Medical Chronicle

Efficacy and Safety of Pantoprazole in patients with GERD using intravenous-oral Regimen

astro-esophageal reflux disease (GERD) is a multifactorial, treatable diathesis affecting a large proportion of the population. The key symptoms include heartburn, acid regurgitation and pain on swallowing. Upon endoscopic examination, several grades of GERD are recognised, ranging from mild to severe and rated as GERD stage I to IV. Neutralisation and reduction of the gastric reflux is a widely recommended therapeutic intervention for GERD. It can be achieved particularly well by inhibiting the secretion of gastric acid with proton pump inhibitors, such as pantoprazole. Oral pantoprazole is safe and efficacious for the treatment of patients with peptic ulcers or GERD. Oral and intravenous pantoprazole administered at the same dose, proved to have equipotent effects upon intragastric pH. Patients, who are temporarily unable to take oral medications but require reliable gastric acid suppression, would clearly benefit from an intravenous administration of pantoprazole. The aim of a recent study was to demonstrate the safety and efficacy of an intravenous-oral regimen in patients with moderate or severe GERD.

five took less than 70% of the study medication between two study visits; four missed one or more scheduled visits; two had their baseline endoscopy performed more than three days before the first administration of the study medication; and

one had clinically relevant elevation of liver enzyme values on entry into the study. No dropouts were reported.

Efficient relief of key symptoms

With respect to relief from symptoms, in the present study, a marked decrease in the score sum of the key GERD symptoms was noted in all per-protocol patients already after the third day of the intravenous treatment. Depending on the symptoms, complete freedom was reported by 97-100% of patients after two weeks of treatment. While the patients' age and gender did not appear to influence healing, several subgroups with different healing rates were identifiable. First, smokers healed slower than non-smokers (69% vs 90%). This was not an unexpected observation, since it is generally accepted that smoking influences both the healing process and the outcome of treatment in gastric-acid-related diseases.

Reliable treatment offers high healing rates

The intravenous/oral regimen was safe and well tolerated, and this was substantiated by the low number of adverse events. After four and eight weeks of treatment, endoscopically proven healing of GERD was achieved in 87% and 95% of patients respectively. These healing rates were higher than those reported for the respective treatment periods in some trials but similar to the results obtained in other studies in which only oral pantoprazole was used.

Conclusion

Pantoprazole (40mg), applied as an intravenous-oral regimen to patients with GERD led to fast resolution of symptoms and high healing rates. For patients, temporarily unable to take oral medications, this regimen offers safe, effective and reliable gastric acid suppression, and allows the possibility of changing between the oral and intravenous administration without the need for dose adjustment.

References on request.

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Study results

Of the 110 patients, 98 patients completed the study according to the protocol (per-protocol population). Twelve patients - classified as protocol violators - were excluded from the pre-protocol analysis for the following reasons:

