2010 年 2 月 7 日（日）実施

『薬物治療塾』第 1 期（前期）薬物治療文献（C-1）コース　修了課題

次の英文（論文抄録）から得られる情報にもとづき、以下の問いに答えなさい

Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS): a phase III, randomised, double-blind, placebo-controlled trial.

Taha AS, McCloskey C, Prasad R, Bezlyak V. Lancet 2009;374:119-25.

BACKGROUND: There are few therapeutic options for the prevention of gastrointestinal mucosal damage caused by low-dose aspirin. We therefore investigated the efficacy of famotidine, a well-tolerated histamine H_2-receptor antagonist, in the prevention of peptic ulcers and erosive oesophagitis in patients receiving low-dose aspirin for vascular protection.

METHODS: Adult patients (aged ≥18 years) from the cardiovascular, cerebrovascular, and diabetes clinics at Crosshouse Hospital, Kilmarnock, UK, were eligible for enrolment in this phase III, randomised, double-blind, placebo-controlled trial if they were taking aspirin 75-325 mg per day with or without other cardioprotective drugs. Patients without ulcers or erosive oesophagitis on endoscopy at baseline were randomly assigned by computer-generated randomisation sequence to receive famotidine 20 mg twice daily (n=204) or placebo twice daily (n=200). Patients had a final endoscopic examination at 12 weeks. The primary endpoint was the development of new ulcers in the stomach or duodenum or erosive oesophagitis at 12 weeks after randomisation. Analysis was by intention to treat, including all randomised patients who received at least one dose of study drug (famotidine or placebo). This trial is registered as an International Standard Randomised Clinical Trial, number ISRCTN96975557.

FINDINGS: All randomised patients received at least one dose and were included in the ITT population. 82 patients (famotidine, n=33; placebo, n=49) did not have the final endoscopic examination and were assumed to have had normal findings; the main reason for participant withdrawal was refusal to continue. At 12 weeks, comparing patients assigned to famotidine with patients assigned to placebo, gastric ulcers had developed in seven (3.4%) of 204 patients compared with 30 (15.0%) of 200 patients (odds ratio [OR] 0.20, 95% CI 0.09-0.47; p=0.0002); duodenal ulcers had developed in one (0.5%) patient compared with 17 (8.5%; OR 0.05, 0.01-0.40; p=0.0045); and erosive oesophagitis in nine (4.4%) compared with 38 (19.0%; OR 0.20, 0.09-0.42; p<0.0001), respectively. There were fewer adverse events in the famotidine group than in the placebo group (nine vs 15); four patients in the placebo group were admitted to hospital with upper gastrointestinal haemorrhage. The other most common adverse event was angina (famotidine, n=2; placebo, n=4).

INTERPRETATION: Famotidine is effective in the prevention of gastric and duodenal ulcers, and erosive oesophagitis in patients taking low-dose aspirin. These findings widen the therapeutic options for the prevention of gastrointestinal damage in patients needing vascular protection.

FUNDING: Merck Laboratories and Astellas Pharma.

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問１．以下の空欄を埋めなさい。

研究デザイン:(____)、ITT解析の有無:(_____)

試験に組入れた患者の特徴：(____)

治療薬の種類：(________________)、治療群の人数：(______________人)

対照薬の種類：(________________)、対照群の人数：(______________人)

治療薬の胃潰瘍予防効果：（RRR=___________%, NNT=___________人）

治療薬の十二指腸潰瘍予防効果：（RRR=___________%, NNT=___________人）

治療薬のびらん性食道炎予防効果：（RRR=___________%, NNT=___________人）

問２．本研究はFamotidine（Gaster®）の製造販売元であるAstellas Pharma Inc., Japanが研究費を提供している。このような研究論文を評価するうえで研究デザイン上特に注意（注目）しておきたい点は何か？思いつく限り挙げなさい。(裏面使用可)

問３．この英文はAbstract（論文抄録）である。Abstractのみから研究内容を評価する危険性について考えを述べなさい。(裏面使用可)

氏名：______________________________