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TEN DAYS QUADRUPLE VERSUS SEQUENTIAL THERAPY AS EMPIRICAL FIRST- AND SECOND-LINE TREATMENT FOR *HELICOBACTER PYLORI* ERADICATION: A RANDOMISED CROSSOVER TRIAL

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INTRODUCTION: *Helicobacter pylori* (HP) is one of the commonest bacterial infections worldwide. The eradication rate of clarithromycin-based and bismuth-based therapy has been declining in the western world. The aim of the study was to compare the efficacy and tolerability of HP eradication with a 10-day sequential therapy versus quadruple therapy as empirical first- and second-line treatment.

METHODS: Eligible HP-positive patients were randomised to receive either sequential (SEQ) therapy (esomeprazole 20 mg twice daily and amoxicillin 1 g twice daily for the first 5 days followed by esomeprazole 20 mg twice daily, clarithromycin 500 mg twice daily and metronidazole 400 mg four times daily for the subsequent 5 days) for 10 days or quadruple (QUAD) therapy (esomeprazole 20 mg twice daily, bismuth subcitrate 120 mg four times daily, tetracycline 500 mg four times daily, and metronidazole 400 mg four times daily) for 10 days. All patients returned 8 weeks after completing the treatment for a urea breath test (UBT) to confirm eradication. Patients who failed the initial UBT would crossover to receive the alternate treatment regimen.

RESULTS: A total of 391 patients were recruited into the study with 213 in the SEQ group and 178 in the QUAD group. The baseline demographics and endoscopic diagnoses were similar in both groups. A total of 200 patients (93.9%) and 163 patients (91.6%) completed treatment in SEQ and QUAD group respectively. By perprotocol analysis, the eradication rate was 96% in SEQ group and 98.7% in the QUAD group (P=0.195). The eradication rate calculated by the intentional-to-treat was 91% (194/213) in SEQ group and 92.7% (165/178) in the QUAD group (P=0.348). The most common adverse events were bitter taste (1.9%) and nausea (2.2%) in SEQ and QUAD group respectively. There were seven cases from SEQ group crossover to receive QUAD therapy and two patients who initially failed QUAD therapy crossover to the SEQ therapy. All of the patients were successfully eradicated from HP after receiving the alternate therapy.

CONCLUSIONS: Both SEQ and QUAD therapy are highly effective in HP eradication as first- and second-line treatment with similar mild adverse events.