New Drug: Cyclizine lactate
Approved indication: prevention of postoperative nausea and vomiting
Valoid (Link Medical Products) ampoules containing 50 mg/1 mL for injection

Australian Medicines Handbook section 1.2.1
About a third of patients will develop postoperative nausea and vomiting if they are not given prophylaxis. It is more common in women, especially after abdominal surgery. Cyclizine, an antihistamine, is already being used (tablets and injectable solution) as an antiemetic after surgery in Australia. However, the solution for injection has only recently been approved by the Therapeutic Goods Administration.
A Cochrane review of antiemetics analysed 10 studies of parenteral cyclizine. The trials were mainly in women having surgery (caesarean, laparoscopy), except for one study in boys. An analysis of these studies found that cyclizine decreased the risk of nausea by 65% and vomiting by 55%, compared to placebo. Overall, cyclizine’s antiemetic effect was comparable to ondansetron. However in the study of boys having surgery for hypospadias, cyclizine was no better than placebo.
In a trial not included in the review, cyclizine was compared to droperidol in patients administering their own analgesia after surgery. Thirty women were randomised to receive cyclizine or droperidol during surgery and then after, intravenously, with patient-controlled morphine. Nausea scores were comparable between treatments, with three patients in each group needing extra antiemetics.
Cyclizine has also been used in combination with other antiemetics. Before anaesthesia, 960 women undergoing day surgery were given intravenous cyclizine 50 mg, intravenous granisetron 1 mg, or both. Postoperative nausea and vomiting were less common with combination treatment than with cyclizine or granisetron alone (17% vs 23% and 24%).
Cyclizine’s antiemetic effect lasts for approximately four hours. The elimination half-life is around 14 hours following a single 25mg intravenous dose. Cyclizine can be given up to three times a day but treatment should not continue beyond 48 hours. Drowsiness is common with cyclizine and it may have additive effects with alcohol and
other drugs that cause nervous system depression such as hypnotics, sedatives and anaesthetics. Other adverse effects include dizziness, dry mouth, constipation, blurred vision, headache, somnolence, dyskinesia, tremor, convulsions, transient speech disorders and injection-site reactions. Disorientation, restlessness, agitation, insomnia and hallucinations have also been reported. Temporary paralysis has occasionally occurred in patients with underlying neuromuscular disorders. Because of its anticholinergic effects, cyclizine may precipitate urinary retention and incipient glaucoma. Monitoring is recommended in patients with glaucoma, obstructive disease of the intestine, liver disease, epilepsy and prostatic hypertrophy. As cyclizine may cause thickening of bronchial secretions, it should be used with caution in patients with asthma or chronic obstructive pulmonary disease. This drug may increase the adverse effects of other anticholinergic drugs. Cyclizine is contraindicated in patients with severe heart failure. It is a category B3 drug and its use in pregnancy and lactation is not recommended. This drug is effective for preventing postoperative nausea and vomiting, and is comparable to other antiemetics such as ondansetron, granisetron and droperidol. Cyclizine is not recommended for children and there have been no studies in older people.

REFERENCES


Commonly prescribed antibiotics ineffective for treating uncomplicated chest infections

London: The antibiotic amoxicillin, that doctors typically prescribe for common lower respiratory tract infections (LRTI) such as bronchitis, is no more effective at relieving symptoms than the use of no medication, even in older patients. The findings are from the largest randomised placebo controlled trial of antibiotics for acute uncomplicated LRTI to date, which was led by the University of Southampton and published in The Lancet Infectious Diseases.

“Patients given amoxicillin don’t recover much quicker or have significantly fewer symptoms,” explains Dr Paul Little, professor of primary care research at the University of Southampton.

“Indeed, using amoxicillin to treat respiratory infections in patients not suspected of having pneumonia is not likely to help and could be harmful. Overuse of antibiotics, which is dominated by primary care prescribing, particularly when they are ineffective, can lead to side effects such as diarrhoea, rash, vomiting and the development of resistance.”

LRTI (chest infections) are one of the most common acute illnesses treated in primary care in developed countries. Although viruses are believed to cause most of these infections, whether or not antibiotics are beneficial in the treatment of LRTI, particularly in older patients, is still hotly debated. Research so far has produced conflicting results.

In the study, from the GRACE (Genomics to Combat Resistance against Antibiotics in Community-acquired LRTI in Europe)
consortium and funded by the European Community’s Sixth Framework Programme, 2061 adults with acute uncomplicated LRTI from primary care practices in 12 European countries (England, Wales, Netherlands, Belgium, Germany, Sweden, France, Italy, Spain, Poland, Slovenia, and Slovakia) were randomly assigned to receive either amoxicillin or a placebo three times a day for seven days. Doctors assessed symptoms at the start of the study and participants completed a daily symptom diary.

Little difference in severity or duration of symptoms was reported between the two groups. This was true even for older patients aged 60 or more who were generally healthy, in whom antibiotics appeared to have a very limited effect.

Although significantly more patients in the placebo group experienced new or worsening symptoms (19.3% vs 15.9%), the number needed to treat was high (30), and just two patients in the placebo group and one in the antibiotic group required hospitalisation.

What is more, patients taking antibiotics reported significantly more side effects including nausea, rash, and diarrhoea, than those given placebo (28.7% vs 24%).

Dr Little adds, “Our results show that most people get better on their own. But, given that a small number of patients will benefit from antibiotics the challenge remains to identify these individuals.”

Writing in a linked comment, Philipp Schuetz from the University of Basel in Switzerland says: “Little and colleagues have generated convincing data that should encourage physicians in primary care to refrain from antibiotic treatment in low-risk patients in whom pneumonia is not suspected. Whether this one-size-fits-all approach can be further improved remains to be seen. Guidance from measurements of specific blood biomarkers of bacterial infection might help to identify the few individuals who will benefit from antibiotics despite the apparent absence of pneumonia and avoid the toxic effects and costs of those drugs and the development of resistance in the other patients.”

**Aurobindo wins approval for HIV drug from US FDA**

The US Food and Drug Administration (FDA) has granted approval to Indian drug maker Aurobindo Pharma for manufacturing and commercialising Abacavir Tablets USP in the strength of 300mg in the US market. The drug, which is the generic form of Viiv Healthcare's Ziagen (abacavir sulfate), is to be used as part of antiretroviral combination therapy to treat children and adults suffering from HIV. The company is ready to roll out the drug in the US. The drug had been approved out of Unit III formulations facility in Hyderabad, India.

**DCGI releases guidance manual for compliance of Indian Pharmacopoeia for stakeholders**

With a view to ensure better understanding of the Indian Pharmacopoeia (IP) by all the stakeholders, the Drug Controller General of India (DCGI), Dr G N Singh released the much anticipated guidance manual for compliance of Indian Pharmacopoeia (IP) in Ghaziabad on December 12. This manual was prepared and published by the Indian Pharmacopoeia Commission (IPC) in collaboration with Central Drugs Standard Control Organisation (CDSCO) and WHO-country office for India after extensive discussions and deliberations with the experts from this field.

This guidance manual a first of its kind for pharmacopoeial standards in India, was drafted with an aim to enable the regulatory bodies to discharge their duties as well as to streamline the functions of their own laboratories and also the in-house laboratories of drug manufacturers and commercial drugs testing laboratories. The document contains details on IP 2010 and addendum 2012 along with its salient features, good laboratory practices (GLP).
along with schedule L1 and its interpretation, reporting of errors and anomalies in the IP, guidelines to users of IP, process of IP monographs development guidelines for stability testing of drug substances active pharmaceutical ingredients (API's) and drug products i.e. finished pharmaceutical products etc. along with other gamut of information that will be beneficial to the manufactures.

According to Dr Jai Prakash, principal scientific officer, IPC, the need for publishing this guidance document was felt by the commission after they observed on several occasion that the stakeholders were not sensitised nor well informed about the IP requirements as mandated. This they found out after several interactions with the stakeholders during many IP related meetings and symposia organised by the IPC over the couple of years.

He reinforced, “Considering the situation it was deemed to be of utmost importance to ensure a platform that will enable the stakeholders to better understand the pharmacopoeia. Through this initiative we aim to ensure easy availability of all the IP related information and data to the interested stakeholders that will enable them to understand and interpret the monographs and other IP related technical data more easily at an affordable price of Rs.300 from our IPC office.”

Dr Singh who is also the secretary-cum-scientific director of the IPC stressed that considering the lack of understanding about the information of the IP among the stakeholders, it was felt necessary by the IPC officials to provide a detailed and simplified version of the same in the form of a guidance document for the over all benefit of the stakeholders. Dr Singh further emphasised with a view to ensure efficient implementation of current standards of IP, it is very essential to ensure that all manufacturers are first well sensitised and educated about the same. As only with such proactive stance can India ensure to make IP at par with other international bodies such as BP, USP etc.

He stressed, “Unless the norms prescribed in IP, the officially recognised book of standards for drugs as per the Drugs and Cosmetics (D&C) Act 1940 and Rules 1945, are understood and adopted by the stakeholders, the purposes of the publication of its new version may to not be achieved. This manual is not an addendum or supplement to the IP or a part of it. However it is intended to enable the users of IP to perform the activities related to performance of the tests or associated activities prescribed in the IP and also to understand or interpret the requirements of IP for proper compliance of the requirements thereof.”

This Guidance Manual can be procured from the office of the Secretary-cum-Scientific Director, IP Commission, Sector-23, Raj Nagar, Ghaziabad-201002 (UP) through Demand Draft for Rs 300/- (Rupees Three Hundred Only) issued in favour of “Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission” payable at Ghaziabad. The price in foreign currency is $ 5.41, £ 3.45. For more details please contact IP Secretariat, IP Commission, Ghaziabad.

Forthcoming Event

The Ramanbhai Foundation
6th International Symposium on "Advances in New Drug Discovery Technologies and Translational Research"
February 4-6, 2013

Symposium Venue :
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