

Clinical pharmacy and clinical trials

Background Despite the expanding knowledge base, much remains to be understood about effective treatments to treat the many symptoms of anti-NMDA receptor encephalitis (anti-NMDA RE).

Purpose To describe the treatment options for a case of refractory status epilepticus associated with non paraneoplastic anti-NMDA RE.

Materials and Methods Revised drug-treatment history of the patient.

Results A 22-year-old woman with a family history of epilepsy and an arteriovenous malformation (AVM) of the brain, presented a generalised tonic-clonic without clear focal onset and post-critical confusion. She was in non-convulsive status epilepticus.

Treatment was initiated with various intravenous drugs during the 50 days of the status: diazepam, phenytoin, valproic acid, levetiracetam, clonazepam, midazolam, propofol, lacosamide, ketamine, and lidocaine.

It was decided to proceed with induction of barbiturate coma three times, requiring supratherapeutic doses in the second one. Oxcarbazepine was administered via feeding tube.

With these treatments, momentary remission status was achieved although epileptiform activity reappeared when the pharmacological effect expired.

Thirty days after admission, it was decided to repeat computed tomography for development of AVM and investigate again whether the cerebrospinal fluid was positive for anti-NMDA. This being the case, treatment was initiated with methylprednisolone and immunoglobulins.

She continued with clinical status, but electrical brain activity began to fade at the same time that the patient was starting to tolerate enteral nutrition and so oxcarbazepine possibly began to be absorbed.

After discontinuing sedation the patient awoke and opened her eyes. Electroencephalogram was repeated and epileptiform activity had disappeared completely. Facial dyskinesias were treated with clonazepam.

Conclusions Whereas the best treatment approach for anti-NMDA RE encompasses a combination of immunotherapy, intensive care, and rehabilitation, there is a dearth of information regarding management of psychiatric and behavioural symptoms [1]. The possibility of resolving the status by oxcarbazepine gavage opens a window into the use of drugs by this route in the event of failure of standard treatment.

Reference

1. Sansing LH, Tütün E, Ko MW, Bacon J, Lynch DR, Dalmau J. A patient with encephalitis associated with NMDA receptor antibodies. *Nat Clin Pract Neurol.* 2007 May;3(5):291–6.

No conflict of interest.

CPC-141 TOLERABILITY AND SAFETY OF CARBOPLATIN-BASED CHEMOTHERAPY IN A HEMODIALYSIS PATIENT WITH BREAST CANCER

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Background The oncology pharmacist was consulted about the neoadjuvant carboplatin-based chemotherapy regimen for a 59-year-old woman with triple negative stage IIA breast cancer and stage 4 chronic kidney disease. She was undergoing haemodialysis three times a week, on a Tuesday-Thursday-Saturday schedule. The chemotherapy regimen was docetaxel 75 mg/m² IV D1, carboplatin AUC 5 IV D1, Q21D, 6 cycles. The major dose-limiting toxicity of carboplatin is myelosuppression, especially thrombocytopenia. As carboplatin is eliminated mainly through the kidneys, dosage

adjustment and timing is required for patients with impaired renal function to prevent severe hematologic toxicity. Carboplatin is removed by haemodialysis.

Purpose To examine the tolerability and safety of carboplatin-based chemotherapy and the applicability of the Calvert formula in a haemodialysis patient with localised breast cancer.

Materials and Methods We reviewed the literature on the pharmacokinetics, efficacy, tolerability and dosage adjustment of carboplatin. In patients on chronic haemodialysis, the issue is how to evaluate the glomerular filtration rate (GFR) in the Calvert formula. We planned the administration of chemotherapy on a non-dialysis day and the following haemodialysis session to occur 24 hours afterwards. The GFR value was assumed to be 0 mL/min and the carboplatin dose calculated was 125 mg.

Results The first two chemotherapy cycles were found to be safe and well tolerated. Neither neutropenia nor thrombocytopenia occurred. After the first cycle, absolute neutrophil nadir count was 5.51 10³/mcL and platelet nadir count was 238 10³/mcL. Neither allergic or hypersensitivity reactions nor delayed nausea or vomiting occurred. CTCAE grade 3 diarrhoea was controlled with loperamide. Furthermore, a significant reduction in the tumour size was attained.

Conclusions Dosage adjustment and timing of carboplatin-based chemotherapy can result in a safe and well-tolerated preoperative treatment option in a haemodialysis patient with localised breast cancer.

No conflict of interest.

CPC-142 TOLERANCE TO THE BEAM PROTOCOL BEFORE AUTOLOGOUS HEMATOPOIETIC STEM CELLS TRANSPLANTATION IN CHILDREN TREATED FOR HODGKIN'S LYMPHOMA

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Background Patients with Hodgkin's lymphoma and refractory to the first line of treatment or in relapse, received the BEAM conditioning regimen (carmustine, etoposide, cytarabine, melphalan) followed by transplantation of hematopoietic stem cells.

Purpose To define the characteristics of patients who received this protocol, evaluate its effectiveness, and analyse the tolerance in relation to the carmustine, a cytotoxic agent responsible for many side effects.

Materials and Methods We conducted a retrospective study on patients who received this treatment between January 2001 and September 2011 in the paediatric haematology oncology ward. A data collection document was created to list the patients' characteristics and information related to the protocol (tolerance, efficacy and previous chemotherapy).

Results 14 children with Hodgkin's lymphoma aged between 5 and 17 were given BEAM protocol transplantation conditioning after a relapse (79%) or after tumoural progression during the previous chemotherapies (21%).

Following the BEAM protocol treatment, the overall remission rate was 57%.

Carmustine treatment led to adverse effects in 66% of patients during the infusion. During the 3 months after the transplantation, the main adverse effects were digestive disorders, fever and hematemesis. In the longer term, various pulmonary disorders were observed (pneumonia, pulmonary tuberculosis, breathlessness on exertion, etc.).

Conclusions This protocol resulted in remission in approximately two thirds of the cases regardless of the disease stage. The overall

tolerance was relatively good, despite some severe pulmonary damage probably related to the toxicity of the carmustine.

In view of these results, the BEAM protocol could be used widely in children with relapsed or refractory Hodgkin's lymphoma.

No conflict of interest.

CPC-143 TRABECTEDIN FOR METASTATIC SOFT TISSUE SARCOMA – A RETROSPECTIVE ANALYSIS

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Background Soft tissue sarcomas (STSs) are rare tumours arising from connective tissues characterised by high morphologic and biologic heterogeneity, as well as by limited responsiveness to cytotoxic chemotherapeutic agents. Trabectedin was approved in 2007 for patients with advanced STS after failure of anthracyclines and ifosfamide, or for patients unsuited to receive these agents.

Purpose To obtain basic epidemiological information on patients with soft tissue sarcomas, standard treatment procedures and results of trabectedin treatment in clinical practise.

Materials and Methods This retrospective study analysed 31 STS patients treated with trabectedin between January 2009 and September 2012. A retrospective cohort study of all patients with a diagnosis of STS treated with trabectedin 1.5 mg/m², D1, 24 hours' continuous IV infusion, every 3 weeks. Toxicity was evaluated using Common Terminology Criteria for Adverse Events (CTCAE). Progression-free survival curves (PFS) and Overall Survival (a 95% confidence interval was used) were estimated by using the Kaplan-Meier method.

Results Median age at the initiation of trabectedin therapy was 52 years (18–79 years).

Leiomyosarcoma was the most frequent tumour (25.8%) and liposarcoma occurred in 16.2% of the patients.

Median number of cycles administered was 6.7 (2–16 cycles).

Thrombocytopenia, leukopenia (16.1% of patients), asthenia (12.9%) and elevation of liver transaminases (9.7% of patients) were the most frequent adverse effects.

Nine patients achieved a partial remission (PR) and in 3 the disease stabilised (SD).

Median overall survival (95% CI) was 6.0 months (0.8; 36.1), median progression-free survival (PFS) (95% CI) was 11.48 months.

PFS for all patients was 90.3% at three months and 79.0% at six months.

Conclusions Our results indicate that trabectedin shows promise as an effective and tolerable new drug for the treatment of patients with STSs.

No conflict of interest.

CPC-144 TRACING THE RE-EVALUATION OF ANTIBIOTICS AT 48–72 HOURS: IT IS NOT AUTOMATIC...

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Background In our hospital, the medication system is totally managed by computers. When physicians sign the computerised prescription, an electronic sheet must be completed for controlled antibiotics. In 2011, pharmacists created a specific second part on the sheet about re-evaluating the antibiotic. Physicians can complete it 72 hours after initiation of empirical treatments as indicated in the recommendations.

Purpose To evaluate the traceability of the re-evaluation of the antibiotic in the paper medical records and in the electronic antibiotics sheets. The results were compared with an audit conducted in 2010 of the re-evaluation in the paper medical records.

Materials and Methods An audit grid was created to assess the traceability of the re-evaluation, the changes of antibiotic treatment after re-evaluation and re-evaluation deadlines.

Results Of 50 medical records audited in the 5 hospital units, 12 were excluded because patients were hospitalised for less than 72 hours. 94.7% of empirical treatments were re-evaluated, 73.5% of them before 72 hours (84% in 2010 and 90.7% of them before 72 hours). Physicians noted the re-evaluation in 58.3% of paper medical records (38.1% explicit re-evaluation, 61.9% implicit) versus 52% in 2010 (36.4% explicit re-evaluation, 63.6% implicit). 100% of electronic antibiotics sheets were completed: 25% by physicians and 75% by the pharmacist after calling the physicians. The re-evaluation led to treatment modification in 41.7% of the patients: change of the prescribed antibiotic (33.3%), change route of administration (26.7%), termination of treatment (20%), adding another antibiotic (20%).

Conclusions The rate of re-evaluation on paper medical records wasn't significantly different to the result from a first audit conducted in 2010. Thanks to the pharmacists' involvement, traceability on electronic sheets is being noted correctly. The results will be passed on to the hospital antibiotics committee. Improvements will be proposed for better multidisciplinary collaboration between bacteriologists, pharmacists and physicians.

No conflict of interest.

CPC-145 TREATMENT OF CUTANEOUS CALCIPHYLAXIS WITH SODIUM THIOSULFATE: A CASE REPORT

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Background Calciphylaxis is a rare and potentially life-threatening condition. It is thought to result from arterial calcification causing complete vascular occlusion and subsequent cutaneous infarction. Most often, it is a complication of end-stage renal failure or hyperparathyroidism. This condition may be present in up to 4% of end-stage renal disease patients. The clinical picture is typically characterised by very painful skin lesions and ulcerations following calcification and occlusion of small cutaneous arterioles. Recently some evidence supports the use of intravenous sodium thiosulfate (STS) (Hayden M.R. et al, Calciphylaxis: calcific uremic arteriolopathy and the emerging role of sodium thiosulfate, Int Urol Nephrol 2008;40:443–451)

Purpose This abstract focuses on a case report of calciphylaxis successfully resolved with IV STS, as randomised controlled studies on STS efficacy are lacking.

Materials and Methods We report a case of calciphylaxis in a 77-year-old white woman with CKD. The acute presentation was seemingly precipitated by a high calcium-phosphorus product. As the patient was already taking bisphosphonates and phosphate binders, STS was suggested as a good treatment alternative. STS was administered intravenously using 25 g diluted in 100 cc of normal saline during dialysis.

Results The calciphylaxis episode was related to a high calcium-phosphorus product ($P^*Ca = 73$), besides a high increase of parathyroid hormone (800 pg/ml). Clinical signs included cutaneous infarction and pain (photo is included). Four months after the initiation of STS injuries began to improve (photo is included) and the P^*Ca was reduced but still remained high ($P^*Ca = 60$). The parathyroid hormone level continued the same. The patient is still on IV STS treatment.