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This third issue of the HITH Review for 2008 includes several interesting articles focusing on safety and risks of HITH therapies including a comparison of safety in an elderly and younger cohort of patients, risk factors for nephrotoxicity associated with continuous infusions of vancomycin and the risks associated with outpatient parenteral antibiotic therapy. Several recently published articles from both English and non-English journals that are relevant to HITH are also listed in this edition.

Most of the articles listed in this review are available from libraries in Australia or journal websites. Copies of articles with an asterisk (★) can be requested from ACA if required for educational or research purposes by using the order form available on the website.

We hope you find the HITH Review to be a valuable resource. Any contributions or feedback is welcome.

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Vancomycin Infusions and Risk Factors for Nephrotoxicity

Ingram PR, Lye DC, Tambyah PA, et al. Risk Factors for Nephrotoxicity Associated with Continuous Vancomycin Infusion in Outpatient Parenteral Antibiotic Therapy. *J Antimicrob Chemother* 2008; 62:168-71. ★

Objectives: Continuous vancomycin infusion is increasingly used for outpatient management of infections, but the relationship between vancomycin and nephrotoxicity is controversial. We investigated the risk factors associated with nephrotoxicity in this setting.

Methods: A retrospective cohort study of patients receiving continuous vancomycin infusion as outpatient parenteral antibiotic therapy (OPAT) was performed. The likelihood of developing nephrotoxicity (50% increase in serum creatinine from baseline) was evaluated in relation to demographic variables, underlying co-morbidities, infectious disease diagnoses, concomitant drug exposures and vancomycin concentration. Logistic regression was used to determine the association of various variables. Classification and regression tree analysis was used to determine the most significant breakpoint for continuous variables.

Results: We examined 102 adult patients between January 2004 and June 2007. The mean±SD age, baseline serum creatinine and steady-state vancomycin concentration were 48.2±17.6 years, 78.0 ±32.5 µmol/L and 15.5±10.8 mg/L, respectively. The majority of the patients (66.7%) were treated for bone and joint infection. The cumulative incidence of nephrotoxicity was 15.7%. Nephrotoxicity was found to be associated with hypertension [odds ratio (OR) 5.302 (95% CI 1.159–24.246), P=0.031], exposure to aminoglycosides [OR 6.594, 95% CI 1.026–42.385, P=0.047], loop diuretics [OR 8.123, 95% CI 1.449–45.528, P=0.017], and steady-state vancomycin concentration 28 mg/L [OR 21.236, 95% CI 2.687–167.857, P=0.004].

Conclusions: We have identified independent risk factors for nephrotoxicity in patients receiving

continuous infusion vancomycin in OPAT. A serum steady-state vancomycin concentration 28 mg/L markedly increases the risk.

Comparison of Safety and Efficacy in Younger & Older HITH Patients

Pérez-López J, Laporte ASJ, Pardos-Gea J, et al. Safety and Efficacy of Home Intravenous Antimicrobial Infusion Therapy in Older Patients: A Comparative Study with Younger Patients. *Internat J Clin Pract* 2008; 62:1188-92. ★

Background: Home intravenous antimicrobial infusion therapy has proved its safety and efficacy in a great number of infections. Despite this there are few published studies about this way of managing in the elderly patient.

Objective: To study the safety and efficacy of home intravenous antimicrobial infusion therapy in elderly patients.

Study design: A prospective and comparative study of an elderly group of patients (70 years old) vs. a cohort of younger adult patients as a control group. All patients were followed until 3 months after discharge.

Setting & Patients: All patients admitted to Hospital at Home Programme (HHP), Internal Medicine Department at Valle de Hebrón Hospital, Barcelona, Spain diagnosed of infections requiring intravenous antibiotic therapy between March 2006 - March 2007.

Results: We included 145 patients, 90 of whom were 70 years or older. Diabetes mellitus, heart failure and respiratory tract infection were more frequent in these elderly patients. In this group 14 (12%) developed some type of adverse event during treatment, phlebitis being the most common. The majority of those in the elderly patients group were discharged because of satisfactory clinical evolution and only 7 (7%) were re-admitted to hospital. Another 13 (14%) were re-admitted to hospital 3 months after discharge from HHP, mostly for chronic diseases. There were no significant differences between these results and those obtained from the control group.

Conclusion: Home intravenous antimicrobial infusion therapy in elderly patients is safe and effective.

Identification of Nephrotoxicity Risk

Factors

Gilchrist M, Franklin BD, Patel JP. An outpatient parenteral antibiotic therapy (OPAT) map to identify risks associated with an OPAT service. *J Antimicrob Chemother* 2008; 62:177-83. ★

Objectives: Administering parenteral antibiotics outside the confines of a ward setting is becoming an attractive way of treating infections in the UK. However, as well as having many advantages, an outpatient parenteral antibiotic therapy (OPAT) service potentially introduces new risks to staff and patients involved. In the United States, healthcare organizations are now prospectively analysing processes to try and prevent errors occurring using the Healthcare Failure Mode Effect Analysis (HFMEATM) tool. The objectives of this study were to map out and agree the OPAT process and sub-processes and to identify potential OPAT system failures using steps 1–3 of the HFMEATM tool, so that the resulting OPAT map can be used to design an OPAT service where risk is minimized.

Methods: The study was undertaken using a consensus development panel to which the HFMEATM process was applied. Key stakeholders in the local OPAT process were invited to join the HFMEATM team with the aim of describing and agreeing (defined as 100% participant agreement) an OPAT map, its sub-processes and potential OPAT system failures.

Results: The HFMEATM team identified 6 processes, 67 sub-processes and 217 possible failures over the course of four meetings. Key areas identified in the OPAT map concerned: identifying and checking patient suitability for an OPAT service, involvement of a multidisciplinary team and robust communication channels.

Conclusions: An OPAT map was developed, which may serve as a practical model for other organizations setting up a similar service.

Safety & Efficacy IV Diuretic Therapy for CHF

Ryder M, Murphy NF, Mccaffrey D et al. Outpatient Intravenous Diuretic Therapy: Potential for Marked Reduction in Hospitalisations for Acute Decompensated Heart Failure. *Eur J Heart Failure* 2008; 10:267-72.

Background: Heart failure patients have frequent readmissions for acute decompensated heart failure (ADHF).

Aims: To examine the feasibility, safety and outcomes of outpatient intravenous (IV) diuretic therapy in treating ADHF.

Methods: A retrospective analysis was performed of all patients included in a hospital-based heart failure disease management programme, who received outpatient IV diuretic therapy for the management of ADHF between 2002 and 2006. Changes in clinical and biochemical parameters from time of therapy to stability were measured.

Results: One hundred and seven patients (mean age 71 ± 11 years) received outpatient IV diuretic therapy for ADHF. IV diuretic administration reduced weight ($p < 0.001$), blood pressure ($p < 0.01$) and BNP ($p = 0.01$). It increased urea ($p = 0.01$) and creatinine ($p = 0.07$). Seventy-two percent of patients stabilised following IV diuretics and did not require admission. No patients were hospitalised for hypotension or hypokalaemia. One patient was hospitalised for renal failure. Two patients died post admission.

Conclusion: Outpatient IV diuretic administration for ADHF is safe, cost effective and reduces hospitalisations. This service may expand the potential of a disease management programme to manage ADHF out of hospital and thereby reduce the hospital dependency of this condition.

Safety & Efficacy of IV Nesiritide in CHF

Yancy CW, Krum H, Massie BM. Safety and Efficacy of Outpatient Nesiritide in Patients With Advanced Heart Failure Results of the Second Follow-Up Serial Infusions of Nesiritide (FUSION II) Trial. *Circ Heart Failure* 2008; 1:9-16. ★

Background: Patients with American College of Cardiology/American Heart Association stage C/D heart failure experience substantial morbidity and mortality, but available interventions beyond standard medical and device therapies are limited. Nesiritide relieves dyspnea and reduces pulmonary congestion, but its risk profile is uncertain. Pilot data suggested a potential benefit of nesiritide given as serial outpatient infusions.

Methods and Results: The Second Follow-Up Serial Infusions of Nesiritide (FUSION II) trial was a randomized, double-blind, placebo-controlled trial of outpatient serial nesiritide infusions for patients with stage C/D heart failure. Patients with 2 recent heart failure hospitalizations, ejection fraction <40%, and New York Heart Association class IV symptoms, or New York Heart Association class III symptoms with creatinine clearance <60 mL/min, were randomized to nesiritide (2-µg/kg bolus plus 0.01-µg/kg-per-minute infusion for 4 to 6 hours) or matching placebo, once or twice weekly for 12 weeks. All patients were treated to optimal goals with evidence-based medical/device therapy facilitated by careful disease management during the study. The primary end point was time to all-cause death or cardiovascular or renal hospitalization at 12 weeks. A total of 911 patients were randomized and treated. The primary end point occurred in 36.8% and 36.7% of the placebo and nesiritide groups, respectively (hazard ratio, 1.03; 95%CI, 0.82 to 1.3; log-rank test P=0.79). There were no statistically significant differences between groups in any of the secondary end points, including the number of cardiovascular or renal hospitalizations, the number of days alive and out of the hospital, change in Kansas City Cardiomyopathy Questionnaire score, or cardiovascular death. Adverse events were similar between groups; nesiritide was associated with more hypotension but less predefined worsening renal function.

Conclusions: Serial outpatient nesiritide infusions do not provide a demonstrable clinical benefit over intensive outpatient management of patients with advanced American College of Cardiology/American Heart Association stage C/D heart failure

Outpatient IV Therapy vs Oral Linezolid

Stein GE, Schooley SL, Havlichek DH, Nix DE. Outpatient Intravenous Antibiotic Therapy Compared With Oral Linezolid in Patients With Skin and Soft Tissue Infections: A Pharmacoeconomic Analysis. *Infectious Dis Clin Pract* 2008; 16: 235-9.

Background: In patients with skin or soft tissue infections that do not require hospitalization, the choice between oral therapy and outpatient parenteral antimicrobial therapy (OPAT) depends on several factors. Oral linezolid is an effective antibiotic for skin

or soft tissue infections and may be a suitable alternative to OPAT in this patient population.

Objective: The aim of the study was to analyze the potential cost-effectiveness of oral linezolid compared with OPAT in adult patients with moderately severe skin or soft tissue infections referred to a hospital-based infusion center.

Methods: Twenty patients with skin or soft tissue infections referred to an infusion center for OPAT were enrolled into a prospective, randomized, pilot clinical trial comparing OPAT to oral linezolid. Patients received their prescribed intravenous antibiotic (normal care group) or oral linezolid (600 mg every 12 hours) for a duration decided by their primary or emergency department physician and followed up for 4 weeks. Outcome measures recorded for the economic analysis included all clinic, emergency department, wound care, and infusion center visits as well as hospitalizations. Any additional medical care, including the number of doses of all antibiotics, was documented for each subject. The costs of care were standardized using Medicare reimbursement payments.

Results: Most infections in each group involved cellulitis of the abdomen or the lower extremities. In the 10 patients who received OPAT, 2 received no additional antibiotics, 4 received additional oral therapy, and 4 were subsequently hospitalized due to lack of improvement. In the 10 patients who received linezolid, 9 were cured and 1 patient received additional oral antibiotics. None of these patients were hospitalized, but 3 received outpatient wound care. The costs for care in this pilot study, based on Medicare reimbursement payments, would average \$1855 in the OPAT group compared with \$1038 in patients who received oral linezolid.

Conclusions: Oral linezolid can be a cost-effective alternative to OPAT in patients with skin or soft tissue infections, but its use could shift a significant amount of cost for care to the patient.

Paediatric Cellulitis

Gouin S, Chevalier I, Gauthier M, Lamarre V. Prospective Evaluation of the Management of Moderate to Severe Cellulitis with Parenteral Antibiotics at a Paediatric Day Treatment Centre. *J Paediatr Child Health* 2008; 44: 214-8. ★

Aim: To assess the clinical outcome of patients with moderate to severe cellulitis managed at a paediatric day treatment centre (DTC).

Methods: Prospective observational study of all patients (3 months to 18 years) with a presumed diagnosis of moderate to severe cellulitis made in a university-affiliated paediatric emergency department (ED) (September 2003 to September 2005). Patients treated at the DTC were given ceftriaxone or clindamycin.

Results: During the study period, a presumed diagnosis of moderate to severe cellulitis was made in 224 patients in the ED. Ninety-two patients were treated at the DTC (41%). The cellulitis had a median width of 7.0 cm (range: 1.0-50.0 cm) and a median length of 6.5 cm (range: 1.0-40.0 cm). Blood cultures were performed in 95.7%; one was positive for *Staphylococcus aureus*. After a mean of 2.5 days of intravenous therapy (first injection in the ED and a mean of 1.5 days at the DTC), 73 patients (79.3%) were successfully discharged from the DTC and switched to an oral agent. For these patients no relapse occurred. Nineteen patients (20.7%) required inpatient admission for further therapy. No patient was diagnosed with necrotizing fasciitis in the course of therapy. Seventy-eight satisfaction questionnaires were handed in and 94.8% revealed very good to excellent parental satisfaction with treatment at the DTC.

Conclusion: Treatment with parenteral antibiotic at a DTC is a viable alternative to hospitalisation for moderate to severe cellulitis in children.

Diabetic Foot Infections

Esposito S, Leone S, Noviello S, et al. Foot infections in diabetes (dfis) in the out-patient setting: an Italian multicentre observational survey. *Diabetic Med* 2008; 25:979-84. ★

Aims: A multicentre observational study was undertaken to describe the management of foot infections in diabetes in the out-patient setting in Italy.

Patients and methods: Ten centres equally distributed nationwide were asked to collect, by means of a spreadsheet (Access/Excel Microsoft program), data concerning 30 consecutive diabetic patients with foot infections deemed suitable for antibiotic treatment

in the out-patient setting. Centres with = 5 years' experience of out-patient management were selected. Data from 271 consecutive patients treated as out-patients were collected and analysed by the central coordinator. Statistical analysis was performed using the SPSS statistical software package.

Results: Lesions were mainly located at the toes and midfoot (33.6 and 30.2%, respectively); 63 (23.2%) patients had multiple ulcers. Seventy (25.8%) patients also had concomitant osteomyelitis. Three hundred and four pathogens, including Gram-positive and Gram-negative aerobes and anaerobes, were isolated in 219/271 patients (80.8%) by culturing debrided tissue (71.2%) or purulent material (28.8%). Infections were polymicrobial in 33.8% of patients. The most common pathogens were *Staphylococcus aureus* (27.3%) and *Pseudomonas* spp. (20.4%); enterobacteriaceae, enterococci, streptococci and anaerobes accounted for 11.5, 7.6, 6.9 and 1.9%, respectively. Antibiotics were frequently administered by parenteral route and frequently in combination. Piperacillin/tazobactam was the parenteral antibiotic most frequently utilized (21.1%). Cure/improvement was observed in 93.4% of patients.

Conclusions: Foot ulcers in diabetes are common and serious; the aetiology is often polymicrobial, often including *S. aureus* and *Pseudomonas* spp. Treatment in the out-patient setting is safe and effective, and penicillins together with β -lactamase inhibitors and fluoroquinolones are the most frequent choice.

List of Medline, Cinahl and other relevant published articles

Adverse Effects

Sharma NS, Masselos K, Hooper MJ, al e. Zoledronic Acid Infusion and Orbital Inflammatory Disease [Letter]. *N Engl J Med* 2008; 359:1410-1. ★

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Miscellaneous

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Potential New Therapies

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Self-Administration

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Thrombosis

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