



<b>Title</b>	<b>A prospective randomized trial comparing the use of omeprazole-based dual and triple therapy for eradication of <i>Helicobacter pylori</i></b>
<b>Author(s)</b>	<b>Chu, KM; Kwok, KF; Choi, HK; Law, SYK; Branicki, FJ; Wong, J</b>
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#### 6.4 D3 gastrectomy for potentially curable stomach cancer: a long-term follow-up study

EKW Ng, N Hayes, SA Raimes, TJ Crofts, SDS Woods, MS Griffin, SCS Chung  
Department of Surgery, Prince of Wales Hospital, Hong Kong, China

**Background:** Gastrectomy with extended lymphadenectomy is the advocated treatment in Japan for patients with 'curable' stomach cancer. Attempts of the technique in units elsewhere failed to show any survival advantage. This study aims to examine the safety and efficacy of radical gastrectomy in a Far East centre outside Japan.

**Methods:** A consecutive series of 121 patients with gastric cancer who fulfilled criteria for radical surgery had total gastrectomy with extended lymphadenectomy equivalent to D3 dissection over a six-year period in a single unit. Early postoperative events were documented prospectively, and all patients were followed up on a 3 monthly basis thereafter. Investigation and/or intervention were performed whenever there was clinical suspicion of tumour recurrence.

**Results:** The operation carried a morbidity of 50 percent, with a peri-operative mortality of five percent. Survival was best predicted by tumor stage: five-year survival for patients with intact gastric serosa was 64 percent, versus 10 percent of those with serosal penetration (Chi square=39.4,  $P < 0.00001$ ). The majority of documented metastases occurred by trans-peritoneal route for serosa-positive patients, but via the hematogenous mechanisms for those who were serosa-negative.

**Conclusions:** Radical gastrectomy with extended lymphadenectomy carries high operative morbidity. Absence of survival benefit is mainly resulted from loco-regional recurrence in patients with T3/T4 diseases. Novel approaches including neo-adjuvant treatment for downstaging of disease and adjuvant regional therapy for stringent local control should be explored.

#### 6.5 A prospective randomized trial comparing the use of omeprazole-based dual and triple therapy for eradication of *Helicobacter pylori*

KM Chu, KF Kwok, HK Choi, SYK Law, FJ Branicki, J Wong  
Department of Surgery, University of Hong Kong Medical Centre, Queen Mary Hospital, Hong Kong, China

**Aim:** We prospectively compared omeprazole-based dual and triple therapies in the eradication of *H pylori* in a randomized manner.

**Methods:** Between June 1995 and March 1997, 1000 consecutive patients with acid-peptic disease associated with *H pylori* infection (duodenal ulcer 388 patients; gastric ulcer 179 patients; duodenitis 173 patients; gastritis 260 patients) were prospectively recruited. They were randomized to either a two weeks (OA) course of omeprazole 20 mg and amoxicillin 1g both given twice daily, or treatment for one week (OCM) with omeprazole 20 mg once daily, clarithromycin 500 mg twice daily, and metronidazole 400 mg twice daily.

**Results:** The age of these 1000 patients ranged from 16 to 90 years with a mean of 54.9 years. Side effects occurred in 29.6% (95%CI 25.6% - 33.8%) and 10.6% (95% CI 8.0% - 13.6%) of patients taking OCM and OA, respectively ( $p < 0.0001$ ). Apart from taste disturbance, however, there were no significant differences in the incidences of side effects between the two groups. One patient of the OA group and four patients of the OCM group could not tolerate the medications and therefore did not complete treatment ( $p = 0.37$ ). Seven and thirteen patients of the OA and OCM groups, respectively, refused second endoscopy ( $p = 0.25$ ). The remaining 975 patients underwent a second endoscopy. Positive endoscopic findings were significantly more common in the OA group (51/492; 10.4%; 95%CI 7.8% - 13.4%) than the OCM group (25/483; 5.2%; 95%CI 3.4% - 7.5%) in per protocol (PP) analysis ( $p = 0.004$ ). On intent-to-treat (ITT) analysis, the overall eradication rates in the OA and OCM groups were 73.6% (95%CI 69.5% - 77.4%) and 92% (95% CI 89.3% - 94.2%), respectively ( $p < 0.0001$ ). On PP analysis, the corresponding rates were 74.8% (95%CI 70.7% - 78.6%) and 95.2% (95%CI 92.9% - 97.0%), respectively ( $p < 0.0001$ ).

**Conclusion:** A course of omeprazole, clarithromycin and metronidazole for one week is a safe, well-tolerated, efficacious, and cost-effective treatment for *H pylori* infection.