mol considering pain relief, pain intensity difference, patient’s global treatment satisfaction and between intravenous paracetamol and metamizole on pain scores and pain scores on coughing. Intravenous paracetamol had safety profile similar to placebo. Adults treated with intravenous paracetamol had 9 times lower risk of adverse events (RR = 0.11; 95%CI: 0.05–0.24) and 30 times lower risk of infusion site reactions (RR = 0.03; 95%CI: 0.01–0.16), comparing with propacetamol.

CONCLUSIONS: Intravenous paracetamol is an effective drug in postoperative pain management in children and adults as superior to oral paracetamol and metamizole, with better safety profile.

PPN2

META-ANALYSIS OF DULOXETINE VS. PREGABALIN AND GABAPENTIN IN THE TREATMENT OF PERIPHERAL DIABETIC NEUROPATHIC PAIN

Quilici S1, Chancellor J1, Lothgren M2, Simon D3, Said G4, Le TK5, Garcia-Cebrian A6, Monz B7, Kajdasz D6
1Innovus, Uxbridge, Middlesex, UK, 2La Pitié-Salpêtrière Hospital, Paris, France, 3Hôpital de Bicêtre, Le Kremlin-Bicêtre, France, 4Eli Lilly, Indianapolis, IN, USA, 5Eli Lilly and Company Limited, Basingstoke, UK, 6Boehringer Ingelheim GmbH, Ingelheim, Germany

OBJECTIVE: To compare the efficacy and tolerability of duloxetine (DLX) with pregabalin (PGB) and gabapentin (GBP) for the treatment of diabetic peripheral neuropathic pain (DPNP).

METHODS: We searched PubMed, Ovid, CENTRAL databases and regulatory websites for randomized, double-blind, placebo-controlled, parallel group or crossover clinical trials (RCTs) assessing DLX, PGB and GBP in DPNP. Study arms using approved dosages with assessments after 5–13 weeks were eligible. Efficacy criteria were: reduction in 24-hour pain severity (24hPS) for all three drugs, and response rate (50% pain reduction) and Patient’s Global Impression of Improvement/Change (PGI-I/C) for DLX and PGB only. Tolerability criteria were: discontinuation, diarrhoea, dizziness, headache, nausea and somnolence. Pooled fixed- and random-effects analyses were conducted on endpoints reported in at least two studies of each drug. Each drug was compared with placebo. DLX was compared indirectly with PGB and GBP by meta-regression.

RESULTS: Three studies of DLX, 6 of PGB and 2 of GBP were eligible. Between-study heterogeneity was insignificant. In random-effects and fixed-effects analyses, all drugs were superior to placebo for all efficacy parameters, with some tolerability trade-offs. Direct comparison of DLX with PGB found no differences in 24hPS, but significant differences in PGI-I/C, favouring PGB, and dizziness, favouring DLX were apparent. Comparing DLX and GBP, there were no statistically significant differences. CONCLUSIONS: From the few studies available for indirect comparison, DLX shows comparable efficacy and tolerability to GBP and PGB in DPNP. Duloxetine provides an important treatment option for this disabling condition.

PPN3

SAFETY OF INTRAVENOUS FORMULATIONS OF METAMIZOLE, KETOPROFEN AND PARACETAMOL—ANALYSIS OF DATA FROM WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

Golicki D1, Niewada M1, Grykier K2, Sciborski C2
1Medical University of Warsaw, Warsaw, Poland, 2Bristol-Myers Squibb, Warsaw, Poland

OBJECTIVES: Comparison of safety of intravenous metamizole, ketoprofen and paracetamol based on data from WHO Programme for International Drug Monitoring.

RESULTS: The data from countries participating in the World Health Organization Programme for International Drug Monitoring are collected and maintained, on behalf of the WHO, by the Uppsala Monitoring Centre, in the Vigibase. An analysis of data on adverse events (AE) of intravenous formulations of metamizole, ketoprofen and paracetamol, reported to Vigibase, from European countries since 1968 up to 29th January 2006 (ref: ER 132/2005), was performed. RESULTS: One thousand three hundred seventy five individual case reports of metamizole adverse events were registered in the Vigibase, compared to 367 and 69 for ketoprofen and paracetamol, respectively. Serious AE were reported in 29 metamizole cases, 47—ketoprofen and none for paracetamol. There were 15 death cases registered for metamizole, 1 for ketoprofen and paracetamol. Hematologic disorders were reported in 187 metamizole cases, i.e. 6 and 31 times more common then for ketoprofen and paracetamol therapy, respectively. Most frequent AE reports for metamizole were: anaphylactic shock (79 cases versus 6 and 3 with ketoprofen and paracetamol, respectively), agranulocytosis (77 vs 3 vs 1), rash erythematous (63 vs 26 vs 3), hypotension (54 vs 6 vs 3), pruritus (53 vs 10 vs 1), rash (51 vs 17 vs 0), leucopenia (48 vs 6 vs 2) and circulatory failure (48 vs 5 vs 2). CONCLUSIONS: Intravenous therapy with paracetamol is safer than with ketoprofen or metamizole, concerning total number of reported adverse events, number of reported serious adverse events and number of hematologic disorders. Death cases were reported 15 times more often with metamizole than with either paracetamol or ketoprofen.

ECONOMIC EVALUATION COMPARING BMP-2 (INDUCTOSTM) VERSUS CURRENT TREATMENT IN CHRONIC LOWER BACK PAIN IN THE SPANISH SETTING

Serrano D1, Rodríguez J2, Lizan L3, Poyatos J4, Chhabra A5
1Medtronic Iberica S.A, Madrid, Spain, 2Medtronic Iberia, Madrid, Spain, 3Universidad Jaume I, Castelló de la Plana, Spain, 4Hospital General de Castellón, Castellón de la Plana, Spain, 5Medtronic Europe SA, Tolochenaz, Switzerland

OBJECTIVE: To evaluate the potential economic benefits of InductOs® compared to autograft, in spinal fusions in patients with DDD in Spain.

METHODS: An analytic decision tree model was developed in order to simulate the clinical pathways of a cohort of 1000 simulated patients with DDD. The analysis was performed from the perspective Spanish National Health System (payer), with a time horizon of 2 years. Clinical and economical data were retrieved from published studies and official tariffs, validated by a clinician trained in the management of these patients in the Spanish setting. RESULTS: In Spain, the use of InductOs® leads to a reduction in operation times and length of stay resulting in savings of €930 per patient, to a reduction of revisional spinal procedures resulting in further savings of €428 per patient, and to a faster return to work by an average of 54 days, resulting in additional savings of €2304 per patient from sickness-leave payments avoided. These savings offset the upfront cost of InductOs® of 2799 resulting in net cost savings of €863 per case treated, as compared to standard care. CONCLUSION: Adding

PPN4

SAFETY OF INTRAVENOUS FORMULATIONS OF METAMIZOLE, KETOPROFEN AND PARACETAMOL—ANALYSIS OF DATA FROM WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

Golicki D1, Niewada M1, Grykier K2, Sciborski C2
1Medical University of Warsaw, Warsaw, Poland, 2Bristol-Myers Squibb, Warsaw, Poland

OBJECTIVES: Comparison of safety of intravenous metamizole, ketoprofen and paracetamol based on data from WHO Programme for International Drug Monitoring. METHODS: The data from countries participating in the World Health Organization Programme for International Drug Monitoring are collected and maintained, on behalf of the WHO, by the Uppsala Monitoring Centre, in the Vigibase. An analysis of data on adverse events (AE) of intravenous formulations of metamizole, ketoprofen and paracetamol, reported to Vigibase, from European countries since 1968 up to 29th January 2006 (ref: ER 132/2005), was performed. RESULTS: One thousand three hundred seventy five individual case reports of metamizole adverse events were registered in the Vigibase, compared to 367 and 69 for ketoprofen and paracetamol, respectively. Serious AE were reported in 29 metamizole cases, 47—ketoprofen and none for paracetamol. There were 15 death cases registered for metamizole, 1 for ketoprofen and paracetamol. Hematologic disorders were reported in 187 metamizole cases, i.e. 6 and 31 times more common then for ketoprofen and paracetamol therapy, respectively. Most frequent AE reports for metamizole were: anaphylactic shock (79 cases versus 6 and 3 with ketoprofen and paracetamol, respectively), agranulocytosis (77 vs 3 vs 1), rash erythematous (63 vs 26 vs 3), hypotension (54 vs 6 vs 3), pruritus (53 vs 10 vs 1), rash (51 vs 17 vs 0), leucopenia (48 vs 6 vs 2) and circulatory failure (48 vs 5 vs 2). CONCLUSIONS: Intravenous therapy with paracetamol is safer than with ketoprofen or metamizole, concerning total number of reported adverse events, number of reported serious adverse events and number of hematologic disorders. Death cases were reported 15 times more often with metamizole than with either paracetamol or ketoprofen.
InductOs® to the standard care in CLBP is a cost saving strategy in the Spanish setting.

STROKE

BUDGETARY IMPACT ANALYSIS OF RECOMBINANT ACTIVATED FACTOR VII IN THE TREATMENT OF INTRACEREBRAL HEMORRHAGE: A US HEALTH PLAN PERSPECTIVE

Earnshaw SR1, Wilson MR1, Joshi AV2
1RTI Health Solutions, Research Triangle Park, NC, USA, 2Novo Nordisk, Inc, Princeton, NJ, USA

OBJECTIVES: Intracerebral hemorrhage (ICH) is among the most costly and debilitating forms of stroke. Results from a recent Phase IIb clinical trial demonstrate that administration of recombinant activated factor VII (rFVIIa) reduces ICH mortality and improves functional outcome. The objective is to examine the health plan budget impact of introducing rFVIIa as a novel treatment for ICH. METHODS: A decision-analytic model was adapted to estimate the budget impact of introducing rFVIIa (40, 80, or 160 μg per kilogram) for treatment of ICH, from a US managed care perspective. The patient population was similar to that of the Phase IIb clinical trial. Model structure and inputs were obtained from published literature, clinical trial data, managed care claims databases, and expert opinion. All costs are presented in 2005 US dollars. Costs and outcomes were discounted at 3 percent annually. Univariate sensitivity analyses were conducted to assess model robustness. RESULTS: Assuming a health plan of 1,000,000 members and an initial 30% uptake of rFVIIa, the annual health plan cost is expected to increase by between $38,868 and $279,057, or between $0.003 and $0.023 per member-month, depending on dose of rFVIIa used. Assuming use of rFVIIa 80 μg/kg dose and an absolute 5% increase in uptake each year (i.e., 55% patients receiving rFVIIa 80 μg/kg 5 years post introduction), the change in a health plan’s annual cost is expected to be $-65,778 (cost savings) compared to the current year’s budget at 5 years after rFVIIa introduction.

RESULTS: Treating eligible patients with rFVIIa improves survival and functional outcome. Impact to a health plan’s budget is modest in the first year after introduction to the market. In addition, due to expected improvements in health outcomes, a decrease in budget impact may be observed using rFVIIa 80 μg/kg as early as 3 years post introduction.

STROKE PATIENT RESOURCE USE AND CAREGIVER BURDEN OUTCOMES BY SEVERITY (RECOVERY) STUDY: METHODS AND PRELIMINARY GERMAN RESULTS

Payne K1, Caro J2, Proskorovsky I3, Lordan N4, Huybrechts KP5, Ishak KJ1, Rylander A1, Kolominsky-Rabas P1
1Caro Research Institute, Montreal, QC, Canada, 2Caro Research Institute, Concord, MA, USA, 3AstraZeneca R&D Sodertalje, Sodertalje, Sweden, 4Interdisciplinary Center for Public Health Studies, University of Erlangen-Nuremberg, Erlangen, Germany

OBJECTIVES: To evaluate the relation between post-stroke physical disability and place of residence (home vs long-term care facility), and, secondarily, between disability and other economic, quality of life and caregiver burden outcomes. METHODS: Randomly selected Erlangen Registry ischemic stroke patients, 18 years of age or older, still alive at least 90 days post stroke and willing to attend a study visit were administered a 30-day retrospective resource use questionnaire, the EQ-5D, the Stroke Impact Scale (SIS-16), Modified Rankin Scale (mRS), and Barthel Index; caregivers reported resource use and hours of informal care. Stroke history was obtained from registry records. Multivariate logistic and linear regressions were used to examine the associations. Preliminary results are reported for the first 200 of the planned 360 subjects. RESULTS: At a mean time post stroke of 4 years (min 0.26—max 11.88 years), 14.5%, 25%, 25%, 13%, 7.5%, and 15% of subjects (49.5% male; mean age 74.3 years) had mRS scores of 0, 1, 2, 3, 4, and 5, respectively. At the study visit, 72% of patients were residing at home, and 28% were residing in a long-term care facility. The probability of residing in long-term care was significantly higher in patients with severe disability (mRS = 3,4,5) vs mild/moderate disability (mRS = 0,1,2) (adjusted for age, sex, and time since index stroke; OR = 14.8, p < 0.0001). Over the previous 7 days, 96% of caregivers of severely disabled subjects cared for at home vs 30% of caregivers of the mildly/moderately disabled patients at home reported ≥1 hour of informal care (p < 0.001); mean informal care time received by patients with severe disability was 26.6 hours; patients with mild/moderate disability received 6.6 hours (p < 0.001). CONCLUSIONS: Results suggest post-stroke impairment remains an important determinant of place of residence and caregiver burden well beyond the acute care period, outcomes which translate into significant additional costs.

RESOURCE UTILIZATION AND COSTS OF STROKES IN A THIRD LEVEL HOSPITAL IN MÉXICO

Carabajal A1, Soto H1, Salazar J2, Zanela O3, Talavera J4
1Hospital de Especialidades, IMSS, Delegacion Cuauhtemoc, Mexico D.F, Mexico, 2Universidad del Estado de Mexico, Toluca, Edo de Mexico, Mexico, 3Hospital de Especialidades, IMSS, Delegacion Cuahtemoc, Mexico D.F, Mexico, 4Universidad del Estado De Mexico, Toluca, Estado de Mexico, Mexico, 5Hospital de especialidades, IMSS, Delegacion Cuahtemoc, Mexico D.F, Mexico

OBJECTIVE: To estimate resource utilization and economic costs of a stroke in Specialty Hospital (SH) of XXI Century National Medical Center (CMNNXXI, in Spanish). METHODS: Data from stroke-diagnosed patients who received medical assistance in SH between 2003–05 were retrospectively collected, with the following inclusion criteria: 1) assistance with <24 hours after first symptoms, 2) CAT or magnetic resonance-confirmed stroke, and 3) >45 years old. The Barthel index was used to assess clinical status. Costs were estimated from the hospital perspective using a bottom-up approach, and only direct medical costs were estimated (hospitalization, treatment, laboratory tests, specialist visit, surgery). Clinical data and resource utilization were obtained from individual clinical. The unitary costs used are those officially published by Mexican Social Security institute (IMSS). A 3% discount rate was used, and prices were adjusted as to February 2006. Results are shown either as mean-standard (SD) or median-range and multivariate analysis test were applied. Sensitivity analyses included variation of the resource use frequency assumptions, percent complicated patients and cost inputs. RESULTS: 88 patients were included, Male 63.64%, age 55.59 (18.68), Mortality were 19.32%. More resources were utilized for complicated patients compared to non-complicated in CAT (1.68 vrs 1.12, p = 0.006), thorax Rx (3.19 vrs 1.44, p = 0.002), angiography (0.41 vrs 0.19, p = 0.04) and days of hospitalization (15 vrs 8.4, p = 0.0019). Total stroke costs were MXN$103,493 ($101,783.2,median = $66,789.15, range $20,158–$501,685.2), 62.36% of total costs were due to hospitalization. Per-patient costs for a complicated and non-complicated stroke were $151,308 and $69,926.03, respectively (p < 0.0015). Sensitivity analysis highlighted the model's sensitivity to the percent complicated patients and cost inputs. CON-