Improved Outcomes of Upper Gastrointestinal Endoscopy with Intensive Counselling and Videotapes; A Randomized Controlled Trial

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Abstract

Objective: The purpose of the study that we are currently conducting is to advise patients, implement various measures (such as videotapes), and permit patients' family members to accompany them inside the endoscopy room for the duration of the process in order to improve patients' levels of compliance.

Material and Methods: A randomized control trial study was conducted in tertiary care private hospital from March to August 2022. Each group has 125 participants. Consecutive sampling was done in study period and participants were randomly allocated to intervention or control groups. Group A, the intervention group, received counselling about EGD's safety and comfort and saw videotapes. Patients' family member was allowed to stay in the endo-scopic room during the procedure. Group B received simply standard protocol counselling. The self-developed questionnaire included socio-demographic characteristics, and an endoscopist assessed procedure difficulty and compliance. Data were entered into SPSS version 20. Compliance, endoscopist evaluation, and esophago-gastroduodenoscopy duration were compared between groups.

Results: A total of 250 study participants were included in the study. 125 were randomized in Group A and 125 were randomized in Group B. The most common comorbidities in study participants were diabetes, hypertension and ischemic heart disease. The chi-square test was used to access the time of the procedure, tolerated procedure, and endoscopist assessment between group A and group B. There was a statistically significant improvement in terms of these outcomes with the intervention.

Conclusion: Extensive counselling, videotapes, and allowing family members to stay in the endoscopy room improves the outcomes of patients in terms of the time of the procedure, tolerated procedure, and endoscopist assessment.

Keywords: Endoscopy, time of the procedure, counselling

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Introduction

The frequency of illnesses affecting the upper gastrointestinal (GI) tract is extremely high among the population as a whole, and this is true not only in industrialized countries but also in less developed nations. An esophagogastroduodenoscopy, often known as an EGD, is a diagnostic endoscopic technique that involves visualization of the oropharynx, the esophagus, the stomach, and the proximal part of the duodenum.[1,2] It is one of the procedures that a gastroenterologist does on a regular basis and is considered to be very common. 10% of patients coming to OPD come with gastrointestinal symptoms and of which half of them present with dyspepsia.[3] EGD is a daycare, safe, and easy invasive procedure without any sedation but throat anesthesia by local 4% Xylocaine gargle or spray is enough to complete the procedure safely.[4] However, in some cases, it provo-

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ked some fears, anxiety, the feeling of difficulty of swallowing, and vulnerabilities with the procedure. Furthermore, in our society, there are some myths regarding the esophagogastroduodenoscopy procedure. Because of all of these factors, doing an EGD and making a diagnosis is extremely challenging.[5]

Indications of this procedure can be diagnostic or therapeutic. Diagnostic indications include pain that is constant in the upper abdomen region, dysphagia, feeding disorders, persistent gastrointestinal reflux disorder, hematemesis, iron deficiency anemia, Chronic diarrhea, malabsorption, evaluation of acute injuries, and precarcinogenic conditions. Therapeutic indications include foreign body removal, dilation of strictures, esophageal variceal ligation, control of upper gastrointestinal bleeding, and treatment of achalasia.[6,7]

This procedure is common in all age groups and is conducted approximately equally in males and females.[8] The complications are relatively infrequent in specialized healthcare facilities. As the patients are not sedated they are anxious during the procedure and do not fully follow the commands of the endoscopist which makes this simple procedure complex. Misinformation about this procedure is relatively common in Pakistan. The literacy rate of this country is lower than the global average the patients do not understand the procedure with traditional consent. With videotapes, the procedure can be explained to the patients so that they are more aware and tolerate the procedure well by following commands given. Allowing family members to make the environment more comfortable provided that appropriate infection control measures are taken.[9] There are a variety of methods available to get around any problems, such as providing thorough counselling to patients on the myths and fears associated with EGD, showing patients videos, and letting family members wait in the endoscopy room with them while the treatment is carried out.[10] The consent form alone does not make the patient fully aware about the information they need. Moreover, there are many infodemics about the procedure. If videotapes are used for explaining procedure and attendant is allowed to stay with the patient during procedure after appropriate infection control measures it improves the ease and patient compliance during the procedure. The aim of this study is to evaluate the role of extensive counselling, showing videos before the procedure, and allowing one family member to stay with the patient during the procedure to improve and easy conduction of the procedure in terms of time and tolerance. Knowledge generated can help highlight the ease of procedure when these simple interventions are done.

Material and Methods

After approval from the institutional review board, a randomized control trial was conducted between March 2022 to August 2022 at a tertiary care private hospital in Lahore. The sample size was calculated to be 125 in each group with a 95 percent confidence interval and 5% margin of error. Patients with an indication of upper gastrointestinal endoscopy were recruited in the study after informed consent. Our inclusion criteria were all patients of age 18-65 years with a valid indication of esophagogastroduodenoscopy. Patients with preexisting psychiatric disorders, having follow-up Endoscopy, or the presence of Neoplastic disease or prior upper Gastrointestinal surgery were excluded from the study. Patients were made nil per oral for 6 to 8 hours before the procedure. After appropriate sedation as per standard guidelines the procedure was done. Allocation concealment and blinding were not done.

Consecutive sampling was done from 1st March 2022 till the completion of sample size. Patients were randomized to Group A or Group B with computer-generated numbers. The allocation ratio was 1:1 between the 2 groups (Figure 1). Group A was the intervention group which included additional counselling detail about the procedure with counselling regarding the safety and comfortability of EGD and showed them videotapes, in addition, family member of patients was allowed to standby in the endoscopy room throughout the procedure. Videotapes were educational videos taken from American Society for Gastrointestinal Endoscopy (ASGE).[11] ASGE has produced educational videos for patients to learn about endoscopic procedures and the conditions they are used to diagnose and treat. These videos were translated to Urdu as it is national language of this country. Family member wore shoes cover, head cover and mask in endoscopy room to control infection. Patients randomized to Group B got only basic standard protocol counselling. Extensive counselling and Videotapes were not shown. Attendants were not allowed to enter the endoscopy room. The self-developed questionnaire developed after literature search consisted of sociodemographic factors and the patients' compliances were monitored during the procedure and an assessment by an endoscopist was made regarding procedure difficulties or easier to perform. For quality assurance questionnaire was pretested on 20 patients undergoing endo-

scopy. Endoscopist evaluated the ease of introduction of the instrument ("easy": no failed attempt of introduction; or "difficult": one or more failed attempts of introduction) and assessed the tolerance of the patients grading it into three steps: "good", "poor", "very bad".[9] Data were collected and after coding entered the statistical Package for the Social science (SPSS version 20) for analysis by using the Chi-square test. All the variable in both groups were compared by means of compliance, assessment of endoscopist regarding endoscopy procedure efficacy, and time duration of esophagogastroduodenoscopy.

Data obtained were entered and analyzed using a statistical package for social sciences (SPSS) version 21. For qualitative variables (like gender, age groups, Hemoglobin categories, Hepatitis and HIV status). Chi-square test was used to compare categories of intervention and control group (Time taken, tolerated procedure and endoscopist assessment, presence of comorbidities). p-value ≤0.05 was considered significant.

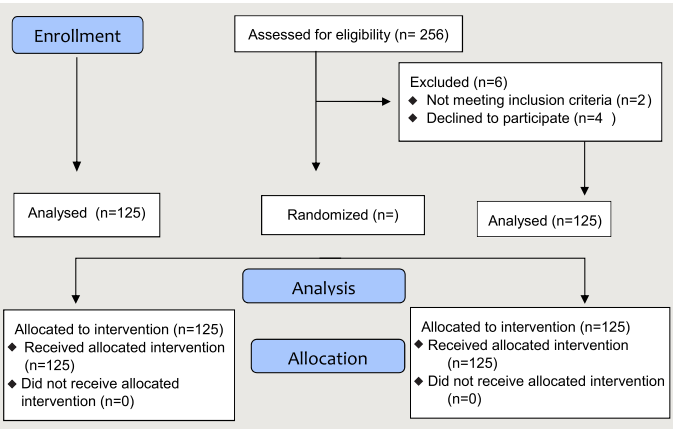

Figure 1: *Consort Diagram Of Study Participants*

Results

A total of 250 study participants from a private sector hospital were included in the study. 125 were randomized in Group A and 125 were randomized in Group B. The sociodemographic characteristics of study participants are shown in Table 1. Comorbidities in study participants are shown in figure 2. The chi-square test was used to access the time of the procedure, tolerated procedure, and endoscopic assessment between group A and group B as shown in Table 2.

Table 3: *Sociodemographic factors of study Participants*

Variable	Frequency	Percentage
Gender		
Male	127	50.8
Female	123	49.2
Age		
18- 35 years	79	31.6
36 to 55 year	143	57.2
56 to onward	28	11.2
Hemoglobin		
More than 13g/dl	140	56.0
Between 10-13g/dl	73	29.2
Between 7-10g/dl	37	14.8
Anti HCV Status		
Negative	220	88.0
Positive	30	12.0
HBsAg Status		
Negative	241	96.4
Positive	9	3.6

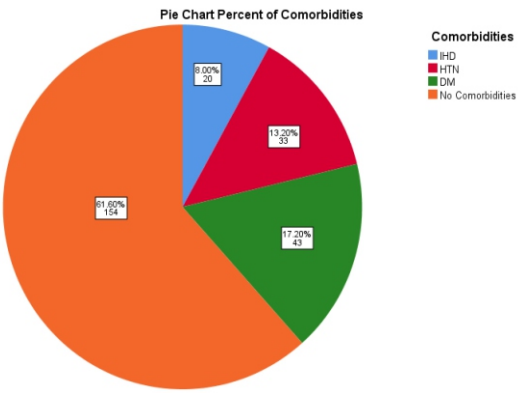

Figure 2: *Comorbidities present in study participants*

Table 2: *Chi square test between recorded variables between Group A and Group B*

Variables	Group A	Group B	Chi-square	p-value
Time Taken				
3minutes	63	51	7.809	0.02
3 to 6 minutes	57	57		
more than6 minutes	5	17		
Tolerated Procedure				
Good	61	37	9.672	0.008
Poor	44	61		
Very Bad	20	27		
Endoscopist Assessment				
easy insertion of scope	62	37	11.863	0.003
difficult insertion of scope	63	86		
failed insertion of scope	0	2		

Discussion

Upper gastroduodenal endoscopy is a daycare procedure with diagnostic and therapeutic benefits. It is also a screening tool for many conditions. Due to myths and infodemics about this procedure in the general population of our country, it becomes difficult to do the procedure with poor patient compliance. The aim of this study was that intensive counselling, showing videotapes, and allowing attendants in the endoscopy room improves the outcome in the patients in terms of improved compliance, time taken, and endoscopist assessment regarding ease of the procedure. This study found an approximately equal gender ratio. This finding is consistent with other studies which show that this procedure occurs both in males and females equally.[12,13] Most of the patients were between 36 to 55 years of age in this study. This procedure occurs in all age groups but studies show that most patients are around 50 years.[13-15] The most common comorbidities in our study were diabetes, hypertension, and ischemic heart disease. These findings are similar to another study but they have also reported chronic liver disease as common comorbidity. This may be due to the fact that they included patients from Medical Emergency Department only. And in this study patients coming from outpatient department were included.[15]

This study found that the time taken for this procedure is statistically significant between the intervention and control group (p-value 0.02). Intervention A has been shown to decrease the procedure time. Another study showed that time, pain, and distress are maximum in participants undergoing this procedure for the first time.[16] The tolerance of procedure and insertion of scope showed improvement with counselling, videotapes, and attendants which is statistically different (p-value 0.008 and 0.003 respectively). These findings are similar to another study in which they compared oral information alone with oral and written information combined.[17] Detailed counselling and psychotherapy improve the compliance of patients. When attendants are allowed the patients feel more comfortable.[18]

The strengths of this study are that it is a randomized control trial and have a good sample size. The limitations of this study are that this study included patients from the outpatient department of one tertiary care hospital. This study highlighted the need to intensive counselling of patient regarding the procedure so that he can be made comfortable. This will improve the outcomes of this procedure. Using videotapes with counselling improves the understanding of our population. This can also be done in other procedures to increase patient awareness and understanding.

Conclusion

Extensive counselling, videotapes, and allowing family members to stay in the endoscopy room improves the outcomes of patients in terms of the time of the procedure, tolerated procedure, and endoscopist assessment.

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Authors Contribution

SL, MN: Conceptualization of Project
SL, HQBS: Data Collection
HQBS: Literature Search
IM, SL, MN: Statistical Analysis
IM: Drafting, Revision
MN: Writing of Manuscript