O-114 VALIDATION OF THE NEONATAL PAIN, AGITATION AND SEDATION SCALE FOR THE ASSESSMENT OF SEDATION IN NEONATAL INTENSIVE CARE PATIENTS

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Background Implementation of sedation protocols based on regular sedation assessment using item-based scales can improve sedative treatment in children. There is a lack of validated tools to assess sedation in neonates.
Objective To validate the Neonatal Pain, Agitation and Sedation Scale (N-PASS) for the assessment of sedation in preterm and term neonates.
Methods The Nurse Interpretation of Sedation Score (NISS) was used to validate the N-PASS with regard to neonatal sedation. Paired assessments of both the N-PASS and the NISS were performed in 50 sedated neonates from 23 to 44 weeks' postmenstrual age.
Results A total set of 503 paired observations were included into analysis. The median N-PASS scores were significantly different for the three NISS categories (over-sedation (-8), adequate sedation (-2), under-sedation (0); p <.0001). Inter-observer agreement for the N-PASS sedation subscale was excellent (linearly weighted Cohen's Kappa:. 93), as was the internal consistency estimated by a Cronbach's alpha of 0.88, which increased to.90 when the vital sign item was excluded from the N-PASS. There was no risk of under-sedation in patients with an N-PASS score <-5 and no risk of over-sedation with an N-PASS score > -2. The N-PASS reliably detected over-sedation. Detection of under-sedation was markedly improved by simultaneous assessment of N-PASS pain scores which were significantly different in patients being considered adequately sedated vs. inadequately sedated (median N-PASS pain subscale score: 2 vs. 5).
Conclusion The N-PASS meets the requirements of a valid clinical tool to assess sedation in neonates and may facilitate the use of sedation algorithms in the neonatal intensive care unit.

O-115 RELATIONSHIP BETWEEN ADVERSE DRUG REACTIONS AND OFF-LABEL/UNLICENSED DRUG USE IN HOSPITALISED NEONATES. REMINEO STUDY

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Background and aim Data regarding the association between the off-label drug use and adverse drug reactions (ADRs) in neonates is scarce. The main aims of this study are to evaluate prospectively the relationship between adverse drug reactions and off-label or unlicensed (OLUL) drugs in 2 neonatal centres in Lyon (France), and to provide more information on prescribing practice, the amplitude, nature and consequences of OLUL drug use.
Methods The French summaries of product characteristics in Theriaque 2012 *(a prescription products guide*) are being used as a primary reference source for determining drug labelling. Detection of ADRs is carried out by health care professionals and research groups using a trigger tool and patients' electronic health records. The causality between suspected ADRs and drug is evaluated using the WHO and the French methods of imputability.
Preliminary results for a 12 month period 910 neonates were included. 671 (73,7%) were preterm. 94,8% (CI 95: 93,3–96,3) of children received at least one OLUL drug, 66% of 8891 prescriptions were used in OLUL manner. 80% of the 96 validated ADRs were classified as severe. 84% of drugs related to ADRs were used in OLUL manner.
Conclusion Our study confirmed that OLUL drug utilisation is common in neonates. This study will bring more evidence on the correlation between OLUL drug use and ADRs. Institutions and pharmaceutical industry should develop clinical trials for neonates, and ensure they do not remain a "therapeutic orphan". A specific reference source for drug used in neonates would be helpful.

O-116 PREMATURE INFANT PAIN PROFILE (PIPP) IN NEONATAL INTENSIVE CARE UNIT: A PILOT STUDY

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Background and aims Premature Infant Pain Profile (PIPP) has been studied and validated in intensive care units but seldom in neonates with ventilatory support. The aim of the study was to assess PIPP (feasibility, inter-rater reproductibility, easiness) while endotracheal suctionning in ventilated newborns in order to use it later for pain treatment monitoring.
Methods Prospective study done in a level III neonatal intensive care unit, from 2013 march 5th to 2013 April 25th. 25 newborns with invasive mechanically ventilatory support were involved and they were filmed during the procedure. Four observators noted individually PIPPscale for each baby: the patient's nurse and a department's resident in the room and, an NIDCAP experienced paediatrician and the resident making the study, after viewing the video. The inter-rater agreement was assessed by the Cohen's Kappa coefficient.
Results 100% of the PIPP scales were done. The global inter-rater agreement was poor, with a kappa coefficient at 0,303 (0,035–0,571) and especially for the mimic items. 33% of the nurses found the PIPP scale difficult to use. Mean PIPP during endotracheal suctionning varied from 8.7 to 9.3.
Conclusions Pain assessment by PIPP scale was poorly reproducible and hard to nurse's use in the ventilated newborns. Neonatal pain and sedation protocol guided by PIPP scale seems us to be difficult to implement in intubated neonates.

Sepsis/Infections

O-117 COMPARISON OF SUPERIOR VENA CAVAL OXYGEN SATURATION (SCVO2) AND FEMORAL VENOUS OXYGEN SATURATION (SFVO2) IN CHILDREN WITH SEPTIC SHOCK

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