International Journal of Research in Medical Sciences
Mahajan U et al. Int J Res Med Sci. 2018 Nov;6(11):3488-3493
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20184404

Original Research Article

A study to compare the efficacy of intermittent versus continuous regimen of pantaprazole in the management of upper gastrointestinal bleed (non variceal)

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Received: 18 August 2018
Accepted: 26 September 2018

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ABSTRACT

Background: UGI bleeding is defined as bleeding that occurs in the digestive tract proximal to the ligament of treitz. Intermittent dosage regimen IV bolus and high dose IV continuous infusion forms helps in achieving and maintaining this pH goal of more than 6 which forms optimal environment for peptic ulcer healing and clot stabilization to occur. Theoretically, high-dose IV continuous infusion should provide the most potent acid suppression. Aims and objective was to compare the efficacy of intermittent dose of pantoprazole given for 3 days i.e. 40mg intravenous twice a day versus continuous infusion dose of pantaprazole i.e. 80mg intravenous bolus followed by 8mg/hour for first 72hours in the treatment of UGI bleed.
Methods: Patients of UGI bleed were randomly assigned to receive either continuous or intermittent regimen of pantaprazole as a part of management.
Results: Among 118 patients of peptic ulcer disease, 7 patients had rebleed and 111 patients had no rebleed.3 patients among 59 patients who received continuous regimen and 4 patients among 59 patients who received intermittent regimen had rebleed with a total of 7 patients among 118 patients. Among 118 patients only 2 patients of the total had need for surgery for stabilization. Among 59 patients who received continuous regimen 2 patients needed surgery while none of the 59 patients who received intermittent regimen needed for surgery. Of the 118 patients 10 patients had mortality at the end of 30 day period. In both the regimes 5 patients died.
Conclusions: The difference between Rockall score of the intermittent and continuous regimen group was statistically insignificant. The incidence of rebleed was 5.1 % for continuous and 6.7% for intermittent regimen which was statiscally insignificant. The incidence of mortality was similar 8.5%in both regimen.

Keywords: Continous, Intermittent, Pantroprazole, Upper GI bleed

INTRODUCTION

Upper gastrointestinal bleeding is defined as bleeding that occurs in the digestive tract proximal to the ligament of treitz.[1] It is a common disease with prevalence rates of up to 102 per 100000 population and a mortality rate of 8-10%.[2-5]

Source of bleeding may be an ulcer, variceal, Mallory Weiss tear, gastrodudenal erosion, neoplasm or

unidentified. Peptic ulcers can be broadly classified into gastric and duodenal ulcer.

In vitro, an intragastric pH of >6 has been shown to promote clot stabilization by reducing pepsin-induced clot lysis and increasing platelet aggregation.[6] Rapid achievement and maintenance of an intragastric pH of >6 theoretically provide the optimal environment for peptic ulcer healing and clot stabilization to occur.[7]

In vitro studies demonstrate that a neutral pH is required for optimal platelet aggregation. However, in a slightly acidic environment, platelet aggregation is impaired, and at pH 6, it is virtually abolished.[8] In an acidic environment, pepsinogen is activated to pepsin, which can easily digest freshly formed blood clots within minutes.[9] Furthermore, plasmin-mediated fibrinolysis is also increased, which may impair reinforcement of the initial platelet clot by a fibrin clot.[10] Thus, profound acid suppression may provide therapeutic benefit for patients with bleeding peptic ulcers.[10]

The gastric H+K+-ATPase is an important target for development of drugs to inhibit gastric acid secretion.[11] which is found in the parietal cell of the stomach. This enzyme appears to be in cytoplasmic tubular membranes in the resting state and then in the microvilli of the expanded secretory canaliculi in the stimulated state of the parietal cell. Once the enzyme moves to the canaliculi, the enzyme secretes acid by the exchange of cytoplasmic hydronium with extracellular K.[12]

Substituted benzimidazoles or proton pump inhibitors are the first group of anti-secretory drugs, acting via inhibition of H+, K+-ATPase.

As intragastric pH above 6 may be required to promote clot formation and stability. High dose, continuous-infusion PPI therapy was consequently studied in an attempt to maintain an intragastric pH above 6.[13] PPIs have been shown to maintain intragastric pH above 6 for 84%–99% of a 24-hour period.[14] (elimzination half-lives of PPI is approximately 1hour). Thus, after clearance of a PPI administered as a bolus, whether i/v or oral, new proton pumps may produce acid suppression. It was therefore hypothesized that a constant infusion would be required to maintain an intragastric pH above 6, with a PPI present continuously to inhibit newly activated proton pumps. A meta-analysis of randomized trials compared high-dose continuous-infusion PPI therapy with placebo or no therapy and showed a significant decrease in further bleeding, as well as surgery and mortality, among patients with high-risk bleeding ulcers after endoscopic therapy.[15]

Intermittent dosage regimen IV bolus (defined as administration with an IV push 40mg of pantaprazole at regular intervals) and high dose IV continuous infusion forms (usually preceded by an 80mg bolus IV push, followed by an infusion at 8mg/h), in achieving and maintaining this pH target goal of >6.[16] Theoretically, high-dose IV continuous infusion should provide the most potent acid suppression. PPIs only inhibit stimulated parietal cells with active proton pumps and this is most successfully and rapidly achieved by administering a bolus dose intravenously; continuous infusion then provides a steady state of the drug to inactivate any newly synthesized proton pumps, as well as any newly recruited proton pumps on parietal cells, which continue to be stimulated by gastrin, histamine and food.[17] Thus infusion dosage regimen seems to be a better alternative in maintaining PH>6 but requires continuous monitoring, more nursing care, hence difficult to administer.

Most of the available literature on the subject cited above is from studies based on urban population and studies in developed countries and inferences obtained may not uniformly applicable to our rural setup. As such no such study has been undertaken in this part of the country

Aims and objective was to compare the efficacy of intermittent dose of pantoprazole given for 3 days i.e. 40mg intravenous twice a day versus those treated via continuous infusion dose of pantaprazole i.e. 80mg intravenous stat followed by 8mg/hour for first 72hours in the treatment of UGI (non variceal).

METHODS

Patients of UGI bleed who had peptic ulcer disease were randomly assigned to receive either continuous or intermittent regimen of pantaprazole as a part of management. A total of 600 patients of UGI bleed underwent endoscopy.

Group A patients were given continuous regimen of pantaprazole which received infusion dose of pantaprozole i.e. 80mg stat followed by 8mg per hour infusion for first 72hours.

Group B patients received intermittent regimen of pantaprazole for 3 days i.e. 40mg intravenous twice daily. The patients were randomly randomised.

Study was conducted in Dr. RPGMC, Kangra, Himachal Pradesh, India. The study was conducted between July 1 2015 and June 30 2016 for a period of 12 months. Patients of UGI bleed who had peptic ulcer disease were included. UGI bleed related to variceal bleed, angiodysplasia and Mallory-Weiss tear were excluded.

The patients demographic and clinical characteristics were recorded. Personel history included h/o drugs use like antiplatelets, anticoagulant, NSAID use. Laboratory investigations like hemogram, BUN, albumin, bilirubin and PT were taken. All subjects were evaluated by UGI endoscopy. Initial shock status, coexisting comorbidities and endoscopic findings were used to calculate Rockell score. Number of ulcers visualized during endoscopy and number of blood transfusions given to the patient were

recorded. Stastistical analysis was done using Mantel-Haenszal and Yates corrected methods to find out the Chi-squares and p-values.

RESULTS

Of the total 118 patients included in the study 22 were females and 96 were males. The youngest patient was aged 22 and eldest was 96 years of age with a mean age of 53.88 years with a SD of 16.318. Continuous regimen had male to female ratio 4.9:1. Intermittent regimen had male to female ratio 3.9:1

Among 118 patients 35 patients (29.66%) presented with hametemesis and 83 patients (70.34%) had no hametemesis. 21 patients had hematemesis in the continuous regimen whereas 14 patients with hametemesis in the intermittent regimen.

Of the total 118 patients, 49 patients (41.53%) presented with malena whereas 59 patients (58.47%) had no malena. In continuous regimen group 22 patients presented with malena and 37 patients had no malena. In the intermittent group 27 patients presented with malena whereas 32 patients had no symptoms of malena.

Of the total 118 patients, 45 patients (38.14%) presented with both symptoms of heamatemesis and malena. In continuous regimen 18 patients had both hematemesis and malena while in the intermittent group 27 patients presented with both the symptoms.

Of the total 118 patients, 84 patients (71.19%) of the patients had no syncope at the time of presentation whereas 34 patients (28.81%) of patients presented with syncope. Of the 59 patients in continuous regimen 15 patients had syncope. In the intermittent group 19 patients had syncope.

Of the 118 patients 20 patients (16.95%) had pain abdomen. In the continuous regimen 14 patients (23.7%) had pain abdomen. In the intermittent regimen 6 patients (10%) had pain abdomen.

Of the total 118 patients with UGI bleed 23 patients (19.49%) had a history of NSAID intake. In the continuous regimen (13.55 %) 8 patients had a history of NSAID intake and in the intermittent regimen (25.42%) 15 patients had a history of NSAID intake.

Of the total 118 patients 8 patients had a history of antiplatelet drug use. Out of 8 patients 1 patient was in the continuous regimen and 7 patients in the intermittent group had a history of antiplatelet drug use.

Of the 118 patients 70 patients had a history of alcohol use. Out of 118 patients, 40 patients in the continuous regimen and 30 patients in the intermittent regimen had a history of alcohol use.

The mean haemoglobin concentration was 8.84gm% with SD 2.974 among 118 patients whereas the mean haemoglobin concentration was 8.89gm% for continuous group and 8.78gm% for the intermittent group.

Among 118 patients 44 patients had no shock, 33 patients had tachycardia and 41 patients were hypotensive. Among the continuous regimen group 14 patients (25.72%) had no shock, 18 patients (30.50%) had tachycardia and (45.76%) 27 patients had hypotension/shock. Among the intermittent regimen group 30 patients (50.84%) had no shock, 15 patients (25.4%) had tachycardia and 14 patients (23.72%) had had hypotension/shock.

Among 118 patients, 115 patients were diagnosed with peptic ulcer disease and 3 patient were diagnosed with malignancy of upper GI tract. Peptic ulcer identified in 58 of 59 patients in continuous group and 57 patients of intermittent group. Malignancy of GI tract identified in single patient of continuous group and two patients of intermittent group.

Among 118 patients, 98 patients 83% had no stigmata of recent bleed which comprises a clean based ulcer /flat pigmented spot (forrest class 2c and 3), 20 patients presented with blood in upper GI tract, activebleeding, visible vessel or clot (forrest class 1a/1b/2a/2b). 8 patients in the continuous regimen and 12 patients in the intermittent regimen had major stigmata of gastrointestinal bleed (blood in the UGI tact, active bleeding, visible vessel or a clot).

Mean Rockall score of 118 patients (388 with a SD of 2.181) and was coincidentally found similar in both the groups which was statistically non significant (p value 1.000). Among 22 patients with score 1, 9 were in continuous group and 13 in intermittent group, among 17 patients with score 2, 11 were in continuous group and 6 in the intermittent group, among 14 patients with score 3, 10 were in continuous group and 4 in the intermittent group, among 18 patients with score 4, 7 were in continuous group and 11 in the intermittent group, among 18 patients with score 5, 6 were in continuous group and 12 in the intermittent group.

Among 13 with score 6, 6 were in the continuous group and 7 patients in the intermittent group, among 11 patients with score 7, 7 were in the continuous group and 4 were in the intermittent group, among 3 patients with score 8, 2 patients were in the continuous group and 1 patient in the intermittent group, only patient with score 9 was in the continuous group and 1 patient with score 10 was in the intermittent group.

Treatment outcome

Among 118 patients, 7 patients (5.93%) had rebleed and 111 patients (94.07%) had no rebleed. 3 patients (5.1%) among 59 patients who received continuous regimen and

4 patients (6.8%) among 59 patients who received intermittent regimen had rebleed with a total incidence of (5.9 5%) 7 patients among 118 patients (Figure 1). This was statistically insignificant.

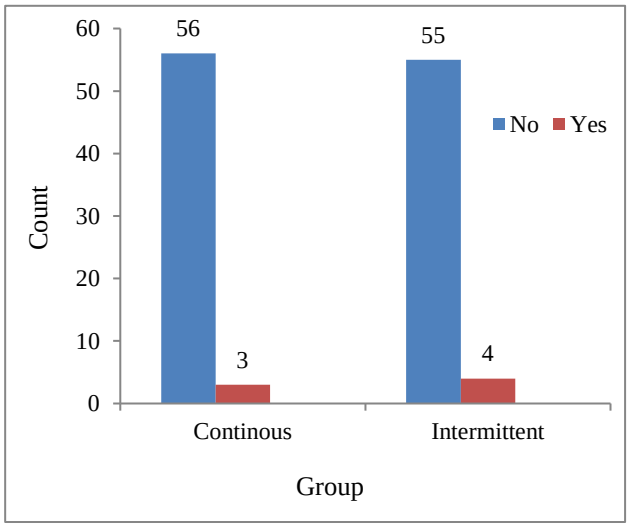

Figure 1: Rebleed in continuous and intermittent group.

Among 118 patients only 2 patients (1.69%) of the total had need for surgery for stabilisation. Among 59 patients who received continuous regimen 2 patients (3.4%) had a need for surgery while none of the 59 patients who received intermittent regimen had need for surgery (Figure 2).

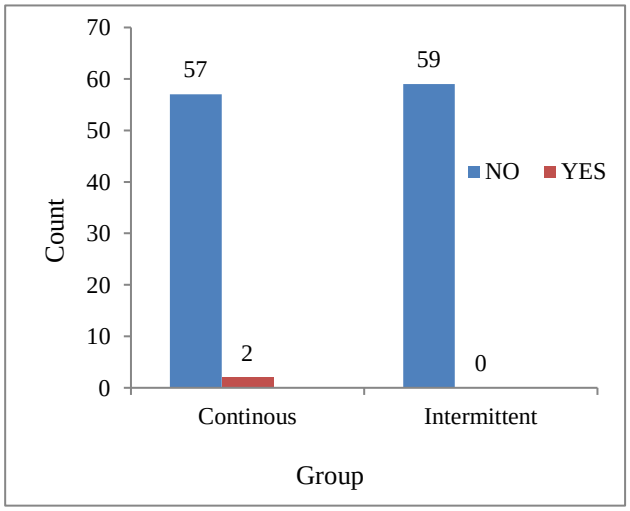

Figure 2: Need for surgery in continuous and intermittent group.

Among 59 patients who received continuous regimen 5 patients (8.5%) had mortality and among the 59 patients who received intermittent regimen 5 patients (8.5%) had mortality thereby reflecting no difference in mortality for the treatment regimen (Figure 3).

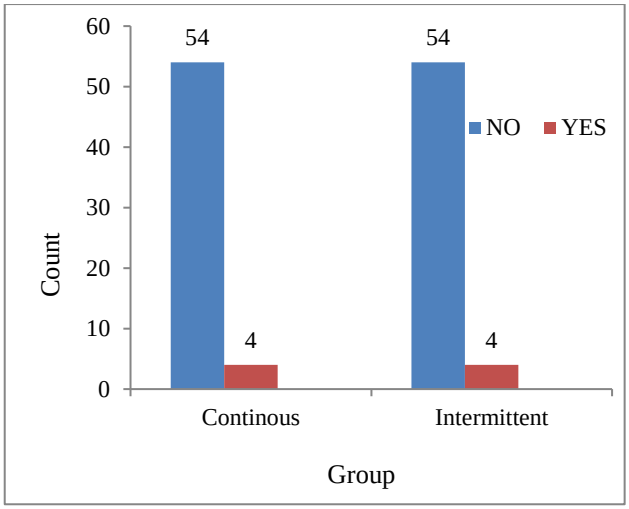

Figure 3: Mortality outcome in continuous and intermittent group.

DISCUSSION

In the present study average age of the patients was 55.81±16.31 years. In the study by Cyrla Z et al, mean age was 54.5±17.5 years.

The male:female ratio in the present study was 4.3:1 (total of 118 patients with males 81.4% and females 18.6 %.). In a study by Koroushi M et al, 67.7% of them were males.[18] Hence the male to female ratio is similar to other studies.

In the present study, haematemesis was seen in 35 patients (29.7%), malena was seen in 49 patients (41.5%) and both haematemesis and malena seen in 45 patients (38.1%). In another study by Lakhani et al, 13 from Ahmedabad where hematemesis was the more common presentation (55%).[19] Pain abdomen as a symptom was seen in less number of patients in the present study compared to study by Lakhani.

Of the 118 patients, 84 patients had no syncope at the time of presentation whereas 34 patients presented with syncope. This symptom was not evaluated in other studies.

In the present study, use of NSAID was found among 23 patients (19.5%). This study showed a lower incidence of NSAID intake leading to UGI bleed.

In the present study, 55 out of 118 (46.61%) had a history of smoking. History of smoking was found to be significantly present at par with other studies. In the present study 70 of 119 patients (59.32%) had a history of alcohol use.

In the study, the mean hemoglobin was 8.84gm%. In the present study mean BUN was 36.89mg/dl and mean creatinine was 1.26mg/dl. Al Naaman et al, reported that

BUN itself predicts the severity of upper GI bleed bleeding.[20] In the present study, the mean platelet count was 1,37000 at the time of presentation. In a study by Minoru et al, platelet count was 27.4±11.2 *104/microliter. The present study 70 of 119 patients (59.32 %) had a history of alcohol use. In a study by Rafi et al, 107 of 196 patients (54.6%) had alcohol use.[21]

In this study mean bilirubin level was 1.46mg/dl and mean conjugated bilirubin was 0.46mg/dl, the mean serum albumin of the patients was 3.11gm/dl. In this study among 118 patients the Mean Prothrombin time was 17.43±1.585.

In this study, 60.1% patients had no co morbidity, 5.9% had CAD/CHF, 33.8% patients had co morbid liver failure/renal failure/metastatic disease (a total of 39.7% had comorbidity).

In the present study, 98 (83%) had no stigmata of recent bleed (forrest class 2c and 3) peptic ulcer while 17% had high stigmata of recent bleed (forest class 1a/1b/2a/2b). In a study by Skendar et al, peptic ulcer was seen in 82.2 % of patients similar to the present study.

Rockell score

Of the 118 patients 18 patients had a Rockall score of 4 (15.25%). 18 patients had a Rockall score of 5 (15.25 %). 24.47% patients had a Rockall score greater than equal to 6.

The mean Rockall score for intermittent regimen was 3.88 and mean Rockall score for the continuous regimen was 3.88 both being similar, and difference was statistically insignificant. For the 7 patients that had malignancy the mean Rockall score was 5.20±1.989. For the 10 patients who had mortality the mean Rockall score was 5.60±2.547. As the Rockall score increases the risk of rebleeding and mortality increases. This score was not evaluated in other similar studies.

Maximum number of patients 103 of 118 (87.28%) had a single ulcer visualized during endoscopy. Maximum number of patients 20 (33.89%) in continuous and 31 (52.54%) in intermittent regimen received a single blood transfusion. In a study by Cryla et al, average no of blood transfusion given was 1.56.

Treatment outcome

Rebleed

In this study 3 (5.1%) among patients of continuous and 4 (6.7%) among intermittent group had rebleeding. The difference was statistically insignificant. In a study by Sachar et al, rebleeding was seen in 8.7% subjects of continuous group and 7.9% of intermittent group.[22] In a study by Chen et al, rebleeding was seen in intermittent 6 of 101 patients (5.94%) and 7 of 100 (7%) patients in continuous regimen group.[23] In a study by Javed et al, re bleeding was seen in 4 among 53 patients (7.54%) in intermittent regimen group and 4 among 53 (7.54%) of continuous regimen group.[24] Hence findings in our study is similar to the findings observed in other similar studies.

Need for surgery

In this study, only 2 of 119 patients 1.69% of total had a need for surgery. Both the patients belonged to the continuous group 2 of 59 patients (3.4%) and no patient in the intermittent group had surgery. In a study by Rafi et al, 24 of 196 patients (12.2%) had surgery. In a study by Madangopalan N et al perforation was reported in 11.72% of a patients.[25] Hence, this study had a lower number of patients needing surgery as compared to other studies.

In this study the mortality from upper gastrointestinal bleed was similar in either regimen, 5 of 59 patients (8.5%) had mortality in both the groups. In a study by Mitchell S et al, mortality varies from 7 to 10%.[26]

In this study 16.95% (20 of 118 patients) malingnancy was a contributing factor for upper GI bleed. In a study by Shivaram P et al, 7.89% cases were attributed to malignancy as a cause for upper GI bleed.[27]

CONCLUSION

Patients presented with varying symptoms of either hematemesis (29.7%) or malena (41.5%) or a combination of both (38.1%). Use of drugs antiplatelet/anticoagulants/NSAID leading to UGI bleed was significantly lower (19.5% of patients) while high alcohol consumption (59.32% of patients) and smoking (46.61%) contributed to UGI bleed in our hill state. The incidence of rebleed was 5.1 % for continuous and 6.7% for intermittent regimen which was statistically insignificant. The incidence of mortality was similar (8.5%) in both regimen. The incidence of need for surgery was relatively less 1.69 % in present study as compared to similar studies. Patients with either rebleed or mortality had a higher Rockall score owing to higher contribution of comorbidity contributing to calculation of Rockall score. To conclude the efficacy of intermittent Pantaprazole regimen is similar to continuous infusion

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mahajan U, Kapoor D, Rana BS, Kumar P, Kumar D, Malakar S. A study to compare the efficacy of intermittent versus continuous regimen of pantaprazole in the management of upper gastrointestinal bleed (non variceal). Int J Res Med Sci 2018;6:3488-93.