

Locally Produced Drugs Need Quality Control

Pages with reference to book, From 226 To 227

Madam, Discovery of H₂ blockers was a major break through in the treatment of peptic ulcer disease with healing rates ranging from 65% to 89%¹⁻³ and a 70% relapse within a year⁴. Delayed response and compliance was a major problem with H₂ blockers. Proton pump inhibitors (PPI) were introduced for better compliance both in terms of dosage and duration and early return to work (due to rapid pain relief). Healing rates with various PPI's are around 100%^{5,6}.

Studies Were conducted at our centre using different omeprazoles like Losec⁵, Sanamidol⁶ and Sante to see the efficacy of locally produced drugs (Sanamidol and Sante) against internationally produced product. All patients had endoscopically confirmed duodenal ulcer. Patients with malignancy, chronic renal or liver disease, those on steroids or NSAID's were excluded from the study. Each patient was given omeprazole (20 mg) to be taken as 1 cap after breakfast, Healing was assessed endoscopically at 2 and 4 weeks. (only non—healers at 2 weeks were given a further treatment for 28 days). Non-healers at 4 weeks were categorized as non responders. Any side effects if noted were also recorded.

The healing rates at 2 and 4 weeks with Losec were 80% and 100%, with Sanamidol were 62% and 85% and with Sante were 64% and 95% respectively. There is a wide range of healing in these studies suggesting that the efficacy of these drugs is variable. As the patient population, examination centre and the endoscopist remain the same, removing the chances of observation bias, therefore it appears that the drug potency is at fault due to various reasons. As the cost of these omeprazoles is also variable therefore most patients tend to buy the cheaper drug without knowing the response rate. Good quality control therefore is essential to make ulcer healing cost effective and a reality.

Huma Qureshi, Waqaruddin Ahmed, Itrat Mehdi
PMRC Research Centre, Jinnah Postgraduate Medical Centre, Karachi.

References

1. Ahrned W, Qureahi H and Zuberi SJ. Healing and relapse rates of duodenal ulcer with various H₂ receptor antagonists. J, Pak. Med. Assoc, 1988;38:319-322.
2. Dammann HG. A single bed time dose of 400 mg Famotidine in short term treatment of duodenal ulcer, Berlin Famotidine international symposium N York. George Thieme Verlag, Stuttgart, 1985;p:60.
3. Boyd EJS, Wilson JA. Wormslay KG. Recurrent ulcer disease in ranitidine. Therapeutic advances. Edited Misiewicz JJ and Wood JR Australian Excerpta Medica, 1984;p:14.
4. Ahmad W. Qureshi H. Alam SE et al Healing and relapse rates of duodenal ulcer with Omeprazole Vs Ranitidine J. Pak, Med. Assoc. 1995;45:89-91.