The Impact of Health Literacy on the ERCP Process

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A B S T R A C T

Background Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive method commonly used for the diagnosis and treatment of hepatopancreaticobiliary diseases. The aim of this study is to assess whether there is a relationship between Health Literacy (HL) levels and the ERCP process.

Material and Methods The study prospectively evaluated the HL data of 72 patients who had ERCP in our hospital between July-November 2020. The Turkish version of the 47-item European Health Literacy Survey Questionnaire (HLS-EU-Q47) was used to assess health literacy. The patients' demographic characteristics, duration of referral to hospital, duration of the ERCP procedure, white blood cells (WBC), alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma glutamyl transferase (GGT), and total-direct bilirubin levels and HLS-EU-Q47 results were recorded and evaluated.

Results AIn our study, 77.7% of the patients had insufficient HL levels. The median body mass index (BMI) was statistically higher in patients with an insufficient HL level (p=0.046). GGT, total and direct bilirubin levels were higher in patients with a low HL level (p=0.009, p=0.031, p=0.008, respectively). The assessment of the duration of referral for ERCP revealed that the median duration of referral was statistically significantly longer in patients with an insufficient HL level (p<0.001). The median duration of cannulation during ERCP was statistically higher in patients with an insufficient HL level (p=0.002).

Conclusions The level of Health Literacy affects the early diagnosis and the success of the procedure in hepatopancreaticobiliary diseases that require ERCP.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a commonly used method for the diagnosis and treatment of benign and malignant hepatopancreaticobiliary diseases.[1] The most common ERCP indications are benign (such as bile duct stones or strictures, biliary pancreatitis and parasitic diseases of the biliary tract) and malignant diseases of the periampullary region, biliary or pancreatic ductal system.[2] Although it was widely used for diagnostic purposes in the early years, it is now used mostly for therapeutic purposes because of the development of non-invasive diagnostic methods such as magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS).[3] The most important factors affecting the success of ERCP include the experience of the endoscopist, the duration of the patient's referral, severity of the disease, and anatomical variations.[3]

Health Literacy (HL) was defined by the WHO (World Health Organization) in 1998 as cognitive and social skills that determine the ability of individuals to access, understand and use information to promote and maintain their health.[4] Parallel to the increase in Health Literacy levels, it has been found that an individual's duration of referral to healthcare services is shorter and health outcomes can be improved by making active decisions for treatment and initiating early treatment.[5,6] Studies have shown that there is a relationship between HL levels and patients' referral process for treatment.[7-10] Our knowledge regarding the effect of HL levels on referral prior to ERCP and the procedure is limited. The aim of our study is to determine the relationship between HL levels and the ERCP process.

Material and Methods

Study Design

The study prospectively recorded and evaluated the data of 72 patients who had ERCP in the endoscopy unit of our hospital between July 2020 and November 2020. The patients were given detailed information and provided their written informed consent prior to the study. The study was conducted in accordance with the principles of the Declaration of Helsinki. The local ethics committee approved the study (2011-KAEK-25 2019/10-18).

Sampling

An ERCP procedure was performed on patients who had elevated total and direct bilirubin (T. Bil, D. Bil), alkaline phosphatase (ALP) and gamma glutamyl transferase (GGT) levels as biochemical parameters and obstructed or dilatated intra-extrahepatic bile ducts on MRCP for diagnostic and therapeutic purposes. The study included outpatients aged from 18 to 80 years, who would have ERCP under sedoanalgesia for the first time and who were competent to fill in the health literacy questionnaire. Patients who previously had undergone ERCP, who did not accept to fill in the questionnaire or who failed to complete it, and who were healthcare personnel, were excluded.

Data Collection

The Turkish version of the European Health Literacy Survey Questionnaire (HLS-EU-Q47) was used in the study.[11] Patients with indications for ERCP were administered the HLS-EU-Q47 before the procedure. The questionnaire is comprised of 47 items, and the patients were asked to choose one of the four options (very difficult, difficult, easy and very easy) for each item. The questionnaire items were divided into three subgroups: items 1–16, health care; items 17–31, disease prevention; and items 32–47, health promotion. The indices were standardized as indicated in the formula below, with 0 indicating the lowest health literacy level and 50 the highest health literacy level on a scale from 0 to 50. Formula Index=(M-1)*(50/3), where the Index is specific index calculated, M is the mean of all participating items for each individual, 1 is the minimal possible value of the mean, 3 is the range of the mean and 50 is the chosen maximum value of the new metric.[11] Health literacy was considered insufficient for scores of 0–33 and sufficient for scores of 33–50.

The patients' hemogram and biochemical parameters were analyzed before and after ERCP. ERCP procedures were conducted under sedation anesthesia in the prone position in the endoscopy

unit under the control of an anesthesiologist. All procedures were performed by the same endoscopist. The pre-cut technique was used for cannulation in patients with failed cannulation using an ERCP catheter or sphincterotome.

Demographic characteristics, duration of referral to hospital, duration of the ERCP procedure, preoperative and postoperative levels of alanine aminotransferase (ALT), aspartate aminotransferase (AST), ALP, GGT, white blood cells (WBC), amylase, lipase, T. Bil, and D. Bil. and HLS-EU-Q47 results of the patients undergoing ERCP were recorded and evaluated.

Statistical Analysis

The Shapiro-Wilk test was used to test the concordance of the data to normal distribution. Continuous and discrete variables are expressed with median and interquartile range values, while categorical variables are reported with frequency and corresponding percentage values. The Mann-Whitney U test was used to compare the continuous and discrete variables between adequate and inadequate health literacy groups. In contrast, the chi-square test and Fisher's exact test were used to analyze categorical variables. Risk factors that are thought to be effective on inadequate health literacy levels were examined by logistic regression analysis. Internal consistency of the Health Literacy Scale was examined by Cronbach alpha coefficient. SPPS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) software was used for performing statistical analysis, and $p < 0.05$ was set for statistical significance.

Results

The study included 72 patients who had ERCP for the first time. Cannulation was successful in 86.1% of the patients. Complications developed in 15.2% of the patients. Of the patients, 8.3% developed moderate pancreatitis and were treated medically. Transient hyperamylasemia occurred in 6.9% of the patients and these patients were followed up conservatively. There was no mortality in this series of patients.

Our study identified insufficient HL levels in 77.7%, and sufficient HL levels in 22.3% of the patients undergoing ERCP *(Table 1)*.

A comparison was made of Health Literacy levels and patient demographic characteristics *(Table 2)*. There was no statistically significant relationship between age and gender and HL levels (p=0.64, p=0.949). Health literacy was found to be insufficient in 78.1% of male and 77.5% of female participants. The median body mass index (BMI) was statistically higher in patients with an insufficient HL level (p=0.046).

The relationship between clinical variables and HL was examined *(Table 3)*. There was no statistically significant relationship between the presence of comorbidity and the American Society of Anesthesiologists (ASA) scores and HL levels (p=0.431, p=0.617). The examination according to the duration of referral for ERCP revealed that the median duration of referral was statistically significantly longer in patients with an insufficient HL level (p<0.001). There was no statistically significant difference in HL levels between patients with and without bile duct dilatation (p>0.99). AST and ALP levels were not significantly related with HL scores (p>0.005), while ALT and GGT levels were statistically significantly

Table 1. Health Literacy Levels of Study Participants

	Insufficient HL	Problematic HL	Sufficient HL	Excellent HL	Cronbach's alpha (α)
Overall HL	31.90%	45.80%	16.70%	5.60%	0.898
Healthcare HL	26.40%	43.10%	23.60%	6.90%	0.881
Disease prevention HL	40.30%	34.70%	19.40%	5.60%	0.909
Health Promotion HL	40.30%	34.70%	16.70%	8.30%	0.954

HL: Health Literacy

Table 2. Comparison of Demographic Characteristics Between Health Literacy Groups

	Health Literacy Level		
	Sufficient (n=16)	Insufficient (n=56)	p-value
Age (years)	53.50(19.50)	58(19)	0.640[a]
Gender			
Female	9(22.50%)	31(77.50%)	0.949[b]
Male	7(21.90%)	25(78.10%)	
BMI (kg/m²)	23.55(3.23%)	26.35(5.18%)	0.046[a]

Data are presented as median (interquartile range).
BMI: Body Mass Index
a: Mann-Whitney U-test, b: Chi-square Test

higher in patients with an insufficient HL level (p=0.028, p=0.009, respectively). Amylase and lipase levels were not significantly related with HL (p>0.05), while T. Bil and D. Bil levels were statistically significantly higher in patients with an insufficient HL level (p=0.031, p=0.008, respectively). There was no significant relationship between WBC and HL levels (p>0.05). The median duration of cannulation during ERCP was statistically higher in patients with an insufficient HL level (p=0.002).

HL levels were not statistically significantly related with the following conditions: papillary localization, success of pancreatic cannulation, necessity to perform pre-cut, presence of malignancies, development of complications and complications that need treatment in the ERCP process (p>0.05).

Discussion

ERCP is used for diagnostic and therapeutic purposes in hepatopancreaticobiliary diseases. The most common indications for ERCP include bile duct stones that cause biliary obstruction, and malignant biliary obstructions.[12] Early diagnosis and treatment have an important role in the success of the ERCP procedure performed for benign and malignant pathologies.[13] The success rate of the procedure increases with early intervention in the treatment of benign biliary obstructions.[13] In malignant biliary diseases, in turn, early diagnosis shortens the time to initiate treatment, and biliary stenting shortens the time to initiate chemotherapy in patients who are not eligible for surgery.[13] Cannulation and treatment success rates have been reported to increase with early consultation to the physician in patients with ERCP indications.[14] It has been reported that HL levels affect healthcare solutions in individuals, and decreased levels of HL have an adverse effect on the duration of referral to healthcare institutions, and diagnostic and therapeutic processes.[15]

Health literacy levels are found to be higher in men, particularly those who are young and single.16 Another study reported lower HL levels in the elderly.[17] In Turkey, the rate of low HL levels was found to be 68.9% in a study conducted by the Ministry of Health.[18] A study involving eight European Union countries found this rate to be 47.6%.[18] According to the national adult literacy study in the United States of America (USA), in turn, this rate was 36%.[18] The present study established that the HL level was inversely proportional to the duration of referral for ERCP and the duration of cannulation. It was found that patients with a high HL level in decision-making about health had an earlier referral for ERCP. In addition, it is thought that the duration of cannulation at these patients would be short at ERCP.

One of the most important factors that affect cannulation success in ERCP is virgin papilla.[14] Since the patient history of ERCP would affect the results, we only included patients who

Table 3. Comparison of Clinical Characteristics Between Health Literacy Groups

	Health Literacy Level		
	Sufficient (n=16)	Insufficient (n=56)	p-value
Comorbidity	0 (1)	1 (3)	0.431[a]
ASA			
I	9(27.30%)	24(72.70%)	
II	6(18.80%)	26(81.20%)	0.617[b]
III	1(14.30%)	6(85.70%)	
Duration of Referral (Days)	10(5)	20(7.50)	<0.001[a]
Bile Duct Dilatation	12(22.20%)	42(77.80%)	>0.99[c]
AST (U/L)	41(102)	44(56)	0.807[a]
ALT (U/L)	27(43)	47(67)	0.028[a]
ALP (U/L)	98(119)	132(94)	0.336[a]
GGT (U/L)	127(81)	189(213)	0.009[a]
Amylase (U/L)	56(106)	47(58)	0.386[a]
Lipase (U/L)	54(197)	45(46)	0.420[a]
T.Bil (mg/dL)	1.50(0.70)	2.50(2.70)	0.031[a]
D.Bil (mg/dL)	1.10(0.60)	2.20(2.60)	0.008[a]
WBC (10^3/uL)	5.10(4.20)	5.70(4)	0.684[a]
Duration of Cannulation (min)	3(3)	5(2)	0.002[a]
Papillary Status			
Abnormal Localization	2(16.70%)	10(83.30%)	>0.99[c]
Normal	14(23.30%)	46(76.70%)	
Pancreatic Cannulation			
Yes	2(13.30%)	13(86.70%)	0.495[c]
No	14(24.60%)	43(75.40%)	
Pre-cut			
Yes	1(16.70%)	5(83.30%)	>0.99[c]
No	15(22.70%)	51(77.30%)	
Successful cannulation	15(24.20%)	47(75.80%)	0.440[c]
Malignancy			
Yes	0	5(100%)	0.580[c]
No	16(23.90%)	57(76.10%)	
Complications			
Yes	2(18.20%)	9(81.80%)	>0.99[c]
No	14(23%)	47(77%)	
Therapy for Complications			
Yes	2(18.20%)	9(81.80%)	>0.99[c]
No	14(23%)	47(77%)	

Data are presented as median (interquartile range).
ASA: American Society of Anesthesiologists, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, ALP: Alkaline phosphatase, GGT: Gamma glutamyl transferase, T.Bil: Total bilirubin, D.Bil: Direct bilirubin, WBC: White blood cell, a: Mann-Whitney U-test, b: Chi-square test, c: Fisher's Exact test

would have an ERCP for the first time. There was no significant relationship between HL levels and cannulation success in our patients.

Our study established that the low HL group presented with high cholestasis enzymes (T. Bil, D. Bil, ALT, GGT) (p<0.05). Factors that affect ERCP success are the presence of chronic pancreatitis or the number (>3) and size (>1 cm) of stones in the common bile duct.[19] Factors such as alcohol, genetics and hyperlipidemia cause chronic pancreatitis, secondary to pancreatic inflammation.[20] Likewise, the time to develop multiple and large common bile duct stones is longer compared to single and small common bile duct stones.[21] It was thought that patients with a low HL level referred late for ERCP and consequently were found to have higher values in liver function tests. However, AST and ALP levels were not associated with HL levels. We attribute this result to the cross-sectional design of our study and to the low patient number included in our study.

There are studies showing that there is no significant relationship between HL and BMI or that patients with a low HL level have a higher BMI.[22,23] Our study established higher BMI values also in patients with a low HL level (p=0.046).

Our study has some limitations due to the relatively small number of cases, single-center study design and variability in health literacy levels in different countries.

Conclusions

Our study is the first research on the relationship between Health Literacy and the ERCP process. HL levels have inversely proportional effect on the referral process for diagnostic and therapeutic ERCP procedure. We believe that the improvement of health literacy would increase the success rates of diagnosis and treatment in patients who require ERCP.

Conflict of interest

The authors have no conflict of interest to declare.

Authors' Contribution

Study Conception: UA, HMC; Study Design: UA, HMC; Supervision: UA, HMC; Funding: UA, HMC; Materials: UA, HMC; Data Collection and/or Processing: UA; Statistical Analysis and/or Data interpretation: UA; Literature Review: UA; Manuscript Preparation: UA; and Critical Review: HMC.

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