Background Little is known about the short and long-term therapeutic management of asthmatic children. The aim of this study was to assess the prescribing patterns of antiasthma drugs in primary care.

Methods This is a retrospective cohort study performed between January 2011 and December 2017 using the EGB (Echantillon Généraliste de Bénéficiaires) database, a 1/97th sample of the French national healthcare insurance system. Claims data for all individuals aged from 5 to 18 years’ old who had received at least one antiasthma drug in the study period without any delivery in the previous 24 months and with 24 months of follow-up after first delivery, were analysed.

Results A total of 7,680 children and adolescents (68.6% aged 5–11, 31.4% aged 12–18 years) were delivered at least one antiasthma drug (ATC code R03) during study period. The majority (66%) did not redeem another prescription in the following year (occasional users), when 18.4% redeemed prescriptions twice (low users) and 15.6% ≥3 times (high users). Most users (67%) were delivered only one class of R03 per dispensing in the first year and short-acting β2-agonists (SABAs) were the most frequently dispensed drugs. However, 33.4% of users were not prescribed SABAs. During the second year, only 27% of first-year users redeemed R03 prescriptions: 15.8% among occasional users, 35.5% of low users and 64.7% of high users. Among low and high first-year users who redeemed R03 drugs during the second year, 39.7% did not use inhaled corticoids alone or in association to LABAs.

Conclusions A high proportion of children and adolescents that used antiasthmatic drugs, even on a regular basis, were not prescribed these drugs in the long term. This finding may correspond either to the widespread use of antiasthmatic drugs in indications other than asthma or to an important under-treatment of asthmatic children and adolescents.

Disclosure(s) Nothing to disclose

P49 A PHARMACOKINETIC EVALUATION OF ORAL CLAVULANIC ACID IN TERM NEWBORNS

1,2FM Kell*, 2RF Kornelisse, 2NG Hartwig, 1J van der Sluijs, 4A van Driel, 5S Kenter, 5Heidema, 3P den Buter, 3BPC Koch, 1IKM Reiss, 1K Allegaert, 1GA Tramper-Stranders.

1Department of Pneumology, Hôpital Robert Debré, APHP, Paris, France
2Maxima Medical Center, Veldhoven; 3Franciscus Gasthuis and Vlietland, Rotterdam; 4Clinical Science, Lund, Lund; 5Department of Public Health and Primary Care, Leuven, Belgium

Background Clavulanic acid is an irreversible beta-lactamase inhibitor which has a weak antibacterial action. When combined with a beta-lactam antibiotic such as amoxicillin, it is effective against a broad range of bacteria. Despite its widespread use, little is known on the mechanism of action and target levels. A few studies on oral clavulanic acid in adults are available reporting great variance (AUC median 4.99 mg·h/L [0.44–8.31]) and a short elimination half-time (1.08h).

Observations in neonates are currently lacking. We therefore evaluated the pharmacokinetics of oral clavulanic acid co-administered with amoxicillin in term newborns.

Methods As part of a multicenter RCT (Clinicaltrials.gov: NCT03247920) evaluating neonatal intravenous-to-oral switch therapy in probable bacterial infection, we measured serum levels in patients allocated to the intervention group. They switched to amoxicillin/clavulanic acid suspension (25/6.25 mg/kg tid), after 48 hours of intravenous penicillin/gentamicin. Two blood samples from different dosing intervals, were obtained and directly stored at -80°C. Initially, and to ensure that amoxicillin levels were attained as safety marker, levels in the second part of the timeframe (4–8 h after administration) were collected. For the second batch, peak levels (1–2 h after administration) were collected. Analysis was performed using Liquid Chromatography and Mass Spectrometry.

Results At submission, samples of the first 15 patients were analysed (first batch). Samples were collected 6.0 ± 1.3 h (mean,S.D.) after antibiotic administration. Clavulanic acid levels were detected in all patients but a great variance was observed (median: 1.4 mg/L; range: 0.20–4.82 mg/L). Extrapolation would lead to an AUC of at least 8.4 mg·h/L.

Conclusions Oral clavulanic acid is absorbed in term newborns, but great variance is seen in trough levels (4–8 h after administration). Extrapolation predicts at least an AUC comparable to those of adults. Peak levels in the first part of the time interval (0–4 h) are needed to further build confidence on this conclusion.

REFERENCES

Disclosure(s) Nothing to disclose

P50 INDIVIDUAL VARIATIONS IN FENTANYL PHARMACOKINETICS AND PHARMACODYNAMICS IN PRETERM INFANTS

1J Kindblom*, 2E Norman, 3A Rane, 4A-C Berg, 5U Schubert, 6B Hallberg, 8M Velliman. 1Sahlgrenska Academy, Institute of Medicine, Sahlgrenska University Hospital, Gothenburg; 2Clinical Science, Lund, Lund; 3Division of Clinical Pharmacology, Karolinska University Hospital Huddinge; 4Department of Neonatology, Karolinska University Hospital and Karolinska Institute, Stockholm, Sweden; 5Children’s Hospital, Helsinki, Helsinki, Finland

Background Fentanyl pharmacokinetics and pharmacodynamics are lacking in preterm infants. Our aim was to study these and their relation with a new formulation of fentanyl 5 mg/mL for procedural pain.

Methods Preterm infants were given 0.5 (n=20, median gestational age 26.5; range 23.3–34.1 weeks) and 2 mg/kg (n=8, 27.4; 25.3–30.7 weeks) fentanyl, respectively, before skin-breaking procedures or tracheal intubation. Blood samples were collected after ten minutes, two, four, eight and 24