South-East Asia Networks for Newborn & Birth Defect

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This Month...

Birth Defects

- Fetal Calcifications Are Associated with Chromosomal Abnormalities.
- Long-term trends and seasonality of omphalocele during 1996-2010 in China: a retrospective analysis based on the hospital-based birth defects surveillance system.

Newborn

- Simplified antibiotic regimens compared with injectable procaine benzylpenicillin plus gentamicin for treatment of neonates and young infants with clinical signs of possible serious bacterial infection when referral is not possible: a randomised, open-label, equivalence trial
- Safety and efficacy of alternative antibiotic regimens compared with 7 day injectable procaine benzylpenicillin and gentamicin for outpatient treatment of neonates and young infants with clinical signs of severe infection when referral is not possible: a randomised, open-label, equivalence trial

Publications

Prevention of Birth Defects in South-East Asia

Birth Defects (BD) are progressively contributing to a greater proportion of infant and childhood mortality since the infectious causes are decreasing due to the extensive and successful use of immunization, control of diarrhoeal disorders and respiratory tract infections and improvement in health care services. Improvement in the care of children with birth defects can be made with even limited resources. Affordable medications, surgical treatments, and community-based rehabilitation can help these children lead more normal lives. This care can be made accessible through existing primary health services, which can make referrals to, and receive support from, secondary and tertiary care facilities.

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Birth Defects

Fetal Calcifications Are Associated with Chromosomal Abnormalities.

PLoS One. 2015 Apr 29;10(4):e0123343. doi: 10.1371/journal.pone.0123343. eCollection 2015.
Sahlin E 1 , Sirotkina M 2 , Marnerides A 2 , Iwarsson E 1 , Papadogiannakis N 2
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Author information

Abstract

OBJECTIVE

The biological importance of calcifications occasionally noted in fetal tissues (mainly liver) at autopsy or ultrasound is largely unexplored. Previous reports hint at an association to infection, circulatory compromise, malformations or chromosomal abnormalities. To identify factors associated with calcifications, we have performed a case-control study on the largest cohort of fetuses with calcifications described thus far.

METHODS

One-hundred and fifty-one fetuses with calcifications and 302 matched controls were selected from the archives of the Department of Pathology, Karolinska University Hospital. Chromosome analysis by karyotyping or quantitative fluorescence-polymerase chain reaction was performed. Autopsy and placenta reports were scrutinized for presence of malformations and signs of infection.

RESULTS

Calcifications were mainly located in the liver, but also in heart, bowel, and other tissues. Fetuses with calcifications showed a significantly higher proportion of chromosomal abnormalities than controls; 50% vs. 20% ($p<0.001$).

CONCLUSION

The presence of fetal calcifications is associated with high risk of chromosomal abnormality in combination with malformations. Identification of a calcification together with a malformation at autopsy more than doubles the probability of detecting a chromosomal abnormality, compared with identification of a malformation only. We propose that identification of a fetal tissue calcification at autopsy, and potentially also at ultrasound examination, should infer special attention towards co-existence of malformations, as this would be a strong indicator for a chromosomal abnormality.

Long-term trends and seasonality of omphalocele during 1996-2010 in China: a retrospective analysis based on the hospital-based birth defects surveillance system.

BMC Pregnancy Childbirth. 2015 Apr 25;15(1):102. [Epub ahead of print] Li X 1, 2 , Dai L 3 , Wang Y 4 , Yi L 5 , Deng C 6 , Deng K 7 , Zhou G 8 , Li Q 9 , Liu Z 10 , Deng Y 11, 12 , Zhu J 13 , Li X 14 .

Author information

Abstract

BACKGROUND:

Little is known about secular trends and seasonal variation in the birth prevalence of omphalocele in China. This study aimed to explore the long-term trends and seasonality of this birth defect, to provide insight into the etiology and prevention of omphalocele.

METHODS:

A retrospective analysis of all births with omphalocele (1322 cases in 8.8 million births) registered in the hospital-based Chinese Birth Defects Monitoring Network between January 1996 and September 2010. Negative binomial cyclical regression models were used to analyze the long-term trends and seasonal fluctuations of omphalocele occurrence in the southern and northern regions and urban and rural areas of China.

RESULTS:

The total prevalence of omphalocele was 1.50 cases (95% confidence interval (CI): 1.42-1.58) per 10,000 births. There was no significant secular trend of omphalocele occurrence in China between 1996 and 2010. The observed prevalence of omphalocele in rural areas was 2.03-2.54 cases per 10,000 births between May and August, which was higher than that observed in other months. The

highest prevalence of births with omphalocele in rural areas occurred at the end of June; on average, the prevalence of omphalocele at that time point increased by 20% (95% CI: 6-35%) compared with other months.

CONCLUSION:
There were no long-term trends found for occurrence of omphalocele in China between 1996 and 2010; however, seasonality was observed for omphalocele in women living in rural areas. These results may help generate hypotheses for further study of environmental factors that vary by season.

Newborn

Simplified antibiotic regimens compared with injectable procaine benzylpenicillin plus gentamicin for treatment of neonates and young infants with clinical signs of possible serious bacterial infection when referral is not possible: a randomised, open-label, equivalence trial

Lancet April 2015.
African Neonatal Sepsis Trial (AFRINEST) group, Tshefu A, Lokangaka A, Ngaima S, Engmann C, Esamai F, Gisore P, et al.

Background
WHO recommends hospital-based treatment for young infants aged 0–59 days with clinical signs of possible serious bacterial infection, but most families in resource-poor settings cannot accept referral. We aimed to assess whether use of simplified antibiotic regimens to treat young infants with clinical signs of severe infection was as efficacious as an injectable procaine benzylpenicillin–gentamicin combination for 7 days for situations in which hospital referral was not possible.

Methods
In a multisite open-label equivalence trial in DR Congo, Kenya, and Nigeria, community health workers visited all newborn babies at home, identifying and referring unwell young infants to a study nurse. We stratified young infants with clinical signs of severe infection whose parents did not accept referral to hospital by age (0–6 days and 7–59 days), and randomly assigned each individual within these strata to receive one of the four treatment regimens. Randomisation was stratified by age group of infants. An age-stratified randomization scheme with block size of eight was computer-generated off -site at WHO. The outcome assessor was masked. We randomly allocated infants to receive injectable procaine benzylpenicillin–gentamicin for 7 days (group A, reference group); injectable gentamicin and oral amoxicillin for 7 days (group B); injectable procaine benzylpenicillin–gentamicin for 2 days, then oral amoxicillin for 5 days (group C); or injectable gentamicin for 2 days and oral amoxicillin for 7 days (group D). Trained health professionals gave daily injections and the first dose of oral amoxicillin. Our primary outcome was treatment failure by day 8 after enrolment, defined as clinical deterioration, development of a serious adverse event (including death), no improvement by day 4, or not cured by day 8. Independent outcome assessors, who did not know the infant’ s treatment regimen, assessed study outcomes on days 4, 8, 11, and 15. Primary analysis was per protocol. We used a prespecified similarity margin of 5% to assess equivalence between regimens.

Findings
In Kenya and Nigeria, we started enrolment on April 4, 2011, and we enrolled the necessary number of young infants aged 7 days or older from Oct 17, 2011, to April 30, 2012. At these sites, we continued to enrol infants younger than 7 days until March 29, 2013. In DR Congo, we started enrolment on Sept 17, 2012, and continued until June 28, 2013. We randomly assigned 3564 young infants to either group A (n=894), group B (n=884), group C (n=896), or group D (n=890). We excluded 200 randomly assigned infants, who did not fulfil the predefined criteria of adherence to treatment and adequate follow-up. In the per-protocol analysis, 828 infants were included in group A, 826 in group B, 862 in group C, and 848 in group D. 67 (8%) infants failed treatment in group A compared with 51 (6%) infants in group B (risk difference –1.9%, 95% CI –4.4 to 0.1), 65 (8%) in group C (–0.6%, –3.1 to 2.0), and 46 (5%) in group D (–2.7%, –5.1 to 0.3). Treatment failure in groups B, C, and D was within the similarity margin compared with group A. During the 15 days after random allocation, 12 (1%) infants died in group A, compared with ten (1%) infants in

group B, 20 (2%) infants in group C, and 11 (1%) infants in group D. An infant in group A had a serious adverse event other than death (injection abscess).

Interpretation

The three simplified regimens were as effective as injectable procaine benzylpenicillin–gentamicin for 7 days on an outpatient basis in young infants with clinical signs of severe infection, without signs of critical illness, and whose caregivers did not accept referral for hospital admission.

Safety and efficacy of alternative antibiotic regimens compared with 7 day injectable procaine benzylpenicillin and gentamicin for outpatient treatment of neonates and young infants with clinical signs of severe infection when referral is not possible: a randomised, open-label, equivalence trial.

Lancet Glob Health 2015 . Published Online April 2, 2015 http://dx.doi.org/10.1016/S2214-109X(14)70347-X
Baqui AH, Saha SK, Ahmed ASM, Shahidullah M, Quasem I, Roth DE, et al.

BACKGROUND:

Severe infections remain one of the main causes of neonatal deaths worldwide. Possible severe infection is diagnosed in young infants (aged 0–59 days) according to the presence of one or more clinical signs. The recommended treatment is hospital admission with 7–10 days of injectable antibiotic therapy. In low-income and middle-income countries, barriers to hospital care lead to delayed, inadequate, or no treatment for many young infants. We aimed to identify effective alternative antibiotic regimens to expand treatment options for situations where hospital admission is not possible.

Methods

We did this randomised, open-label, equivalence trial in four urban hospitals and one rural field site in Bangladesh to determine whether two alternative antibiotic regimens with reduced numbers of injectable antibiotics combined with oral antibiotics had similar efficacy and safety to the standard regimen, which was also used as outpatient treatment. We randomly assigned infants who showed at least one clinical sign of severe, but not critical, infection (except fast breathing alone), whose parents refused hospital admission, to one of the three treatment regimens. We stratified randomisation by study site and age (

Findings

Between July 1, 2009, and June 30, 2013, we recruited 2490 young infants into the trial. We assigned 830 infants to group A, 831 infants to group B, and 829 infants to group C. 2367 (95%) infants fulfilled per-protocol criteria. 78 (10%) of 795 per-protocol infants had treatment failure in group A compared with 65 (8%) of 782 infants in group B (risk difference –1.5%, 95% CI –4.3 to 1.3) and 64 (8%) of 790 infants in group C (–1.7%, –4.5 to 1.1). In group A, 14 (2%) infants died before day 15, compared with 12 (2%) infants in group B and 12 (2%) infants in group C. Non-fatal relapse rates were similar in all three groups (12 [2%] infants in group A vs 13 [2%] infants in group B and 10 [1%] infants in group C).

Interpretation

Our results suggest that the two alternative antibiotic regimens for outpatient treatment of clinical signs of severe infection in young infants whose parents refused hospital admission are as efficacious as the standard regimen. This finding could increase treatment options in resource-poor settings when referral care is not available or acceptable.