의학 석사 학위논문

Predictive Factors of Therapeutic Intervention in On-call Endoscopy for Suspected Gastrointestinal Bleeding

위장관 출혈 의심 환자에서 응급 내시경의 시술적
치료에 관한 예측 인자

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Abstract

Predictive Factors of Therapeutic Intervention in On-call Endoscopy for Suspected Gastrointestinal Bleeding

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Background and Aims: Performing an endoscopy out of hours confer significant burdens on limited health-care resources. However, not all on-call endoscopies lead to therapeutic interventions. The purpose of the present study was to analyze predictive factors for performing therapeutic intervention in patients with suspected gastrointestinal bleeding.

Methods: We reviewed and analyzed electronic medical records regarding on-call endoscopy that were prospectively collected for quality control. The subjects were patients with suspected gastrointestinal bleeding who underwent on-call endoscopies at night, on weekends, and on holidays between April 2013 and January 2017 in Seoul National University Bundang Hospital. To determine predictive factors for performing therapeutic intervention, the following variables were analyzed: symptoms, patient status, coexisting disease, laboratory findings, and medications. To clarify the association between the likelihood of therapeutic intervention in on-call endoscopy and AIMS65 score, the included variables were divided by cutoffs.

Results: A total of 270 patients (male: 72.6%, mean age: 62.6 years) with suspected gastrointestinal bleeding had on-call

endoscopies and 153 (56.7%) patients had therapeutic intervention. Gastroscopy, colonoscopy, and both endoscopic techniques were performed in 215, 42, and 13 patients, respectively. In the multivariate analysis, hematemesis ($p < 0.001$, odds ratio [OR], 2.484) and prolonged prothrombin time-international normalized ratio (PT-INR) ($p = 0.033$; OR, 1.958) were correlated with performing therapeutic intervention in on-call endoscopy. AIMS65 score with a cutoff of 2 was associated with the likelihood of intervention ($p = 0.043$).

Conclusions: Hematemesis and prolonged PT-INR were predictive factors of therapeutic intervention when on-call endoscopy was performed in patients with suspected gastrointestinal bleeding.

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Introduction

Gastrointestinal bleeding is one of the most common disease presentations that frequently require clinical interventions and is associated with significant morbidity and mortality. Recent studies showed that the annual incidence rates of upper and lower gastrointestinal bleeding are 37–172/100,000 and 87/100,000 adults, respectively[1, 2, 3, 4].

Several risk scoring systems have been established to identify patients with poor prognosis and requirements of clinical interventions for gastrointestinal bleeding [5, 6, 7, 8]. Early endoscopy (≤24 hours) is recommended to patients with suspected severe or ongoing active bleeding [9, 10]. Moreover, some studies revealed the benefits of very early endoscopy (<12 hours) in aspects of reducing transfusion requirements and all-cause in-hospital mortality among patients with high-risk features [11, 12]. However, this topic is controversial, and it is a fact that not all early endoscopies lead to therapeutic interventions, which is important for changing the outcomes in clinical practice.

Providing on-call coverages confer considerable burdens on limited health-care resources [13, 14]. To perform an emergent endoscopy out of hours for patients with suspected gastrointestinal bleeding, additional costs, facilities, and an on-call endoscopic team, including endoscopy specialists and well-trained nurses, are required. The quality of medical care is also affected by overloading the endoscopic team because of after-hours care.

To optimize the prognostic outcome of patients with gastrointestinal bleeding while minimizing health-care resources, thoroughly differentiating between high and low likelihood of performing hemostasis before an on-call endoscopy is crucial [15, 16, 17]. However, the predictive factor for performing a therapeutic intervention in on-call endoscopy has not been clarified. Given this background, the aim of this study was to analyze predictive factors for therapeutic intervention in patients with suspected upper and/or lower gastrointestinal bleeding who underwent on-call endoscopy.

Methods

Study Subjects

The subjects were patients with suspected gastrointestinal bleeding who had on-call endoscopies at night, on weekends, and holidays between April 2013 and January 2017 in Seoul National University Bundang Hospital. The inclusion criteria for this study were as follows: (i) ≥18 years old; (ii) symptoms of melena, hematochezia, hematemesis, or clinically suspected gastrointestinal bleeding with hemoglobin drop; (iii) underwent on-call endoscopy after final decision of the endoscopic team. After notification from nurses, physicians in the emergency department or on night duty evaluate patients with suspected gastrointestinal bleeding and activate the on-call endoscopy contact system when deemed necessary. Reevaluating the patient's medical history, symptoms, physical examination, laboratory data, and vital signs, the junior gastroenterology staff makes the final decision on performing on-call endoscopy. Contacts for on-call endoscopy were available everywhere in the hospital, including the emergency department, general wards, and intensive care units. Data regarding on-call endoscopy has been collected prospectively from electronic medical records for quality control since April 2013. We retrospectively reviewed and analyzed these data.

Definition of Therapeutic Intervention and Measurements of Clinical Parameters

Therapeutic intervention was defined as endoscopic variceal ligation, hemoclipping, argon plasma coagulation, and injection of epinephrine or histoacryl. Therapeutic interventions were performed in patients with spurting (Forrest IA), oozing (Forrest IB) bleeding, non-bleeding visible vessel (Forrest IIA) [18] or variceal bleeding on gastroscopy, and single bleeding focus on colonoscopy, such as diverticular hemorrhage, angiodysplasia, and bleeding from the polypectomy or endoscopic mucosal resection

site. To determine the predictive factors of therapeutic intervention, the following variables were analyzed: symptoms (hematemesis, melena, and hematochezia), patient status (age, sex, mentality, and systolic blood pressure), coexisting disease (hypertension, diabetes mellitus, liver cirrhosis, chronic renal failure, and calculation of the Charlson Comorbidity Index [19]), laboratory findings (serum hemoglobin, albumin, creatinine, blood urea nitrogen, and prothrombin time-international normalized ratio [PT-INR]), and medications (proton pump inhibitors, nonsteroidal anti-inflammatory drugs, antiplatelets, and anticoagulants). Aspirin, clopidogrel, and cilostazol were included in the antiplatelet category, and low-molecular-weight heparin, unfractionated heparin, vitamin K antagonist, and direct oral anticoagulant were included in the anticoagulant category. The blood sampling for laboratory data was performed between recognition of gastrointestinal bleeding symptoms and on-call endoscopy. In subjects with clinically suspected gastrointestinal bleeding, the laboratory data at that time were obtained.

Hypertension was defined as a systolic blood pressure of ≥140 mm Hg, a diastolic blood pressure of ≥90 mm Hg, and/or current treatment with antihypertensive drugs. Diabetes mellitus was defined as HbA1c levels of ≥6.5%, fasting plasma glucose levels of ≥126 mg/dL, and/or current use of antidiabetic drugs [20]. Liver cirrhosis was diagnosed using liver biopsy and/or unequivocal clinical, laboratory, and imaging data despite any etiology. Chronic kidney disease was defined on the basis of decreased kidney function (glomerular filtration rate, <60 ml/min per 1.73 m2) or the presence of kidney damage for 3 or more months [21]. In addition, comorbidity was also defined using the Charlson Comorbidity Index.

To clarify the association between the likelihood of therapeutic intervention in on-call endoscopy and AIMS65 score [6], which is known as the prognostic score for predicting outcomes in upper gastrointestinal bleeding, the included variables were divided by cutoffs. The cutoff values of systolic blood pressure, serum hemoglobin, albumin level, and PT-INR were 90 mm Hg, 10.0 g/dL,

3.0 mg/dL, and 1.5, respectively.

Statistical Analysis

The significant differences between the groups with or without therapeutic intervention were analyzed using the Student t test for continuous variables and the chi-square or Fisher exact test for categorical variables.

To investigate the independent predictive factors for therapeutic intervention among patients who underwent on-call endoscopy, a multivariable logistic regression analysis was applied. Considered clinically fundamental and important, age and sex as demographic data were included in the multivariate analysis with variables that were proven to be significant in the univariate analysis. A P value of <0.05 was considered statistically significant. All statistical analyses were performed using the IBM SPSS Statistics software ver. 20.0 (IBM Inc., Armonk, NY, USA).

Ethical Considerations

The study was approved by the international review board (IRB) of Seoul National University Hospital (IRB no. B-1707-409-115) and was conducted in accordance with the Declaration of Helsinki for the participation of human subjects in research.

Results

Baseline Characteristics

A total of 270 patients (male, 72.6%; mean age, 62.6 ± 15.8 years) with suspected gastrointestinal bleeding had on-call endoscopies, and 153 (56.7%) had therapeutic interventions. Gastroscopy, colonoscopy, and both endoscopic techniques were performed in 215, 42, and 13 patients, respectively, and therapeutic interventions were performed for 128 (59.5%), 23 (54.8%), and 2 patients (15.4%), respectively. Subjects from the emergency department

were the most common (73.0%), followed by those from the general wards (21.5%) and intensive care units (5.5%). Almost all the patients with suspected gastrointestinal bleeding routinely had intravenous pantoprazole (dose of 80 mg, followed by 8 mg/hour infusion) before performing on-call endoscopy, except for 2 patients.

The baseline characteristics of the patients with and those without therapeutic intervention are compared in Table 1. No significant differences were found between the two groups in the variables of age (p = 0.237) and sex (p = 0.279). The patients who had symptoms of hematemesis were more likely to have a therapeutic intervention during the on-call endoscopy (p < 0.001). However, melena was shown as a negative predictive factor in therapeutic intervention (p = 0.002). The prevalence of liver cirrhosis was significantly higher in the patients with therapeutic intervention (37.9% vs 20.5%, p = 0.002), whereas the prevalence of hypertension was lower (23.5% vs 35.9%, p = 0.026). Any laboratory parameters and medications could not be shown as having a predictive value for therapeutic intervention.

As final diagnosis, ulcer constitutes the largest proportion (37.8%), followed by varices (24.8%) and obscure gastrointestinal bleeding (13.7%), in the patients with suspected gastrointestinal bleeding (Table 2). Diagnosis was not available in 5 cases of on-call endoscopy because of food materials, massive hemorrhage, and clots.

Table 1. Baseline characteristics of subjects with suspected gastrointestinal bleeding who had on-call endoscopy with and without therapeutic intervention

Variables	All (n = 270)	Therapeutic intervention (n = 153)	No intervention (n = 117)	p value
Demographic and clinical parameters				
Age, years	62.6 ± 15.8	61.6 ± 15.8	63.9 ± 15.9	0.237
Male sex	196 (72.6)	115 (75.2)	81 (69.2)	0.279
Alert mentality	243 (90.0)	135 (88.2)	108 (92.3)	0.269
Systolic blood pressure, mm Hg	114.9 ± 22.0	113.1 ± 21.7	117.2 ± 22.4	0.124

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Symptoms				
Hematemesis	137 (50.7)	94 (61.4)	43 (36.7)	<0.001
Melena	69 (25.5)	28 (18.3)	41 (35.0)	0.002
Hematochezia	66 (24.4)	33 (21.6)	33 (28.2)	0.209
Coexisting disease				
Hypertension	78 (28.9)	36 (23.5)	42 (35.9)	0.026
Diabetes mellitus	65 (24.1)	35 (22.9)	30 (25.6)	0.598
Liver cirrhosis	82 (30.4)	58 (37.9)	24 (20.5)	0.002
Chronic renal failure	26 (9.6)	14 (9.1)	12 (10.2)	0.760
CCI score	2.9 ± 2.3	3.0 ± 2.2	2.9 ± 2.4	0.780
Age adjusted CCI score	4.7 ± 3.0	4.7 ± 2.8	4.7 ± 3.2	0.853
Laboratory parameters				
Serum hemoglobin, g/dL	9.1 ± 2.5	9.1 ± 2.3	9.1 ± 2.6	0.843
Serum albumin, g/dL	3.1 ± 0.7	3.1 ± 0.7	3.1 ± 0.6	0.591
PT-INR	1.44 ± 0.68	1.50 ± 0.71	1.37 ± 0.63	0.129
Serum creatinine, mg/dL	1.40 ± 1.56	1.42 ± 1.60	1.37 ± 1.51	0.811
Blood urea nitrogen, mg/dL	33.2 ± 25.1	33.6 ± 25.9	32.6 ± 24.2	0.763
AIMS65 score	1.3 ± 1.1	1.4 ± 1.1	1.2 ± 1.1	0.116
Medication				
NSAIDs	12 (4.4)	4 (2.6)	8 (6.8)	0.095
Antiplatelet agents	77 (28.5)	40 (26.1)	37 (31.6)	0.323
Anticoagulant agents	22 (8.1)	12 (7.8)	10 (8.5)	0.834

Variables are expressed as mean ± standard deviation or n (%).
CCI, Charlson Comorbidity Index; PT-INR, prothrombin time-international normalized ratio; NSAIDs, nonsteroidal anti-inflammatory drugs.

Table 2. Endoscopic diagnosis of patients according to therapeutic intervention status

Diagnosis	All (n = 270)	Therapeutic intervention (n = 153)	No intervention (n = 117)
Ulcer	102 (37.8)	62 (40.5)	40 (34.2)
Varix	67 (24.8)	53 (34.6)	14 (12.0)
Obscure GI bleeding	37 (13.7)	0 (0.0)	37 (31.6)
Procedure-related bleeding	26 (9.6)	21 (13.7)	5 (4.3)
Mallory-Weiss syndrome	13 (4.8)	11 (7.2)	2 (1.7)
Neoplasm	7 (2.6)	2 (1.3)	5 (4.2)
Others*	13 (4.8)	4 (2.6)	9 (7.7)
Limited study	5 (1.8)	0 (0.0)	5 (4.3)

Variables are expressed as n (%).
*Erosion, diverticulum, angiodysplasia, and hemorrhoid.

Multivariate Analysis for Verifying Independent Predictive Factor

Adjusting for covariates that affect conducting therapeutic intervention, we applied a multivariable logistic regression analysis by using age, sex, hematemesis, melena, hypertension, liver cirrhosis, and PT-INR of >1.5. As shown in Table 3, hematemesis (p < 0.001; odds ratio [OR], 2.484) and prolonged PT-INR (p = 0.033; OR, 1.958) showed the association with performing therapeutic intervention in on-call endoscopy.

Table 3. Multivariate analyses producing odds ratio of predictive factors for therapeutic intervention among the subjects with suspected gastrointestinal bleeding who had on-call endoscopies

Variables (Cutoff value)	Adjusted OR (95% CI)	p Value
Hematemesis	2.484 (1.497–4.124)	<0.001
PT-INR (>1.5)	1.958 (1.056–3.631)	0.033

OR, odds ratio; CI, confidence interval; PT-INR, prothrombin time-international normalized ratio.

Adjusted Characteristics according to AIMS65 Score

Among the five components of the AIMS65 scoring system, only PT-INR of >1.5 was observed as a predictive factor of therapeutic intervention (p = 0.005; Table 4). Although no significant relationship was observed with the AIMS65 score and therapeutic intervention, AIMS65 score with a cutoff of 2 was associated with the likelihood of intervention (p = 0.043). The percentages of therapeutic intervention in subjects satisfied with each AIMS65 cutoff value are shown in Figure 1. A cutoff of 2 was observed as the highest percentage (64.0%), whereas the baseline percentage was 56.7%.

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Table 4. Risk factors and AIMS65 scores by cutoff value according to therapeutic intervention status

Variables (Cutoff value)	All (n = 270)	Therapeutic intervention (n = 153)	No intervention (n = 117)	p Value
Risk factors of AIMS65				
Age, years (>65 years)	124 (45.9)	65 (42.5)	59 (50.4)	0.219
Systolic blood pressure, mm Hg (<90 mm Hg)	26 (9.6)	15 (9.8)	11 (9.4)	>0.999
Serum hemoglobin, g/dL (<10.0 g/dL)	186 (68.9)	104 (68.0)	82 (70.1)	0.791
Serum Albumin, g/dL (<3.0 g/dL)	114 (42.2)	71 (46.4)	43 (36.7)	0.136
PT-INR (>1.5)	67 (24.8)	48 (31.4)	19 (16.2)	0.005
AIMS65 score				
AIMS65 (≥1)	194 (71.8)	112 (73.2)	82 (70.1)	0.572
AIMS65 (≥2)	111 (41.1)	71 (46.4)	40 (34.2)	0.043
AIMS65 (≥3)	41 (15.2)	26 (17.0)	15 (12.8)	0.344
AIMS65 (≥4)	9 (3.3)	6 (3.9)	3 (2.6)	0.736
AIMS65 (≥5)	1 (0.4)	1 (0.6)	0 (0.0)	>0.999

Variables are expressed as n (%).
PT-INR, prothrombin time-international normalized ratio.

Figure 1. Percentage of patients who underwent therapeutic intervention according to the AIMS65 score
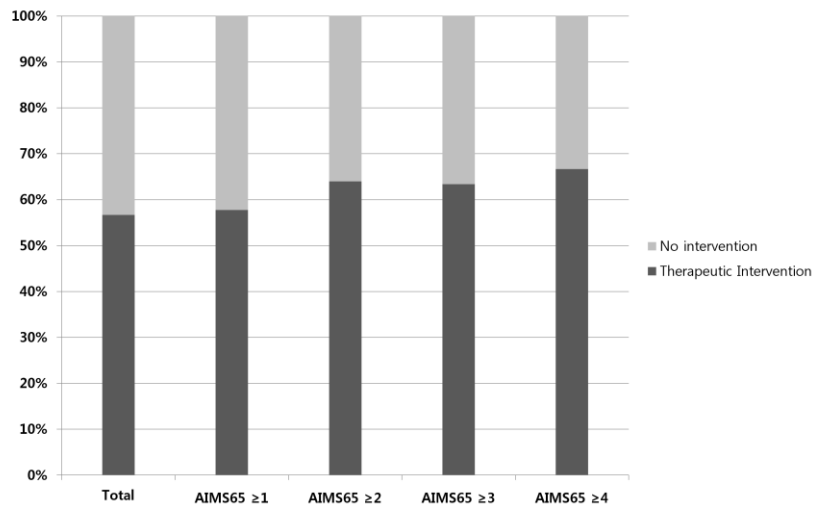
Discussion

In this study, symptoms of hematemesis and laboratory finding of prolonged PT-INR in patients with suspected gastrointestinal bleeding were associated with therapeutic intervention in on-call endoscopy. Patients with hematemesis showed an approximately 2.5-fold increase in odds and prolonged PT-INR exhibited approximately 2-fold increase in odds of performing hemostasis through endoscopy. The role of hematemesis in predicting intervention can be explained by the amount and rapidity of bleeding. By contrast, melena might be present within 4 to 20 hours after hemorrhage and could last for a few days even if the bleeding has stopped. Melena may not indicate the rapidity or presence of hemorrhage at the time of passage [22]. It is also necessary for clinicians to consider performing on-call endoscopies in patients with prolonged PT-INR, which implies decreased coagulation function and accompanying liver disease.

Approximately only half of patients received therapeutic intervention even though they were selected for undergoing on-call endoscopy because of suspected active bleeding. The percentage of the endoscopies performed among total patients contacted by the on-call system could not be calculated because the specific data of the subjects rejected from performing on-call endoscopy were not obtained. However, we expect the percentage of patients who required therapeutic intervention to be much lower among all the patients with symptoms of gastrointestinal bleeding out of hours. This suggests that selecting patients at high risk is difficult and emphasizes the importance of revealing risk factors.

To date, several studies have proposed predictive factors for patients with either upper or lower gastrointestinal bleeding to predict outcomes such as mortality, recurrent bleeding, length of hospital stay, and need for clinical intervention, which includes blood transfusion and endoscopic or surgical intervention [5, 6, 7, 8, 23, 24]. However, these factors and risk stratification scores were not specifically developed for predicting therapeutic intervention in

on-call endoscopy, which is crucial to decide whether the endoscopy should be done early or in the regular working hours the next day. Moreover, previously developed risk scoring systems are sometimes not suitable for patients in an emergency whose bleeding is often difficult to localize on the basis of clinical symptoms. Therefore, our study illustrates the predictive factors for performing endoscopic therapeutic intervention outside regular working hours in patients with suspected upper and/or lower gastrointestinal bleeding.

The AIMS65 score, which was developed for predicting outcome, does not rely on the medical history of patients and can be easily applied in clinical practice. In the present study, AIMS65 score was calculated in all the subjects, and a cutoff of 2 showed a significant association with therapeutic intervention in on-call endoscopy. However, only PT-INR showed significant association as a predictive factor among the components of the AIMS65 scoring system. This suggests that previous prognostic scoring system does not appropriately suit for early endoscopy in after-hours care setting.

It is interesting that in a study by Adamopoulos et al. [25], red blood on nasogastric aspiration, hemodynamic instability, hemoglobin (>8 g/dL), and white blood cell count (>12000/ L) significantly predicted active upper gastrointestinal bleeding as pre-endoscopic variables among patients who underwent on-call endoscopies in the multivariate analysis. We included patients with suspected upper and/or lower gastrointestinal bleeding, including hospitalized patients, whereas Adamopoulos et al. limited the subjects only for upper gastrointestinal bleeding cases and excluded patients who presented symptoms of bleeding during hospitalization for other illnesses. Gastrointestinal bleeding occurs regardless of location in the hospital, and the focus of the bleeding is often difficult to clearly differentiate just by clinical symptoms such as melena and hematochezia. Therefore, our study design implies a more practical concern in clinical decision. In addition, 26.8% of patients were evaluated as having active upper gastrointestinal

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bleeding and those underwent therapeutic intervention in a study by Adamopoulos et al. By contrast, more than 50% of patients who had on-call gastroscopy underwent hemostasis in this study. These differences can be explained by the on-call system of Seoul National University Bundang Hospital, where gastroenterology junior staffs thoroughly reevaluate patients and perform on-call endoscopies in high-risk patients.

In this study, gastroduodenal ulcer (45.9%) was the most frequent cause of upper gastrointestinal bleeding, which is concordant with previous reports [1, 4, 7, 26, 27]. However, the most frequent cause of lower gastrointestinal bleeding was procedure-related bleeding (40.0%), such as that in polypectomy and endoscopic mucosal resection, instead of diverticular disease. which is not compatible with the findings of previous studies [2, 3, 28]. Although the reason is not clear, this phenomenon can be explained in part by the selected study population, who underwent endoscopy out of hours. In our present study, patients who were discharged after polypectomy or endoscopic mucosal resection in regular working hours visited the hospital because of symptoms of bleeding. On-call endoscopy was likely to be performed in these patients who were strongly considered to require hemostasis.

The first strength of this study was that we demonstrated predictive factors for therapeutic intervention in on-call endoscopy after adjusting for confounding variables and applied the well-known AIMS65 score. Second, patients with suspected upper and/or lower gastrointestinal bleeding were included. Therefore, the predictive factors can be informative for clinicians in decision making on on-call endoscopy before identifying the bleeding focus. The third strength is that the patients enrolled were from all locations in a tertiary care, university-affiliated hospital, including the emergency department, general wards, and intensive care units.

This study has several limitations. First, this study was a retrospective analysis of prospectively collected data. However, because we prospectively collected and reviewed data regarding on-call endoscopy every month to monitor and control the quality

of on-call endoscopy, the quality of data is high and missing data were few. Second, no objective criteria have been established for decision making on performing on-call endoscopy in patients with suspected gastrointestinal bleeding. However, medical staffs who are specialists in gastrointestinal endoscopy with experience of >5-8 years reevaluated all the notified patients to select patients at high risk. Third, demonstrating predictive factors of therapeutic intervention in on-call endoscopy, this study did not solve the cost-effectiveness and risk-benefit problems. Further studies dealing with cost-effectiveness and risk-benefit problems are warranted to elucidate the application of these predictive factors in clinical practice.

In conclusion, this study demonstrated that hematemesis and prolonged PT-INR are predictive factors for performing therapeutic intervention during on-call endoscopy in patients with suspected gastrointestinal bleeding. Given the fact that prediction of therapeutic intervention is possible, symptoms of hematemesis and/or prolonged PT-INR are important information for clinicians to decide whether to perform on-call endoscopy.

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국문 초록

연구 목적: 정규 근무 시간외에 응급 내시경 검사를 시행하는 것은 제한적인 의료 자원에 상당한 부담을 준다. 또한 사실상 내시경을 받는 모든 환자들이 시술적 치료를 필요로 하는 것은 아니다. 본 연구는 위장관 출혈이 의심되는 환자에서 시술적 치료의 예측 인자를 분석하고자 하였다.

연구 방법: 분당서울대학교 병원에서 2013 년 4 월부터 2017 년 1 월까지 밤, 주말, 공휴일에 내시경 검사를 받은 위장관 출혈 의심 환자들을 대상자로 선정하였고 전자 의료 기록을 검토 및 분석하였다. 시술적 치료에 대한 예측 인자를 알아보기 위해 환자의 증상, 동반 질환, 혈액 검사 및 약물 등의 변수를 분석하였다.

연구 결과: 위장관 출혈로 의심되는 270명의 환자들이 (남성 72.6 %, 평균 나이 62.6세) 응급 내시경 검사를 받았고 이들 중 153명 (56.7 %)의 환자가 시술적 치료를 받았다. 위 내시경 검사, 대장 내시경 검사는 각각 215 명, 42 명에서 시행되었고 13 명의 환자는 위와 대장 내시경 모두 시행 받았다. 다변량 분석에서 토혈과 (p <0.001, odds ratio [OR], 2.484) 프로트롬빈시간국제표준비율의 연장이 (p = 0.033; OR, 1.958) 응급 내시경에서의 시술적 치료와 연관성을 보였다. AIMS65 점수가 2점 이상일 경우 시술적 치료를 할 가능성이 높았다. (p = 0.043).

결론: 위장관 출혈이 의심되는 환자에서 토혈과 프로트롬빈시간국제표준비율의 연장은 정규시간 외에 응급 내시경 검사를 시행함에 있어 시술적 치료의 예측 인자이다.

주요어: 위장관 출혈; 내시경; 위험 인자; 시술적 치료
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