to the other conditions comprising severe maternal morbidity, such as heart or renal failure, which likely disproportionately affect women with pre-existing comorbidities (e.g., diabetes, hypertension). More research is needed to identify if these results highlight an opportunity to reduce maternal morbidity at low acuity facilities by targeting interventions to optimize the appropriate identification and treatment of intrapartum infections, thus avoiding the progression to sepsis.

Our findings are generalizable to hospitals across the United States, as the analysis leveraged data from nearly 50% of all deliveries in the country. Some patients, such as those being treated in rural areas, may not have timely access to resources that may ultimately improve their outcome, such as imaging modalities, blood products, or an intensive care unit, regardless of whether they are ultimately transferred. For this reason, we also performed our analysis in the subgroup of urban hospitals, where patients and hospitals presumably would be in closer proximity to a higher acuity center. The adjusted risk ratios for maternal morbidity were the same in the urban hospital group, strengthening our findings.

Our ability to adjust for confounders and effect modifiers were limited by the availability of information that was provided or that could be extracted using ICD-9 codes in the NRD. The high E-values from the sensitivity analysis suggest that it is unlikely that unobserved confounders would nullify the conclusions for the high-risk patients. Furthermore, the analysis was constructed based on groupings of patient risk status. The estimated risk differences of between high- and low-risk patients were similar between the two hospital groups (5.0 vs 5.9%) though their risk ratios were notably different. These findings suggest that the patient-defined cohorts (i.e., “low risk” and “high risk”) may not ultimately reflect the same patient in low and high acuity centers. This concern should be considered in future studies of hospital factors affecting patient outcomes based on a patient’s underlying risk status, especially in future implementation studies of the levels of maternal care.

Finally, we recognize our definition of acuity is imperfect and uses a hospital-level variable derived from patient level information; this definition may result in reverse causality leading to biased estimates. We also may have misclassified hospitals; for example, a tertiary care center with the resources to manage the most complicated patients could have been classified as a low acuity center if they had a small volume of high-risk patients or vice versa. We hypothesize that we were equally likely to

misclassify hospitals in either direction, such that this potential bias is not likely to negate our findings. Ideally, a hospital-level analysis should be performed using the actual level of care designations that are advocated by SMFM and ACOG or a variable based on services and resources available at a hospital that may enable them to best care for high-risk patients.(1) However, until such designations are formally made and publicly reported, the ability to study the effects of hospital acuity on outcomes will be limited to the data currently available, namely patient information. Using our definitions, there was no significant pPAR for hospital acuity among high-risk patients; we hypothesize that this null finding could be due to the limited sample size of the dataset restricted to high-risk only patients and the overall rare prevalence of the outcome. Ideally, policy decisions on regionalization should be based on a similar analysis that uses the actual levels of maternal care.

SMFM and ACOG advocate for implementing the maternal levels of care designation. The goal of this designation is to ensure that patients deliver at a facility with the appropriate resources to manage their labor and possible complications specific to their comorbidities and underlying risk factors. Findings from this study suggest that high-risk patients have a lower risk of severe maternal morbidity at high acuity hospitals and support the concept of regionalization of maternity care to improve outcomes for high-risk patients. Further research is needed on the efficacy of the maternal levels of care; a centralized designation system or public reporting of a hospital's level of maternal care will facilitate this future work.

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Tables

1. Patient and hospital characteristics at low and high acuity hospitals
2. Adjusted risk ratios for severe maternal morbidity by patient risk status at low and high acuity hospitals
3. Rates of the individual conditions comprising severe maternal morbidity at low and high acuity hospitals

Figures

1. Conditions and associated weights comprising the comorbidity index
2. Distribution of hospitals based on the percent of high-risk delivering patients

363 Table 1: Patient and hospital characteristics at low and high acuity hospitals.
364

Characteristics	Low Acuity Hospitals n=185,414*	High Acuity Hospitals n=702,920*	p-value
Patient comorbidity risk			
Low risk	68.2	53.0	<0.001
Intermediate risk	31.0	43.7	
High risk	0.8	5.5	
Primary insurance type			
Private	47.5	55.1	<0.001
Public	46.8	40.6	
Uninsured/self-pay	5.5	4.1	
Missing	0.2	0.3	
Median Income of Zip Code			
Quartile 1	26.3	26.2	<0.001
Quartile 2	33.3	21.5	
Quartile 3	27.2	23.7	
Quartile 4	11.7	27.7	
Missing	1.5	0.9	
Urban-Rural Classification			
“Central” county (metro area pop. >1 million)	12.1	47.8	<0.001
“Fringe” county (metro area pop >1 million)	16.7	24.9	
County in metro area pop 250,000-999,999	20.1	17.7	
County in metro area pop 50,000-249,999	16.7	5.5	
Micropolitan	21.3	3.0	
Rural	12.8	2.0	
Missing	0.1	0.1	
Hospital Ownership			
Public / government	15.4	14.4	<0.001
Private, not-for-profit	61.4	71.9	
Private, for-profit	23.2	7.7	
Hospital Teaching Status			
Metropolitan non-teaching hospital	58.8	22.7	<0.001
Metropolitan teaching hospital	10.4	75.5	
Non-metropolitan hospital	30.7	1.8	

365
366 *Number of patients.
367 All data presented as percentages.

Table 2: Adjusted risk ratios for severe maternal morbidity by patient risk status at low and high acuity hospitals.

Patient Comorbidity Risk	**Low Acuity Hospitals** aRR (95%CI)	**High Acuity Hospitals** aRR (95%CI)
Low Risk	*Reference*	*Reference*
Intermediate Risk	1.53 (1.33-1.77)	1.57 (1.49-1.65)
High Risk	9.55 (6.83-13.35)	6.50 (5.95 -7.09)

Log-binary regression models adjusted for patient primary insurer, quartile of the median income of the patient's residence zip code, urban-rural designation of the patient's county of residence, hospital ownership, hospital teaching status, and the number of deliveries per hospital. All p-values for the adjusted odds ratios listed in the table are <0.001.

Table 3: Rates of the individual conditions comprising severe maternal morbidity at low and high acuity hospitals.

Severe Maternal Morbidity Conditions	Low Acuity Hospitals n=1,335*	High Acuity Hospitals n=11,076*	p-value
Acute heart failure	3.2	5.0	***0.003***
Acute renal failure	4.3	7.3	***<0.001***
Acute liver disease	41.4	39.9	0.277
Acute myocardial infarction	0.2	0.2	0.574
Acute respiratory distress syndrome and/or respiratory failure	5.2	6.7	***0.034***
Disseminated intravascular coagulation	25.6	33.6	***<0.001***
Coma	0.0	0.2	0.082
Delirium	1.1	1.6	0.207
Puerperal cerebrovascular disorders	1.8	2.8	***0.027***
Pulmonary edema	1.4	4.2	***<0.001***
Pulmonary embolism	1.4	2.0	0.136
Sepsis	17.5	5.9	***<0.001***
Shock	3.0	4.2	***0.041***
Status asthmaticus	0.7	0.9	0.398
Status epilepticus	0.3	0.2	0.446

*Number of cases of severe maternal morbidity.

Data presented as percentages. Note: column totals do not add up to 100% as patients could have more than one condition.