

Background Neonatal abstinence syndrome (NAS) is a complex of symptoms in newborns exposed to substances/drugs in-utero or after birth. Clonidine is a central alpha-2 agonist and recent studies have shown it can decrease NAS symptoms in opiate withdrawal.

Objective To determine the efficacy of clonidine as an adjunctive agent to phenobarbitale (PB). To elucidate demographic factors, maternal drug profile, nature of the symptoms in infants. To compare NAS profile with PB and PB+clonidine. To show associated side effects with clonidine.

Design/Methods Retrospective review of infants ≥ 35 weeks GA admitted to HSC, Winnipeg from January 2005 to July 2010. Abstinence scores 20 hours before and 40 hours after PB and PB+clonidine were measured by Finnegan scoring system and compared by ANOVA.

Results Twenty four infants (GA 39.3 ± 1.4 wks, BW 3316 ± 595 g) were treated by PB+clonidine combination. Fifty eight percent exposed to multiple drugs. Methadone was the most common drug of exposure. Tremor, increased tone, regurgitation and poor feeding were common symptoms. When PB was used alone as initial therapy, NAS scores increased from 6.9 ± 3.3 to 7.5 ± 3.0 ($p > 0.05$) at pre and post medication periods respectively. Clonidine was added to PB at 3.5 to 5.3 mg/kg/day and NAS scores were decreased from 8.7 ± 3.4 to 7 ± 3.5 ($p < 0.001$). There were no recorded side effects for clonidine.

Conclusions Our study suggests that clonidine may be a useful adjunctive treatment of NAS in infants who respond incompletely to PB. Cardiovascular side effects were not common in our study.

1647

UNLICENSED AND OFF-LABEL MEDICATION USE IN THE NEONATAL INTENSIVE CARE UNIT: A PROSPECTIVE COHORT STUDY

doi:10.1136/archdischild-2012-302724.1647

^{1,2,3}E Kieran, ⁴N O' Callaghan, ^{1,2,3}CP O' Donnell. ¹Neonatology, The National Maternity Hospital; ²The National Children's Research Centre, Crumlin; ³School of Medicine and Medical Sciences, University College Dublin; ⁴Pharmacy, The National Maternity Hospital, Dublin, Ireland

Background Many medications have not been extensively studied in children. Medications may be prescribed for indications for which their use has not been approved (unlicensed use); or may be given for an approved indication, but to an age group or at a dose or frequency or by a route that has not been approved (off-label use). We wished to determine the extent of unlicensed and off-label prescription in our NICU.

Methods We prospectively studied infants admitted to our tertiary level NICU over 2 months. We recorded demographic data and all medications prescribed for all infants. We compared the use of each medication to their licensed indications as contained in the Summary of Product Characteristics.

Results 110 infants were admitted. All infants received a prescribed medication. 79 different medications were prescribed to these 110 infants, a median (IQR) of 4 (3, 12) each. 41% of prescribed medications were given in an unlicensed manner and 15% in an off-label manner. 12 (11%) infants received an unlicensed medication, 5 (4%) infants received an off-label medication and 38 (35%) infants received both an unlicensed and off-label medication. Of infants < 32 weeks, 91% received unlicensed and 85% off-label medications. 100% of infants < 28 weeks received an unlicensed and an off-label medication. There were 2 adverse events related to medications.

Conclusions Most medications prescribed to newborn are unlicensed or given for off-label indications. Many infants, and the majority of preterm infants, admitted to NICU receive unlicensed and off-label prescriptions. Adverse events appear uncommon.

1648

CLINICAL COURSE AND DRUG SUSCEPTIBILITY FOR INFANTS WITH UREAPLASMA INFECTION

doi:10.1136/archdischild-2012-302724.1648

SM Lee, HS Eun, R Namgung, MS Park, KI Park, C Lee. *Pediatrics, Yonsei University College of Medicine, Seoul, Republic of Korea*

Objectives Ureaplasma species were associated bronchopulmonary dysplasia in preterm infants. We aim to analyze the antibiotic susceptibility of ureaplasma urealyticum and clinical manifestations in preterm infants with ureaplasma urealyticum colonization.

Methods In a retrospective study, 416 preterm infants (\leq gestation 32 wk) and their mothers admitted to Severance Children's Hospital and Gangnam Severance Hospital NICU between Jan 2008. to Jun 2011, were reviewed. Ureaplasma test was done by culture for mothers and PCR in urine and tracheal aspirates for preterm infants. Ureaplasma colonization was confirmed 7.5% of infants, and 31% of the mothers. If positive result was noted, all infants were initially treated with erythromycin empirically.

Results Thirty one infants who had positive ureaplasma PCR test (28.3 ± 3.1 wk, 1050 ± 490 g) and 385 infants with negative test (29.0 ± 3.2 wk, 1190 ± 550 g) were recruited as controls. Infants with ureaplasma infection had longer durations of oxygen administration ($p = 0.039$) and mechanical ventilation ($p = 0.041$). The incidence of pathologic chorioamnionitis were significantly higher ($p < 0.001$). Infants with ureaplasma infection had higher incidence of moderate/severe BPD. For antimicrobial susceptibility, 23% of erythromycin resistance, 16% of zithromycin resistance, 38% of ciprofloxacin resistance and no jasamycin resistance were shown. Among 31 infants with erythromycin treatment, 18 (58%) of susceptible, 6 (19%) of intermediate were cured after 13 days of treatment, and 4 showed poor response erythromycin treatment, 2 changed to josamycin and 2 infants to clarithromycin and all were completely treated.

Conclusion Ureaplasma colonized infants showed higher incidence of BPD. Proper antimicrobial use may reduce the morbidity associated with ureaplasma colonization.

1649

RETROSPECTIVE ANALYSIS OF DOXAPRAM FOR THE TREATMENT OF APNEA OF PREMATURITY

doi:10.1136/archdischild-2012-302724.1649

¹J Winter, ¹B Fekker, ²A Gerhold-Ay, ¹A Kidszun, ¹Schmidtmann, ¹C Whybra-Trümppler, ¹E Mildenerberger. ¹Neonatology, Children's Hospital; ²Institute of Medical Biometry, Epidemiology and Informatics, University Medical Center of the Johannes Gutenberg University, Mainz, Germany

Background and Aims Only one small randomized controlled study on doxapram to treat apnea of prematurity is available. Before the implementation of a local treatment protocol, we aimed to evaluate the frequency of administration of doxapram in our NICU. We asked, if frequency and severity of apneas were affected by doxapram, if intubation for apnea was avoided, and if side effects occurred.

Methods We retrospectively analysed all premature infants < 30 weeks treated with doxapram during 03/2008 to 03/2010. We registered the number of apneas, bradycardias, and desaturations, an hour before, at the start of, and during 48 hours after onset of treatment.

Results 17 of 64 (27%) infants (mean gestational age 26.1 weeks, mean birth weight 733g) were treated during two years. All of them had been treated with caffeine before doxapram was applied. 70 therapy courses of 16 infants were analyzed. In 8 of 70 (11%) therapy courses, infants were intubated because of apnea during 48 hours of doxapram treatment. The frequency of apneas (2.24 vs. 0.17), bradycardias < 80 /min (0.93 vs. 0.14), and desaturations

< 80% (3.29 vs. 1.21) per hour decreased. No heart block occurred. However, restlessness was observed more frequently.

Conclusions Doxapram was applied to roughly a quarter of all very immature infants. Frequency and severity of apneas appeared to be reduced. Intubation because of apnea was avoided in a large proportion of infants. No severe side effects were recorded. More systematic studies on efficacy and safety of doxapram in premature infants are needed.

1650 RATIONAL USE OF ANTIBIOTICS IN NEWBORN

doi:10.1136/archdischild-2012-302724.1650

O Stanojlović, N Todorović, N Jovanović, N Miljković. *Neonatology, Clinical Medical Center 'Zvezdara', Belgrade, Serbia*

Side effects of antibiotics must always be considered, especially in neonatal period. Our aim was to analyse the antibiotic use in our neonatal ward (2nd level perinatal care). We analysed number of babies who received therapy, indications and time of starting antibiotics, duration and antibiotics used, laboratory analysis (CBC, CRP, swabs and cultures of babies and mothers) and discharge diagnosis in one-year period.

2299 babies were born in 2011, and 125 (5.4%) received antibiotics. 49% had risk factors for infection. In 62% therapy started in 1st or 2nd day of life, and average duration was 5–7 days, in 83%. Ampicillin+Gentamycin was given in 82%; Ampicillin for GBS colonisation and cephalosporines for UTI. There were no multiresistant strains.

Diagnosis

Respiratory: 43 (34.4%),
Asphyxia: 17 (13.6%),
Urinary tract infections: 15 (12%),
Sepsis: 6 (4.8%),
Others: 13 (10.4%),
Without diagnosis: 31 (24.8%).

Risk factors for infection were present in 20% (ITU group) to 58% (group without diagnosis). Positive laboratory analysis were present from 42% (respiratory problems) to 100% in sepsis and UTI.

Most of the children received therapy for clinical symptoms of infection, mostly RD. The only single risk factor for starting the therapy was chorioamnionitis. Among children without diagnosis, 4 received short-course therapy based on risk factors, 6 because of GBS colonization, some had risk factors accompanied with positive laboratory findings and 10 babies because of positive laboratory findings only.

We noticed the decrease in antibiotic use in our hospital in past few years, specially in prophylactic use and therapy based on laboratory analysis. We consider clinical findings the most important criteria. But we can make further reduction by establishing firm criteria for antibiotic use, improving laboratory techniques and probably shortening the duration of therapy in some children.

1651 ANGIOTENSIN II RECEPTOR ANTAGONIST RELATED FETOPATHY - A CASE REPORT

doi:10.1136/archdischild-2012-302724.1651

K Wegleiter, E Griesmaier, M Waltner-Romen, R Trawoeger, U Kiechl-Kohlendorfer. *Department of Paediatrics II, Medical University Innsbruck, Innsbruck, Austria*

Fetal angiotensin II receptor antagonist exposure during pregnancy is associated with major congenital malformations including premature birth, oligohydramnios, acute renal failure, pulmonary hypoplasia and hypocalvaria. Fetopathy is mainly caused by renal insufficiency due to severe hypotension and disturbance of renal development. Therefore administration during the second and third trimester of pregnancy is contraindicated.

We report on a 35 year-old woman with arterial hypertension who was referred to our obstetrical department because of oligohydramnios. She reported to receive treatment with Olmesartanmedoxomil (5mg/day). The condition resolved after changing anti-hypertensive treatment to metoprolol at 26 6/7 weeks of pregnancy. The patient was born at term by C-section and showed the following signs of fetopathy: hyperechogenic multicystic kidneys and hypocalvaria. Renal function was normal, nevertheless arterial hypertension was present but treatment was not required. Discharge from hospital was possible at the age of 9 days. Regularly follow-up visits are necessary to monitor renal function and to evaluate long term effects.

Incidence of sartan-related fetopathy is unknown, therefore consistent reporting is mandatory. We present a case with mild presentation of symptoms, probably related to low therapeutic dosage and early change of antihypertensive treatment.

1652 EPIDEMIOLOGICAL STUDY ON ACUTE INTOXICATIONS IN THE ADMITTED CHILDREN

doi:10.1136/archdischild-2012-302724.1652

¹CE Singer, ¹P Stancu, ¹SC Cosoveanu, ¹A Botu, ²C Cristea, ²S Costache. ¹2nd Pediatric Clinic, University of Medicine and Pharmacy Craiova; ²2nd Pediatric Clinic, Emergency County Hospital Craiova, Craiova, Romania

Objectives Study on the incidence of acute intoxications (AI) within general pathology and various parameters (sex, social environment, age, etiologic spectrum).

Material and Method A retrospective study of AI in the children aged 0–16 years, admitted to the 2nd Pediatric Clinic of the Emergency County Hospital Craiova from January 1st to December 31st 2011.

Results 95 children with various AI were admitted, representing 4.1% of the total admitted children; 41 (43.2%) presented acute involuntary intoxications (AII), while 54 (56.8%) acute voluntary intoxications (AVI).

AII: distribution of children according to sex M/F=27/14, social environment U/R=18/23, age group (years): 0–1/1–3/3–5/5–10/10–14/14–16=11/10/9/5/4/2; etiologic spectrum: drugs in 9 children, nitrates in 7, carbon monoxide 7, mushrooms 6, corrosive substances 5, insecticides/anti-parasitary 3, ethylic alcohol 2, medicinal alcohol 1, and acetone 1.

In AVI, the sex ratio was M/F=21/33, social environment U/R=27/27, age group (years): 5–10/10–14/14–16=12/17/25. Causes of AVI: drugs in 32, ethylic alcohol 12, ethno-botanical 4, corrosive substances 3, unknown causes 2, caffeine 1 case. There were registered 2 deaths because of nitrates intoxication, in rural infants, aged 1 and 2 months.

Average period of hospitalization (days): in AII 4.79±3.12 (1–16), in AVI 3.25±1.3 (1–10).

Conclusions AI represented 4.1% of the total admitted cases. Drugs represented the most frequent cause both in AII and AVI. AII were more frequent in males and rural areas; AVI prevailed in females. Deaths because of AI represented 2.1% of the total number of AI cases.

1653 ACUTE INTOXICATIONS WITH DRUG SUBSTANCES IN CHILDREN - A CLINICAL EPIDEMIOLOGICAL STUDY

doi:10.1136/archdischild-2012-302724.1653

¹CE Singer, ¹P Stancu, ¹SC Cosoveanu, ¹A Botu, ²S Costache, ²C Cristea. ¹2nd Pediatric Clinic, University of Medicine and Pharmacy Craiova; ²2nd Pediatric Clinic, Emergency County Hospital Craiova, Craiova, Romania

Objectives Incidence of acute drug intoxications (ADI) within general pathology and various parameters (sex, social environment, age group, etiologic spectrum, clinical form, average period of hospitalization).