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ABSTRACTS

the interventions made by the pharmacist using a scale that evaluates the importance and relevance of the intervention. The secondary outcome was the pharmacy intervention acceptance rate. Appropriate statistical analysis will be applied to the data set.

RESULTS: Research ongoing

CONCLUSION: Research ongoing

Pediatrics

453. Buprenorphine withdrawal in an infant after cessation of breastfeeding: A case report and review of the literature. *Hani Elladki, Pharm.D., Candidate¹*, Paul Thill, Pharm.D., BCPS²; (1)Ferris State University, Dearborn Heights, MI; (2)Ferris State University College of Pharmacy, Saginaw, MI

PURPOSE: To report a case of buprenorphine withdrawal in an infant after an abrupt cessation of breastfeeding and to review the published literature on the topic. It is well known that exposure to buprenorphine in utero, can lead to neonatal abstinence syndrome (NAS). We report here a 4-month old infant who displayed symptoms of withdrawal approximately 2 days after the mother stopped breastfeeding. Symptoms included frequent yawning, sneezing, pupillary dilation, agitation, sweating, hyperactive Moro reflex, myoclonic jerks, tremors and insomnia. The mother stated that she was using buprenorphine throughout her pregnancy and there were no signs of NAS at birth. Upon diagnosis the infant was placed on methadone and experienced immediate improvement of her withdrawal symptoms. Patient was discharged after 3 days on a methadone taper. The Naranjo scale suggests this is a probable adverse event.

METHODS: We performed a MEDLINE search (1966–May 2011) using keywords: buprenorphine, breastfeeding and withdrawal. Review articles, case reports and primary research publications were included in this search.

RESULTS: No case reports were found describing buprenorphine withdrawal in infants secondary to cessation of lactation. One case report found insignificant levels in breast milk for a child experiencing NAS. Two studies investigated buprenorphine concentrations in breast milk and determined the concentration was unlikely to have adverse effects on lactating infants. This case report represents an issue that has not been discussed extensively or studied in the literature and it is likely healthcare providers do not consider it in the care of newborn infants or education of breastfeeding mothers on buprenorphine.

CONCLUSION: Although buprenorphine has generally been considered safe during lactation, this case report is in contrast to that assumption. Until more evidence is published, healthcare providers should specifically counsel lactating mothers taking buprenorphine to watch for signs of withdrawal and avoid rapid cessation of breastfeeding.

454. Evaluation of busulfan targeted therapy and pharmacokinetics in pediatric patients undergoing hematopoietic cell transplantation. *Shirley Yan, B.S.*, Christopher C. Dvorak, M.D., Lisa Musick, Pharm.D., Jason Law, M.D., Morton J. Cowan, M.D., Biljana Horn, M.D., Janel R. Long-Boyle, Pharm.D., Ph.D.; University of California, San Francisco, San Francisco, CA

PURPOSE: Busulfan is an alkylating agent routinely used in the conditioning regimens of pediatric hematopoietic cell transplantation (HCT). Identifying covariates that influence busulfan exposure is important for the development of better dosing strategies in HCT. This study aims to evaluate patient-specific covariates as contributors to the variability of busulfan exposure in pediatric HCT recipients using a population pharmacokinetic (PK) approach, as these remain poorly defined.

METHODS: We retrospectively collected PK data from the routine therapeutic monitoring of busulfan levels in pediatric HCT recipients at UCSF Benioff Children's Hospital between January 2007 and January 2011. Patients were included in the analysis if they had undergone a related or unrelated HCT including busulfan therapy, were between 0 to 18 years of age, and had busulfan time-concentration data available for analysis. Busulfan drug levels and potential covariates influencing drug exposure will be analyzed with standard population PK methodologies using non-linear mixed effects modeling software (NONMEM).

RESULTS: This study will utilize busulfan time-concentration data

available in 52 pediatric HCT recipients (36 males/16 females) for a total of 117 individual PK profiles. Subjects range in age from 1 month to 18 years. Median weight is 20 kg (range, 3–101) and includes 10 subjects with an actual body weight less than 12kg. A total of 785 quantifiable concentrations are available for PK modeling. The range of observed busulfan concentrations is 0–3163 ng/mL. Forty-three subjects (83%) had intensive PK performed on more than one occasion.

CONCLUSION: Data collection is complete. PK analysis will be completed and results available at the time of the ACCP Annual Meeting.

455. A retrospective descriptive study of combination antifungal therapies in pediatric oncology patients. *Whitney L. Davis, Pharm.D. Candidate*, William L. Greene, Pharm.D., Jerry L. Shenep, M.D., Randal T. Hayden, M.D., Brandon M. Triplett, M.D.; St. Jude Children's Research Hospital, Memphis, TN

PURPOSE: Invasive fungal infections are a major cause of mortality and morbidity in immunocompromised patients such as those treated at St. Jude Children's Research Hospital. Though they have not been adequately evaluated in clinical trials, combination antifungal therapies are sometimes used to treat invasive fungal infections. The risk-to-benefit profile of antifungal therapies is unknown as they are more expensive than monotherapies and potentially more toxic. This study is an observational description of combination antifungal therapy administered to pediatric and adolescent oncology patients. Our goal is to identify practices which vary from currently published treatment guidelines, and to stimulate further study and performance improvement efforts involving treatment of these patients.

METHODS: We will conduct a retrospective chart review using an electronic medical record system. All medical records reflecting an admission between February 2006 and June 2011 during which a patient received concurrent therapy with two or more systemic antifungal drugs for more than 48 hours will be evaluated. Specific drug combinations, drug class combinations, dosages, routes, frequencies, durations of therapy, and serum concentrations will be described as well as perceived toxicities and breakthrough infections.

RESULTS: Initial review of the electronic medical record system shows 137 patients receiving combination antifungal therapy as it has been defined for this study. While most patients received one instance of combination antifungal therapy there are some patients that received multiple regimens involving different antifungal agents. Thorough data analysis will be completed by October 2011.

CONCLUSION: Combination antifungal therapy is utilized in clinical practice at St. Jude Children's Hospital. More definitive conclusions characterizing this practice will be available by October 2011.

456. Improved safety of intermittent infusion delivery in the neonatal intensive care unit: establishing a need for the standardization of medication administration. *Amy Mitchell, Pharm.D., Candidate¹*, Thomas Young, M.D.², Nancy Gary, RN², Angela Peake, Pharm.D.², Rhonda Zillmer, Pharm.D.², Laura Hayn, Pharm.D., BCPS²; (1)Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC; (2)WakeMed Health and Hospitals, Raleigh, NC

PURPOSE: Variations in medication administration can result in incomplete medication delivery, inappropriately rapid infusion times, and/or administration of excessive fluid volumes. This study is an interdisciplinary quality improvement project involving pharmacy, nursing and medicine that includes standardization of the medication administration process along with infusion and flush time practice in a neonatal intensive care unit (NICU).

METHODS: This study assessed variability in practice of drug infusion times, flush infusion times, and flush infusion volumes in a NICU via a voluntary, anonymous survey of nursing staff. Three drugs that require different infusion and flush times were used in the survey: ampicillin (slow push), gentamicin (30 minutes) and vancomycin (60 minutes). The nurses listed their current practice of drug infusion times, flush infusion times, and flush infusion volumes for each drug and responses were compared.

RESULTS: Overall, 34 out of 93 nurses completed the survey. A total of 33 (97%) respondents documented appropriate medication infusion rates. Only 2 (5.9%) respondents documented an appropriate flush

alcohol withdrawal.

Transplant/Immunology

470. Effectiveness and safety of influenza vaccine in first six months post-lung transplant. *Kalynn A. Rohde, Student, John J.M. Moran, B.S., Mary S. Hayney, Pharm.D., M.P.H.; University of Wisconsin School of Pharmacy, Madison, WI*

PURPOSE: Clinicians may be reluctant to administer influenza vaccine to the recently transplanted because of hypothesized low immune responses and the possibility of inducing acute rejection. Because the influenza vaccine changes annually, all patients must be immunized each season. We hypothesized that individuals receiving influenza vaccine within the first six months following transplantation would have similar antibody responses and rates of acute rejection to those who had been transplanted up to 24 months ago.

METHODS: As part of a five-year study of influenza antibody response in lung transplant patients, we obtained serum prior to and 2-4 weeks following influenza immunization for each season. The recently transplanted group consisted of individuals who were immunized within six months of transplant date. The control group consisted of individuals who were immunized 6-24 months following transplantation. Influenza vaccine antibody concentrations in serum were measured using hemagglutination inhibition assays. Seroprotection (antibody titer at least 1:40) and seroconversion (four-fold increase in antibody concentration following immunization) rates between the two groups were compared. Rates of acute rejection in months following vaccination for the recently transplanted (November, December, and January) were compared to rates in months distant from vaccination for the control group (June, July, and August).

RESULTS: Seroprotection rates were similar between the two groups (Recently transplanted (n=15) vs. control (n=17) 87-93% vs. 88-94%; not significant (NS); χ^2). Seroconversion rates ranged from 7-33% in recently transplanted and 25-31% in controls (NS; Fisher's exact). Episodes of acute rejection rates were similar between the two groups (4 (27%) recently transplanted group vs. 3 (18%) control group; NS; Fisher's exact).

CONCLUSION: The rates of seroprotection, seroconversion, and acute rejection in the recently transplanted and control group are similar. Lung transplant patients should receive the influenza vaccine each season without regard to time since transplantation.

Women's Health

471. The pharmacokinetics of metoprolol during pregnancy. *Tracy Yep, B.S.¹, Sara Eyal, Ph.D.², Thomas R. Easterling, M.D.³, Danny D. Shen, Ph.D.⁴, Edward J. Kelly, Ph.D.⁴, Gary D.V. Hankins, M.D.⁵, Steve Caritis, M.D.⁶, Linda Risler, B.S.¹, Mary F. Hebert, Pharm.D., FCCP³; (1)University of Washington Department of Pharmacy, Seattle, WA; (2)Institute of Drug Research, Jerusalem, Israel; (3)University of Washington Departments of Pharmacy and Obstetrics & Gynecology, Seattle, WA; (4)University of Washington, Department of Pharmacy, Seattle, WA; (5)University of Texas Medical Branch Department of OB/GYN, Galveston, TX; (6)Magee-Womens Hospital, Pittsburgh, PA*

PURPOSE: The objective of this study was to evaluate the steady-state pharmacokinetics of metoprolol during pregnancy.

METHODS: Plasma and urine concentrations of metoprolol and its metabolite, α -hydroxymetoprolol, were measured in twelve women treated with metoprolol (25-750 mg/day) for therapeutic reasons. Maternal and umbilical cord blood samples were obtained at delivery from 4 mothers and breast milk samples were obtained over one dosing interval in 2 mothers. Pharmacokinetic parameters were assessed by non-compartmental methods.

RESULTS: Metoprolol apparent oral clearance is higher during pregnancy (549±576 L/hr (NS; n=6) mid-pregnancy and 978±702 L/hr ($P<0.05$; n=9) late pregnancy) than in the non-pregnant state (249±132 L/hr (n=6) postpartum). Correspondingly, α -hydroxymetoprolol formation clearance was higher during pregnancy (82.7±122.8 L/hr (NS, n=5) mid-pregnancy and 106.0±75.4 L/hr ($P<0.05$, n=8) late pregnancy) than in the non-pregnant state (13.6±9.0 L/hr (n=6) postpartum). Metoprolol umbilical cord plasma

concentrations ranged between non-detectable and 3.3 ng/mL. Relative infant exposure through breast milk to metoprolol and α -hydroxymetoprolol combined, was less than 2% of the mother's weight-adjusted dose.

CONCLUSION: Metoprolol pharmacokinetics change during pregnancy and the magnitude of change is highly variable. Metoprolol is readily transferred across the placenta, but exposure to metoprolol through breast milk is low. Due to the large gestational changes in metoprolol pharmacokinetics, clinicians should consider using an alternative β -blocker in this patient population.

472. Computer algorithm: a more sensitive tool than standard visual scoring for analyzing immunohistochemistry staining of the placental vasculature.

Michael P. Drozdowicz, Pharm.D., Candidate, 2012¹, Katie Jaenecke, Pharm.D.¹, Andrew Tong, Pharm.D.¹, Albert Franco, M.D.², Daniel Brazeau, Ph.D.³, Nilsa Ramirez, M.D.⁴, Thomas J. Barr, B.S., MBA⁴, William Beyer, BSEE, MSEE⁴, Patty Fan-Havard, Pharm.D.¹; (1)University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Amherst, NY; (2)Carolinas Medical Center, Charlotte, NC; (3)University of New England, Portland, ME; (4)The Research Institute at Nationwide Children's Hospital, Columbus, OH

PURPOSE: The gold standard for interpreting immunohistochemistry (IHC) stains relies on the subjective visual score made by an experienced pathologist. Computer analysis of IHC staining may offer greater sensitivity and reliability in detecting changes in protein expression. The aim of this study is to assess and compare these two techniques in their ability to detect differences in protein expression of β -catenin and VE-cadherin within the placental vasculature.

METHODS: Tissue-micro-arrays were created from cores of placental samples from healthy mothers (control), gestational diabetic mothers (GDM), and mothers being treated for HIV (n=68) and then IHC stained for beta-catenin or VE-cadherin. Fetal capillaries were selected and analyzed for protein staining by a pathologist's visual inspection and Aperio ImageScope positive pixel count algorithm, which respectively yielded a visual score and pixel count that were based on the following scale: 1-negative; 2-weakly positive; 3-positive; and, 4-strongly positive.

RESULTS: Using ANOVA analysis, significant correlations were found between visual score and strong positive pixel count ($p<0.05$) as well as intensity ($p<0.05$) for β -catenin and VE-cadherin. Computer-aided analysis detected significant differences in staining between GDM and control groups for both beta-catenin and VE-cadherin and between HIV and control groups for beta-catenin; visual scores failed to detect these differences.

CONCLUSION: Our preliminary data suggest that while visual scores and Aperio analysis are correlative, the computer-aided quantitative method may be more sensitive in the detection of differences between exposure groups than visual examination by a clinical pathologist.

LATE BREAKERS

ADR/Drug Interactions

473. Clindamycin induced acute kidney injury: Is this for real?

Nidhi Bansal, MBBS, Jiwan Thapa, MBBS; SUNY Upstate Medical University, Syracuse, NY

PURPOSE: Clindamycin is commonly associated with gastrointestinal side effects. There is paucity of literature on its potential renal adverse effects.

METHODS: We report a case of 70 yo man presenting with leg cellulitis. Past medical history was significant for DM2, nephropathy, MRSA infection and left foot ulcers. He recently took oral ciprofloxacin without much response. He was allergic to penicillin and cephalosporins. Thus he was empirically started on clindamycin pending cultures. On day 3, serum creatinine rose to 1.7 mg/dl from baseline of 1.2 mg/dl. There was low grade fever, myalgias, fatigue but no rash/ joint pains and no signs/symptoms of hypovolemia/dehydration. Medications were reconciled to discontinue any offending drugs. By day 5, creatinine rose to 2.2 mg/dl. Urine analysis showed hematuria and pyuria. Differential WBC count revealed eosinophilia. Other urine, blood and radiologic investigations couldn't pinpoint underlying etiology. Repeat medication reconciliation revealed that clindamycin was the only new drug added.

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