AstraZeneca

STUDY REPORT SUMMARY

A SURVEY OF NON-VARICEAL UPPER GASTROINTESTINAL BLEEDING IN SELECTED HEALTH CARE CENTRES IN VIETNAM

Background: Non-variceal upper gastrointestinal bleeding (NUGIB) can be caused by many different causes and one of the most common causes is duodeno-gastric ulcer. Upper gastrointestinal bleeding(UGIB) were studied and reported in many international articles ([3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17]) and The Viet Nam Association of Gastroenterology also gave the recommendations for the diagnosis, care and treatment of UGIB([18]). However, the specific information on how the patient is treated, the success rate when applying different treatment approaches as well as the main factors associated with the clinical outcomes in Vietnam are remained unknown.

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No
ACTIVE INGREDIENT: No

Study No:
NIS-GVN-DUM-2010/1

Developmental Phase: Not applicable
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OBJECTIVES: This study aims to assess the rate of recurrent UGIB in NUGIB patients to supplement the epidemiological data sources in the country and contribute to the improvement the management of NUGIB.

METHODS:

This was an observational non-interventional, cohort, multicentral study. Eligible patients will be recruited into the study at 17 participating hospitals until the study reaches a required number of studied participants. Data from each patient, including demographic data, disease status, clinical treatment approaches (diagnostic methods, treatment regimens and follow-up) and the final results will be collected for a whole episode of NUGIB, starting from the date of hospitalization of UGIB for up to 7 days later and until the time of hospital discharge. Data were processed and analyzed using STATA 12.0

RESULTS:

The study has enrolled 1,036 UGIB patients with the mean of age of 54.8 years old. The median of the waiting time from admission until the first endoscopy was 14.5 hours, mean of the waiting time from admission until the first endoscopy was 22.5 hours (SD = 26 hours). The percentage of patients receiving the first endoscopy within 24 hours was 71.8% (95% CI: 67.9% -75.4%). The results showed that endoscopic intervention has significantly reduced the unexpected clinical outcome of the treatment, both statistically and clinically. Specifically, the rate of patients continued bleeding after endoscopic intervention in the group without initial endoscopy was 9.1% (95% CI: 7.0% -11.6%), in the intervention group only 3.7% (95% CI: 1.9% -6.2%). The rate of patients with bleeding recurrent during their time in hospital (up to 7 days) without and with endoscopy was 6.9% (95% CI: 5.1% -9.2%) and 3.4% (95% CI: 1.8% -5.8%) respectively.

The rate of recurrent UGIB within 7 days after UGIB in this study (the gross rate of recurrent UGIB during hospital stay (within 7 days) and were discharged from the hospital (within 7 days) was 6.1% for all patients, and for UGIB patients diagnosed as high risk at endoscopy, this rate was 7%.

Logistic regression analysis between recurrent UGIB status and its predictors was built. Independent variables was determined by stepwise-regression algorithm and has shown that age group of 65 increases the risk of recurrent UGIB (OR = 2, CI 95%: 1.4 to 4, 7), while manipulating endoscopic therapy also reduces the risk of recurrent UGIB (OR = 0.29, 95% CI: 0.1 to 0.7), UGIB at high risk also increases the risk of recurrent UGIB after treatment (OR = 3.1, 95% CI: 1.4 -7.2). The rate of surgical patients in the study was 2.6% (95% CI: 1.8% - 3.8%), the rate of patient with complication was 2.2% (95% CI: 1.7% -3.7%) and the death rate was 0.5% (95% CI: 0.2% -1.2%).

Other findings of the study included the rate of patients with high-dose PPI therapy during the waiting time for the first endoscopy under the guidance of The Viet Nam Association of Gastroenterology wass only about 50%, and 50% of UGIB patients clasified as high risk was not dosed with high-dose PPI therapy after endoscopic following the guidance of the Association of Gastroenterology. Helicobacter pylori test was performed only on 18.9% of the patients (95% CI: 16.5% -21.4%) with a positive rate of the tested patients was 58.7%. Another finding was that 73% of high-risk UGIB patients is treated during endoscopy, in which Epinephrine injection is done mainly with approximately 90% of patients (95% CI: 85.5% - 92.1%) and in high-risk groups of UGIB, only a low percentage of 5.4% (95% CI: 3.6% -7.9%) at endoscopic intervention, were treated with combined therapies (Epinephrine injection combined with vascular clamp or injected fibre into the ulcer).

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