International Journal of Advances in Medicine
Singh P et al. Int J Adv Med. 2020 Mar;7(3):435-438
http://www.ijmedicine.com
pISSN 2349-3925 | eISSN 2349-3933
DOI: http://dx.doi.org/10.18203/2349-3933.ijam20200654

Original Research Article

An adaptive clinical trial on patients with non variceal upper gastrointestinal bleed with the help of endoscopy

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Received: 14 December 2019
Accepted: 31 January 2020

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ABSTRACT

Background: Acute upper gastrointestinal hemorrhage (UGIH) is a common condition worldwide frequently leads to hospital admission also has a significant associated morbidity and mortality, especially in the elderly. A systematic diagnostic and definite therapeutic approach is essential to establish a diagnosis, relevant to specific investigations for appropriate treatment in tertiary medical care center.
Methods: A comparative trial was done on n=109 cases with an objective to find out the different causes of UGI bleed in population, to assess the requirement of blood transfusion in patients with massive GI Bleed and to compare the treatment outcome of Proton pump inhibitors over Tranexamic acid and Octreotide in non-variceal UGI bleed. The cases were assigned to three different groups by lottery system. Proton pump inhibitors (Omeprazole), Somatostatin (Octreotide), Anti-fibrinolytic (Tranexamic acid), outcome was assessed after complete treatment and follow up.
Results: Out of 150 cases, 109 were diagnosed with non-variceal GI bleed, 35 cases were treated with Omeprazole out of which 11.42% cases received blood transfusion, and 4 had history of re bleeding, Mean Duration of stay in hospital was 4.4±1.75, when compared to the other two group the duration of hospitalization was least as the P value was <0.0001.
Conclusions: In this study it was demonstrated the use of PPI in case of Non-Variceal Bleeding significantly reduces the need of blood transfusion. Even it reduces the cases of re bleeding and duration of hospital stay.

Keywords: Anti-fibrinolytic agent, Proton pump inhibitor, Somatostatin, Upper gastrointestinal bleed

INTRODUCTION

Upper gastrointestinal (GI) bleeding defined as bleeding derived from a source proximal to the Ligament of Treitz is a common and potentially life-threatening GI emergency with a wide range of clinical severity ranging from insignificant bleeds to catastrophic exsanguinating hemorrhage and is associated with significant morbidity and mortality.[1,2] Causes of upper gastrointestinal bleeding (UGIB) in patients can be grouped into two categories: Variceal that includes lesions that arise by virtue of portal hypertension, namely gastroesophageal varices and portal hypertensive gastropathy and the second, non-variceal includes lesions seen in the general population (peptic ulcer, erosive gastritis, reflux esophagitis, Mallory-weiss syndrome, tumors, etc.)[3]

The diagnosis of and therapy for Non-Variceal UGIB has evolved since the late 20th century from passive diagnostic esophagogastroduodenoscopy with medical therapy until surgical intervention was needed to active intervention with endoscopic techniques followed by

angiographic and surgical approaches if endoscopic therapy fails.[4]

The underlying mechanisms of Non-Variceal bleeding involve either arterial hemorrhage, such as in ulcer disease and mucosal deep tears, or low-pressure venous hemorrhage, as in telangiectasia and angioectasia. In variceal hemorrhage, the underlying pathophysiology is due to elevated portal pressure transmitted to esophageal and gastric varices and resulting in portal gastropathy.

METHODS

It was an adaptive clinical trial. The study was conducted in KPS Institute of Post Graduate Medicine Department and Lala Lajpat Rai Hospital (GSVM Medical College) Kanpur, Uttar Pradesh during year 2017-2019.The duration of study was 2 years. Patients of age 18 to 60 years presenting with hematemesis, melena, Chronic NSAID abuse, Chronic steroids abuse were included in the study.

Case's with coagulopathy, prior abdominal surgery, history of trauma, chronic liver disease and alcoholic liver disease were excluded. A comparative trial was done on n=109 cases with an objective to find out the different causes of UGI bleed in population, to assess the requirement of blood transfusion in patients with massive GI Bleed and to compare the treatment outcome of proton pump inhibitors over Tranexamic acid and Octreotide in non-variceal UGI bleed.

The cases were assigned to three different groups by lottery system. Group A Proton pump inhibitors (Omeprazole) 80 mg IV bolus, followed by 40 mg 8 hourly. Group B Somatostatin (Octreotide) 50 mcg IV bolus, followed by 25 mcg/hr. Group C Anti-fibrinolytic (Tranexamic acid) 1 gm loading followed by 3 gm maintenance in infusion for 24 hours. Cases were assessed for outcome after successful treatment and follow up. Comparison of means between the groups was done using unpaired Z- test, p value less than 0.05 was considered to be significant.

RESULTS

There were of total of 150 cases who underwent Upper GI endoscopy, out of which 109 were diagnosed with Non-Variceal Upper GI bleed. Out of total cases 73% were male and 27% female respectively. Maximum number (52%) of cases come underage group of 31-55 years. The commonest cause for non-variceal bleed was gastric ulcer 45 cases, followed by mild antral gastritis 24 cases, then 12 cases with antral gastritis, 6 cases each of duodenal ulcer, viral esophagitis and duodenitis, 4cases of fundal ulcer, 3 cases of schatzki ring and esophagitis (Table 1).

Table 1: Frequency of diagnoses for cases of non-variceal gastrointestinal bleed.

Diagnosis	Cases	Percentage
Gastric ulcer	45	41.28%
Mild antral gastritis	24	22.01%
Antral gastritis	12	11%
Duodenal ulcer	6	5.50%
Viral esophagitis	6	5.50%
Duodenitis	6	5.50%
Fundal ulcer	4	3.66%
Schatzki ring	3	2.75%
Esophagitis	3	2.75%

Table shows the causes of non-variceal bleed in our patient study group. Peptic ulcer disease was the commonest cause encountered in our study. This was followed by duodenal ulcer, viral esophagitis, duodenitis and duodenal ulcer. Shaztki ring and esophagitis were relatively rare and occurred in only 3 patients each (Table 1).

The cases treated with Omeprazole were 35, the mean age of this group cases was 41±13.63, M:F ratio was 3:2.There were 4 cases out of 35 (11.42%) who received blood transfusion, and 4 had history of re bleeding. There were 38 cases treated with Octreotide, with the mean age of 45.23±12.44, M:F ratio of 2:1 with 12 cases (31.5%) with blood transfusion and 8 with history of re bleeding (Table 2).

The number of patients, age and gender distribution were similar in each of the three groups. Vital parameters including pulse rate and systolic blood pressure, and hemoglobin level at presentation were also comparable among the groups (p=NS) (Table 2).

Table 2: Demographic data's and outcome of different study group.

	Group A (Omeprazole)	Group B (Octreotide)	Group C (Tranexemic acid)
N(case)	35	38	36
Age	4113.63	45.23±12.44	40.41±14.84
M:F	3:2	2:1	2:1
Pulse Rate	83.6±14.23	90.73±13.94	93.7±5.4
Systolic BP	112.06±16.31	116±9.59	113.1±19.59
Hemoglobin	11.74±2.62	10.57±3.59	10.94±3.01

There were 36 cases who received tranexamic acid, with mean age of 40.41±14.84, male: female of 2:1 with 6 cases requiring blood transfusion and 5 cases with history of rebleeding (Table 3). The majority of patients presenting with gastro-intestinal bleed responded well to all three modalitis of treatment. However, in those with complications like occurrence of re-bleeding or significant blood loss requiring blood transfusion, there were no statistically significant differences between the three groups (p=NS) (Table 3).

Table 3: Comparison of clinical outcomes according to treatment received.

	Group A (Omeprazole)	Group B (Octreotide)	Group C (Tranexemic acid)
Blood Transfusion	4 cases	12 cases	6 cases
Rebleeding	4 cases	8 cases	5 Cases

Table 4: Duration of hospital stay according to treatment received.

	Group A (Omeprazole)	Group B (Octreotide)	Group C (Tranexemic acid)
Days of Hospitalisation	4.4±1.75	7.15±2.84	6.72±2.14

The mean duration of stay in hospital was 7.15±2.84, when comparison was done between group B and group C the p value was 0.46 (p=NS) Mean Duration of stay in hospital was 4.4±1.75, when compared to the other two group the duration of hospitalization was least as the p value was <0.0001 (Table 4).

Length of stay in hospital was significantly lower in Group A patients who received omeprazole, compared to patients in Groups B and C who received somatostatin and tranexamic acid respectively (p<0.05). Thus, outcomes appeared to favor the diagnosis of acid peptic disease amenable to treatment with omeprazole, as compared to other conditions or modalities of treatment (Table 4).

DISCUSSION

In this study maximum case presented with Upper GI bleed in our hospital come underage group of 30-50 years, that is 52 %. In a study conducted by Deep Anand, Rohit Gupta, Minakshi Dhar, Vivek Ahuja, On clinical and endoscopic profile of patients with upper gastrointestinal bleeding at tertiary care centre of North India. The mean age of the study group was 49 years.[5] In another study conducted by Rathi et al, the mean age group of patients was 42.[6] In our study out of total cases 73% were males and 27% were females. In study conducted by Deep Anand, Rohit Gupta, Minakshi Dhar, Vivek Ahuja, UGI bleed was found to be more common in males that is 83.33% as compared to women and male to female ratio was 5:1.And in another Indian study by Shenoy and Rao, UGIB was more common in males that was 74.2%.[7] The commonest cause for non-variceal bleed was gastric ulcer 45 cases, followed by Mild Antral Gastritis 24 cases, then 11 cases with Antral Gastritis, 5 cases each of Duodenal ulcer, Viral Esophagitis and Duodenitis, 2 cases each of fundal ulcer, Schatzki ring, and Esophagitis.

In a study conducted by Wang J et al, on the clinical epidemiological characteristics and change trend of upper gastrointestinal bleeding over the past 15 years, they demonstrated that the first etiology of UGIB was Peptic ulcer bleeding, accounting 65.25% (605/928), duodenal ulcer 47.8% (444/928), gastric ulcer 8.3% (77/928), stomal ulcer 2.3%(21/928), compound ulcer 6.8%(63/928), the second was cancer bleeding 7.0%,(65/928) and the third was esophageal and gastric varices bleeding 6.4% (59/928). But with time the ratio of peptic ulcer disease decreased.[8] The cases treated with omeprazole were 35, the mean age of this group cases was 41±13.63, M:F ratio was 3:2. There were 4 cases out of 35 (11.42%) who received blood transfusion, and 4 had history of re bleeding. Mean Duration of stay in hospital was 4.4±1.75, when compared to the other two group the duration of hospitalization was least as the P value was <0.0001. In a study conducted by Valizadeh Toosi SM et al, on comparison of oral versus intravenous proton pump inhibitors in preventing re bleeding from peptic ulcer after successful endoscopic therapy, in his study the rates of re bleeding were 2.3% in IV group and 3.3% in oral group.[9] There were 38 cases treated with Octreotide, with the mean age of 45.23±12.44, M:F ratio of 2:1 with 12 cases (31.5%)with blood transfusion and 8 with history of re bleeding. The mean duration of stay in hospital was 7.15±2.84, when compared to Tranexemic acid group the duration of stay the p value was 0.46.

Choi CW et al, described in a study on Somatostatin adjunctive therapy for nonvariceal upper Gastro intestinal re bleeding after endoscopic therapy, that early re bleeding rates were not significantly different p = 0.766.[10] Disappearance of endoscopic stigma on the second endoscopy was not significantly different between treatment groups p = 0.696.

There were 36 cases who received Tranexemic acid in our study, with mean age of 40.41±14.84, M:F of 2:1

with 6 cases requiring blood transfusion and 5 cases with history of re bleeding. The mean duration of hospital stay was 6.72±2.14. In a Cochrane meta-analysis evaluating the use of tranexamic acid in 1654 UGIH patients showed a beneficial effect of tranexamic acid on mortality when compared with placebo (relative risk [RR] 0.61, 95%CI 0.42–0.89), but not on other patient outcomes including bleeding, surgery, or transfusion requirements.[11]

CONCLUSION

From current study we can conclude that the commonest cause of Non-Variceal bleeding was Gastric ulcer. The risk of non-variceal bleeding increases with increase in age. Use of PPI in case of Non-Variceal Bleeding significantly reduces the need of blood transfusion. Even it reduces the cases of re bleeding and duration of hospital stay.

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: Singh P, Singh G, Kumar V, Chawla G. An adaptive clinical trial on patients with non variceal upper gastrointestinal bleed with the help of endoscopy. Int J Adv Med 2020;7:435-8.