MAIN RESEARCH ARTICLE

Epidemiology of stillbirth in low-middle income countries: A Global Network Study

ELIZABETH M. McCLURE[1], OMRANA PASHA[2], SHIVAPRASAD S. GOUDAR[3], ELWYN CHOMBA[4], ANA GARCES[5], ANTOINETTE TSHEFU[6], FERNANDO ALTHABE[7], FABIAN ESAMAI[8], ARCHANA PATEL[9], LINDA L. WRIGHT[10], JANET MOORE[1], BHALCHANDRA S. KODKANY[3], JOSE M. BELIZAN[7], SARAH SALEEM[2], RICHARD J. DERMAN[11], WALDEMAR A. CARLO[12], K. MICHAEL HAMBIDGE[13], PIERRE BUEKENS[14], EDWARD A. LIECHTY[15], CARL BOSE[16], MARION KOSO-THOMAS[2], ALAN H. JOBE[17] AND ROBERT L. GOLDENBERG[18] on behalf of the Global Network Investigators[*]

[1]Research Triangle Institute, Durham, NC, USA; [2]Aga Khan University, Karachi, Pakistan; [3]Jawaharlal Nehru Medical College, Belgaum, India; [4]University of Zambia, Lusaka, Zambia; [5]San Carlos University, Guatemala City, Guatemala; [6]Kinshasa School of Public Health, Kinshasa, DRC; [7]University of Buenos Aires, Buenos Aires, Argentina; [8]Moi University, Eldoret, Kenya; [9]Indira Medical College, Nagpur, India; [10]Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD, USA; [11]Christiana Health Care, Newark, DE, USA; [12]University of Alabama at Birmingham, Birmingham, AL, USA; [13]University of Colorado Health Sciences Center, Denver, CO, USA; [14]Tulane School of Public Health and Tropic Medicine, New Orleans, LA, USA; [15]Indiana University, Indianapolis, IN, USA; [16]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [17]University of Cincinnati, Cincinnati, OH; [18]Drexel University, Philadelphia, PA, USA

Abstract

Objective. To determine population-based stillbirth rates and to determine whether the timing and maturity of the stillbirths suggest a high proportion of potentially preventable deaths. *Design.* Prospective observational study. *Setting.* Communities in six low-income countries (Democratic Republic of Congo, Kenya, Zambia, Guatemala, India, and Pakistan) and one site in a mid-income country (Argentina). *Population.* Pregnant women residing in the study communities. *Methods.* Over a five-year period, in selected catchment areas, using multiple methodologies, trained study staff obtained pregnancy outcomes on each delivery in their area. *Main outcome measures.* Pregnancy outcome, stillbirth characteristics. *Results.* Outcomes of 195 400 deliveries were included. Stillbirth rates ranged from 32 per 1 000 in Pakistan to 8 per 1 000 births in Argentina. Three-fourths (76%) of stillbirth offspring were not macerated, 63% were ≥37 weeks and 48% weighed 2 500g or more. Across all sites, women with no education, of high and low parity, of older age, and without access to antenatal care were at significantly greater risk for stillbirth ($p < 0.001$). Compared to those delivered by a physician, women delivered by nurses and traditional birth attendants had a lower risk of stillbirth. *Conclusions.* In these low-middle income countries, most stillbirth offspring were not macerated, were reported as ≥37 weeks' gestation, and almost half weighed at least 2 500g. With access to better medical care, especially in the intrapartum period, many of these stillbirths could likely be prevented.

Introduction

An estimated 3.2 million stillbirths occur worldwide each year with more than 98% of these in low to middle-income countries (1,2). Stillbirth rates may be as high as 30–40 per 1 000 births in low-income countries, especially areas of sub-Saharan Africa and south Asia, while rates as low as 3–4 per 1 000 are reported in many high-income countries (2–8). In low-income countries, a gestational age of 28 weeks or a birthweight of 1 000g is often selected as the lower limit of viability (4). In high-income countries, stillbirth has generally been defined as a fetal loss beyond 20 or 22 weeks; however, some high-income countries such as Sweden have used 28 weeks as the lower cutoff as recently as 2010 (9). The World Health Organization has recommended using a gestational age and birthweight cutoff of 28 weeks and 1 000g, respectively,

as the lower limits for international comparisons (4). Health care providers in high-income countries frequently determine whether the stillbirth occurred in the intrapartum period. When the timing of the fetal death is not available, the extent of skin maceration is often used as a surrogate measure. Stillbirths that occur more than 12–24 hours prior to delivery generally have skin that is macerated, whereas those occurring in the intrapartum period or immediately prior to or during delivery generally have intact skin (10). In high-income countries, fewer than 10% of all stillbirths are intrapartum, whereas in some countries with minimal resources, up to half of all stillbirths are thought to occur in the intrapartum period (3,10). Intrapartum stillbirths, especially those occurring close to term, are generally considered potentially preventable, as they often are often associated with limited access to, or poor quality of, obstetric care (2,10).

Because stillbirths are not reported routinely in the vital statistics in many low-income countries, much is still unknown about the timing and circumstances associated with these stillbirths, where about half of all deliveries occur at home (11,12). For many reasons, stillbirth has been understudied, under-reported, and rarely considered in attempts to improve pregnancy outcomes in low-income countries. We sought to determine population-based stillbirth rates and to characterize health care at delivery in prospective, well defined community-based birth cohorts in community settings in low-middle income countries.

Material and methods

The study was conducted by the Global Network for Women's and Children's Health Research (Global Network), a National Institutes of Health-funded, multi-country research network. The study was conducted in nine sites in seven countries: Argentina, Guatemala, Democratic Republic of Congo (DRC), Kenya and Zambia, India (sites in Orissa, Belgaum, Nagpur), and Pakistan. Prospective data registries were initially created to establish baseline delivery and pregnancy outcome rates for the FIRST BREATH Trial, a trial of neonatal resuscitation training to improve birth outcomes (13–15). The registries were then maintained and expanded to additional sites and included a total of 195 400 deliveries and 4 301 stillbirths at the end of the study period. This study was reviewed and approved by the institutional ethics review committees of all participating study sites, the partner institutions in the USA and the data center, Research Triangle Institute. Consent was obtained at the community level; women provided informed consent to collect data regarding their pregnancy and its outcome.

Each Global Network site included six to 28 distinct geographic clusters, generally representing health districts, with approximately 300–500 annual births per cluster. The outcomes of all deliveries occurring in the clusters were collected. Each site went to great lengths to ensure completeness of pregnancy outcome data for all births. Data collection was overseen by trained study coordinators (health workers, nurses or physicians). Each cluster had one or more paid registry administrators to collect data. Community birth attendants were also provided with clean delivery kits with the expectation that they would notify the study team of each delivery, and in any case were contacted by study staff on a regular basis to ascertain any recent deliveries. Data were monitored on a monthly basis to make sure that there were no unexplained inconsistencies over time. In sites where some or all women delivered in hospitals, hospital logs were routinely checked for women living in the study clusters. Sites also utilized additional culturally appropriate methods to ensure completeness of reporting. In one country, for example, village elders were provided with a cell phone to notify the study team of deliveries in his village. In addition, as another effort to identify all deliveries, pregnant women were generally identified and registered between 24 weeks of pregnancy and delivery. Finally, in those areas which had vital records available, these were periodically reviewed for cases missed by our other types of surveillance. We believe that by using multiple methods of ascertainment, we came very close to achieving 100% identification of all pregnancies and delivery outcomes.

Active birth attendants were prospectively trained to collect data and assess basic clinical variables and outcomes, including differentiation of stillbirths and neonatal deaths at birth, type of stillbirth, birthweight, and assessment of gestational age. Birth attendants were also taught to distinguish 'macerated' from 'fresh' stillbirths using pictures depicting forms of maceration. After delivery, the study coordinator collected the data recorded by the birth attendant. Data included maternal demographics, and neonatal and maternal outcomes at delivery. A stillbirth was defined as any delivery greater than or equal to 1 000g, corresponding to approximately 28 weeks' gestation, in which no signs of life (breathing, crying, heartbeat, movement) were evident. Stillbirth offspring were identified as having signs of maceration or not. Gestational age was estimated using last menstrual period (LMP), or clinical data such as physical examination, ultrasound and other available information when LMP was unknown. The birthweight was taken within 48 hours of delivery using study scales. When birthweight could not be obtained by scale, weight was estimated to distinguish infants weighing less than and greater than 1 000g and 2 500g. Models and pictures were used to teach these concepts to community birth attendants. The type of delivery attendant included physician, nurse or equivalent, traditional birth attendant (TBA), family or unattended. Location of delivery included hospital, health center or home (including the TBA's home or in transit). Finally, antenatal care was defined as having at least one visit with a skilled health provider.

Table 1. Stillbirths: characteristics by site.

	Births, *n*	Stillbirths, *n*	Stillbirth rate per 1 000	Skin Intact/ not macerated, *n*	Percentage	Stillbirth, ≥2500 g* *n*	Percentage	Term stillbirth**	Percentage
Argentina	9 125	72	7.9	41	56.9	33	47.8	33	47.8
Guatemala	16 879	253	15.0	222	87.7	144	62.3	174	69.3
DRC	14 306	355	24.8	276	77.7	206	60.9	267	75.6
Kenya	6 334	142	22.4	112	78.9	91	77.1	102	75.6
Zambia	30 698	433	14.1	283	65.4	200	51.3	258	60.4
India (Orissa)	19 255	526	27.3	406	77.2	65	46.8	413	78.5
India (Belgaum)	45 635	842	18.5	630	74.8	250	36.5	496	61.9
India (Nagpur)	7 403	212	29.5	177	83.5	61	40.4	79	41.1
Pakistan	45 765	1 466	32.1	1 139	77.7	223	41.6	761	57.6
Total	195 400	4 301	22.1	3 286	76.4	1 273	47.9	2 583	63.4

*Birthweight available for 83% of stillbirth offspring ≥1 000g.
**Gestational age available for 95% of stillbirth offspring.

All data were entered at each study site and transmitted for central analyses; data edits, including inter- and intra-form consistency checks, were performed at entry with additional edits performed by the data center. The relationships between stillbirth prevalence and key demographic and clinical characteristics (maternal age and education, parity, antenatal care visits, type of birth attendant, and delivery location) were evaluated using log binomial multivariate regression models with generalized estimating equations (GEE) used to account for correlation of events within clusters. *p*-values were calculated for both single and multivariate analyses. The data were analyzed using sas-version 9.2 (Cary, NC, USA).

Results

From March 2005 to August 2010, of the 198 436 pregnant women identified, the study recorded 195 400 births which were ≥1 000g in the 129 study clusters. A total of 4 301 stillbirths were recorded and the mean ≥1 000g stillbirth rate across all births in all sites was 22 per 1 000 deliveries, ranging from 8 per 1 000 in Argentina to 32 per 1 000 deliveries in Pakistan (Table 1). About three-quarters (76.4%) of the still-

birth offspring had intact skin with no signs of maceration, with a range of 56.9–87.7% among the sites. Birthweights were available for 83% of stillbirths and 99% overall. The mean birth weight for the stillbirth offspring for which we had data was 2 423g, with a range of mean birthweights among the sites of 2 199–3 004g. For all births, the mean birthweight was 2 883g, with a range of 2 598–3 008g among the sites (data not shown). Of the stillbirths, 47.9% weighed ≥2 500g. The majority of stillbirths (63.4%) were recorded as ≥37 weeks (or term) and overall, 95.6% of the births were recorded as ≥37 weeks.

Most women (93.5%) received at least one antenatal care visit, with rates ranging from 85.6% in Kenya to 99.9% in Nagpur, India (data not shown). In Argentina, 99% of the deliveries were conducted by a skilled health provider (physician or nurse), whereas in five sites (DRC, Kenya, Zambia, Pakistan, and Guatemala), fewer than 50% of deliveries were conducted by a skilled health provider (Figure 1). In those sites, fewer than 5% of the deliveries were conducted by a physician. Fewer than half (42.8%) of the deliveries were conducted in a health care facility (hospital or health center). Cesarean section rates ranged from less than 1% in the
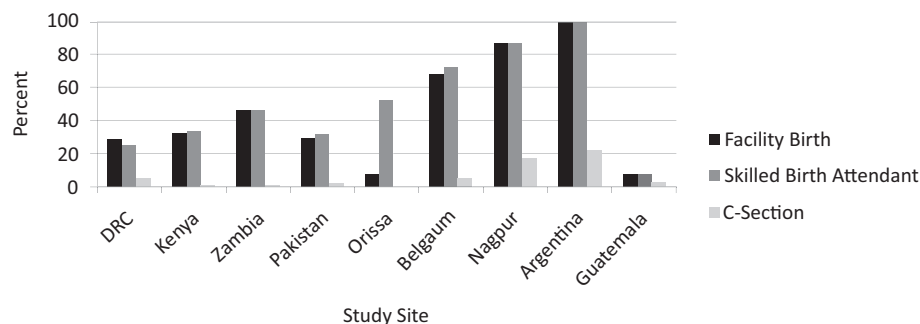

Figure 1. Health care characteristics at delivery by site.

Table 2. Characteristics by birth outcome.

	Stillbirth, *n*	Percentage	Live birth, *n*	Percentage	Unadjusted *p*-value*	A Relative risk (95%CI)	Adjusted *p*-value**
Education							
≥1 year formal schooling	1 822	1.8	98 373	98.2	<0.001	1.0	Ref
No formal schooling	2 232	2.9	75 045	97.1		1.4 (1.2, 1.5)	<0.001
Maternal age, years							
<20	411	2.1	19 427	97.9	<0.001	0.9 (0.8, 1.1)	0.3
20–35	3 346	2.3	144 749	97.7		1.0	Ref
>35	305	3.3	8 906	96.7		1.4 (1.2, 1.6)	<0.001
Parity							
0	1 130	2.6	42 638	97.4	<0.001	1.3 (1.2, 1.5)	<0.001
1–4	2 201	2.0	106 602	98.0		1.0	Ref
≥5	698	2.8	24 030	97.2		1.2 (1.1, 1.3)	0.004
Antenatal care							
One or more visit	3 646	2.2	163 424	97.8	<0.001	1.0	Ref
No antenatal care	445	3.8	11 166	96.2		1.6 (1.4, 1.9)	<0.001
Birth attendant							
Physician	902	2.4	35 905	97.6	<0.001	1.0	Ref
Nurse/midwife	1 186	2.0	57 200	98.0		0.7 (0.6, 0.8)	<0.001
TBA	1 275	1.9	67 098	98.1		0.6 (0.5, 0.7)	<0.001
None	930	3.0	30 294	97.0		0.9 (0.8, 1.1)	0.5
Delivery location							
Hospital	1 075	2.2	48 083	97.8	0.02	1.0	Ref
Health center	690	2.0	35 588	98.0		0.9 (0.8, 1.1)	0.8
Home/other	2 533	2.3	108 871	97.7		1.0 (0.8, 1.2)	0.3

*Chi-squared test, adjusted for the site cluster using generalized estimated equations (see Materials and methods section for site cluster definition).
**Regression model, adjusted for site cluster and all other variables in Table 2.

DRC and Orissa, India to 22.1% in Argentina. Five of the remaining sites had Cesarean section rates of 3% or less.

Table 2 presents characteristics among women with and without stillbirths and relative risks for stillbirth. Women who were older than 35 years of age at delivery, those who had no formal education, and those who received no prenatal care had a significantly higher risk of stillbirth compared to those without these risk factors. Women who were primiparous or who were in their 5th or more pregnancy also had increased risk of stillbirth compared to women in their second through fourth pregnancies. There were also significant differences in delivery outcomes by the type of birth attendant. The risk of stillbirth was higher among physician deliveries than among deliveries by nurses and traditional birth attendants. Stillbirth rates were generally similar across delivery locations and, when adjusted for other variables, the birth location was not a significant risk factor for stillbirth.

Discussion

We captured delivery outcomes for almost 200 000 births in distinct, geographically defined clusters in seven countries,

representing one of the largest studies of this kind to date. Although other studies have reported hospital-based stillbirth rates, few to date have examined hospital and community births to estimate the overall population rates for defined geographic areas (6,7,15). The overall stillbirth rate of 22 per 1 000 births, with individual country rates ranging from 8 per 1 000 in the Argentinean clusters to 32 per 1 000 in the Pakistani clusters, closely approximates the estimated country rates reported for these countries in some modeling studies (1,2). These rates are significantly greater than the rates of three to five per 1 000 reported from many high-income countries.

Stillbirth offspring weighing <1 000g, or those occurring at about 20–28 weeks, were not included in this study but are often included in reported USA and other high-income country rates. In the USA, for example, stillbirths occurring at 20–27 weeks account for almost half of the reported stillbirths and similar results have been reported in other high income countries (16,17). Thus, the disparity between the stillbirth rates between high and low income countries may be even larger than suggested by our results.

When examining the socio-demographic and health care characteristics, the risk factors for stillbirth were consistent

with previous studies from both low and high income countries (7,17–20). Women >35 years of age, those who had no formal schooling, who received no prenatal care, and who were either primiparous or with grand-multiparity (≥5 prior pregnancies) were also at greater risk to experience a stillbirth.

Access to health care was of particular interest. For the entire study sample, 94% of the women had at least one antenatal care visit, 51% delivered at home, 16% had no health care provider available at delivery, and 34% had an unskilled attendant. Only 4% had a Cesarean delivery, with rates of less than 1% reported in several countries. Women who had no antenatal care had a higher risk for a stillbirth compared to those women with antenatal care. Although we did not formally test the association between stillbirth and Cesarean section due to the confounding factors reported elsewhere (21–24), with one exception, the sites with the lowest Cesarean section rates tended to have the highest stillbirth rates. Of interest, in Nagpur, India, 17% of the births were delivered by Cesarean section, but the stillbirth rate was high (22 per 1 000 births). Rising Cesarean rates in low-resources settings are a topic of recent debate, especially as the Cesareans in these settings may be done for the wrong indications or may not improve outcome (23). However, when performed on the appropriate patients, it remains clear that Cesarean section can save maternal and fetal lives and that a Cesarean section rate of at least 5% deliveries represents the minimal rate necessary to address preventable perinatal mortality, as recommended by a number of international organizations (24).

The observation that among the providers, the physicians had the highest stillbirth rates, and that stillbirth rates did not differ markedly whether the delivery occurred in a home clinic or hospital, led us to speculate about the potential reasons for these observations. Most likely, women with high risk conditions such as bleeding or seizures may have been more likely to seek care with physicians in facilities. However, many facilities at our sites are characterized by limited equipment, few medicines, and long waits for life-saving interventions such as Cesarean section. Whether a physician was present or not, the lack of resources might explain the failure of facility or physician delivery to substantially reduce stillbirth rates.

This study had several strengths. First, it is one of the largest prospective studies to register women during pregnancy and to capture birth outcomes for a representative population-based sample. Because the study was conducted in geographic areas where a substantial proportion of the births occurred at home, data from this study are likely to be more representative of these geographic areas than many hospital-based studies. In addition, we used trained coordinators to supervise and evaluate the quality of the data collected, as well as a number of methods to ensure that data from all births were captured. Few low-income country studies of stillbirth in communities have captured birthweight or gestational age, often because of cultural or other barriers (1). By repeated training, we worked very hard with our study staff to identify barriers to registering stillbirths and, where applicable, to overcome their initial reluctance to handle or register stillbirth offspring.

One of the potential limitations of the study that may have resulted in reporting bias was our inability to ensure that all births were captured; however, in each site, our staff used several methods to determine who in each community was pregnant and who had delivered. In addition, the pregnancy outcomes obtained by our staff were compared with the available health records. Finally, the evaluation of delivery and stillbirth rates and inter-cluster variability ensured that large unexplained variations in either the birth or stillbirth rates were not occurring over time. Another potential limitation is the quality of the data collected for unattended births. To address this issue, our study coordinators interviewed each mother and other family members. Obtaining information on these home births is critical as they represent a substantial proportion of the live births and of the stillbirths in these geographic areas.

Still another potential limitation deals with the data regarding maceration. Despite training on this issue using graphic pictures and descriptions, it is possible that mild cases of maceration were misclassified. However, our results are in the same direction as other studies which have found that fewer than half of all stillbirths in low-income countries are macerated (2,10). Signs of maceration have been used as one indicator to distinguish antepartum from intrapartum stillbirth (10,20). However, we expect that an unknown proportion of the non-macerated stillbirths occurred prior to labor, and recognize that the concordance between 'non-maceration' and intrapartum death is not 100%. Finally, a potential limitation to the data relates to the estimates of gestational age. Because few of the sites had ultrasound to confirm LMP-derived gestational ages, we suspect that the actual percent of term births and especially term stillbirths may have been somewhat lower than the numbers reported here. Nevertheless, because the gestational age and birthweight distributions paint a similar picture, we are confident that most stillborn offspring were born at or near term, and most were not macerated.

A primary gap in stillbirth research and policy planning has been the reliance on hospital studies to estimate stillbirth rates, especially as the majority of the stillbirths worldwide occur in home settings and are never registered, and thus no vital statistics are available (11,25). The mean stillbirth rate of more than 22 per 1 000 births represents more than a five-fold increase compared to high-income country rates (1). An important observation is that in the less developed communities, where most deliveries occurred in home settings without trained health providers, rates were as high as 32 per 1 000, compared to the stillbirth rates in Argentina of 8 per 1 000, where nearly all deliveries occurred in hospital

settings. Of particular note, the majority of the stillbirths occurred at term and had no signs of maceration and almost half were ≥2 500g. Thus, if delivered before fetal death, most infants should not suffer the adverse effects of preterm birth and would likely survive. These results strongly suggest that the majority of stillbirths could be salvaged with access to appropriate obstetrical care. Although our data suggest that higher quality of health care at delivery, especially access to health care providers and appropriate Cesarean section, is associated with lower stillbirth rates, more research on the specific causes of these stillbirths would assist in defining appropriate interventions. Our findings suggest that the majority of stillbirths in these developing countries could be prevented.

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