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Quality Standards in Upper Gastrointestinal Endoscopy in a Tertiary Care Centre

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Abstract

Objective: Upper Gastrointestinal Endoscopy (UGIE) is a minimally invasive diagnostic modality which is used widely in Sri Lanka. We have noted a deficiency in maintaining quality standards during the procedure and documentation. The aim of this study was to assess the degree to which UGIE performed in a tertiary care unit in a developing country maintains quality standards compared to established guidelines.

Material and Methods: Data of 68 patient's UGIE assessed prospectively over 6 months, is compared with the quality standards (16 selected components) from the British Society of Gastroenterology (BSG) and American Society of Gastrointestinal Endoscopy (ASGE). Our quality is graded as poor, fair, moderate, good or excellent in agreement, relative to the BSG/ASGE standards, using kappa values.

Results: Among the 16 components of quality standards assessed only 4 (kappa >0.81) were in excellent agreement. Another 4 (kappa >0.61 and <0.80) were good. One (kappa >0.0 and <0.20) was fair. One (kappa >0.41 and <0.60) was moderate. Six components were poor (kappa <0).

Conclusion: Most of the accepted quality standards are not adequately maintained during UGIE procedures. Following a protocol and filling a pro-forma would increase the quality of UGIE in managing patients with upper gastrointestinal pathologies. A pro-forma would be developed taking in to consideration the components required, to be used in a follow up study.

Keywords: Endoscopy, Quality, Standards, Pro-forma, Guidelines

INTRODUCTION

Upper Gastrointestinal Endoscopy (UGIE) is the gold standard investigation of upper abdominal symptoms [1]. Together with lower gastrointestinal endoscopy, UGIE represents one of the most frequently performed procedures in the health care system [2]. It allows direct mucosal visualization, tissue acquisition and when required therapeutic interventions.

To reduce the variation in practice, there are several quality standard guidelines which were initially presented by Z. Maratka [3]. Examples are

from those issued by the British Society of Gastroenterology (BSG) and the American Society of Gastrointestinal Endoscopy (ASGE) [4,5].

Comparing the performance of a person or a group with an ideal can be used to measure the quality of health care. The term quality indicator or standard is named as that particular parameter for comparison. There are widely accepted quality standards for UGIE [4]. They can be categorized into pre procedure, procedure, disease specific and post procedure. To have a proper indication is a pre procedure quality standard which ensures a higher chance of finding a

clinically relevant lesion. Obtaining consent both verbally and in writing is another pre procedure quality standard which is considered important. Allocating an appropriate time slot and adhering to a safety check list are widely accepted quality standards. BSG suggests 20 minutes to be allocated for a standard UGIE and basic domains in a safety check list which will reduce unnecessary and unsafe procedures [6]. Barrett's inspection time $>1\text{cm}/\text{min}$ is associated with a higher chance of detecting dysplastic lesions and adeno carcinoma [7].

Quality standards in the procedure component are limited to the endoscopist and to the endoscopy room. It is recommended that to be a quality endoscopist, one should perform >100 UGIE per year [8-9]. The endoscope should have a high definition video endoscopy system which will enable better mucosal visualization and acquisition of tissue samples [4]. Except in oesophageal and gastric outlet obstruction, all the recommended anatomical landmarks should be examined during UGIE according to the guidelines. This should include retroflexion of the stomach in all UGIE as there is a recent increase in gastric cardia cancers [10]. There is no evidence to support the practice of photo documentation. But this practice will be an initiative to encourage mucosal cleansing, mucosal inspection and ensure a complete examination. Photo documentation may also act as a legal document of a complete procedure [4]. BSG recommends a systematic approach to photo documentation with eight anatomical landmarks [11]. With widespread availability of electronic technology, this is an achievable target. In addition, for safe sedation, endoscopy room should be composed of safe sedative drugs, relevant antidotes, resuscitation team with equipment and proper monitoring system.

This study is to show the deficiencies of the recommended quality standards during performing UGIE in a tertiary care centre, in a developing country. Most of our UGIEs probably do not adhere to quality standards recommended by BSG or ASGE. Thus, our study is to see the importance of maintaining quality standards in a busy tertiary care centre. Adhering to these quality standards would mitigate unnecessary intervention, facilitate the diagnosis, prevent complications and make it easier to follow up patients.

MATERIALS AND METHODS

This is a prospective observational study conducted in a tertiary care centre in Sri Lanka, conducted from 01.10.2019 to 31.03.2020 (6 months). All patients who underwent elective upper gastrointestinal endoscopy in which, indication was decided by a consultant or higher surgical trainee and age >16 was included. Patients with previous upper gastrointestinal surgeries, emergency UGIE, UGIE for therapeutic procedures were excluded. Surgeons, senior registrars and medical officers performed the UGIE.

The standard quality indicators of both British Society of Gastroenterology (BSG) and American Society of Gastrointestinal Endoscopy (ASGE), were considered. Sixteen components from these quality indicators were selected by 4 consultants in the unit, for the study, based on the relevance and feasibility.

The endoscopist was aware of an audit being carried out but was not privy to the components that were assessed. Pre procedure, procedure, disease specific and post procedure data were recorded on a pre-tested, printed pro-forma. Collected data were classified as frequencies under the above four main categories. Sixteen components were studied and compared with standard guidelines as indicated in the table under the above mentioned 4 categories (Table 1). Each component has a grade of recommendation and a performance target according to the standard guidelines (Figure 1). The variability of categorical data was measured using kappa statistics, where a weighted kappa was used for analysis of ordinal data (e.g. proper indication). Agreement was categorized as poor ($k \leq 0.2$), fair ($0.21 \leq k \leq 0.40$), moderate ($0.41 \leq k \leq 0.60$), good ($0.61 \leq k \leq 0.80$) or excellent ($0.81 \leq k \leq 1.00$) based on the value of kappa as described by Altman. 95% confidence interval (CI) was used to measure the precision of kappa. The analysis was done using SPSS statistical software for cross tabulation of results and using Excel software (Microsoft Corporation) for measures of kappa and confidence intervals.

RESULTS

There was a total of 68 patients in our study with 28 males. Age range was 16-76 years.

Out of the 5 components that were selected as pre-procedure quality standards, only the safety check list achieved a level of "excellent" ($k=0.844$). The

kappa values for the other 4 selected components were – proper indication ($k=0.544$), informed consent ($k=0.124$), assessment of fitness ($k=0$), appropriate time slot ($k=0.844$).

With regards to the components assessed related to the procedure, safe sedation ($k=1$) and quality of instrument ($k=1$) were in “excellent” agreement to quality standards. Quality of endoscopist ($k=0.793$) was “good” agreement. Complete examination with documentation was “poor” with a kappa value of zero.

Five disease specific standards were assessed – Barrett’s, hiatus hernia, varices, gastric biopsy and any other lesions. Except for the gastric biopsy specimen which had a kappa value of 0.799, all the others had a kappa value of zero (poor agreement)

Two components were assessed under the post procedure category, and they had kappa values of 0.785 (PPI therapy) and 1.0 (auditing).

DISCUSSION

Our study showed only four components which were in “excellent” agreement with the recommended guidelines. They were - safety checklist, safe sedation, quality equipment and auditing. Although these components were done in a satisfactory manner, there was lack of documentation in most of them.

There were five components in our study which showed no agreement with the recommended quality standards at all. Patient’s fitness was not assessed completely, probably not being aware of the importance of it. Although the endoscopist examined all parts of upper gastrointestinal tract, there was no evidence to prove this, either by written or photo documentation. Limited needless documentation which was not fulfilling the recommended criteria was done either in clinic books or diagnosis cards. If there is pro-forma with those landmarks, endoscopist

Table 1: Comparison of quality standards with established guidelines

	Components	Level of Evidence	Performance Target	Percentage in the study	Kappa value	Interpretation
Pre procedure	Proper indication	1C+	80%	93%	0.544	Moderate agreement
	Informed consent	1C+	98%	58%	0.124	Fair agreement
	Assessment of fitness	2A	100%	0%	0.000	Poor agreement
	Appropriate time slot	2A	100%	46%	0.630	Good agreement
	Safety check list	1C	100%	34%	0.844	Excellent agreement
Procedure	Quality trainer	3	98%	97%	0.793	Good agreement
	Complete examination with documentation	1C+	98%	0%	0.000	Poor agreement
	Safe sedation	2A	100%	100%	1.000	Excellent agreement
	Quality instrument	2A	90%	100%	1.000	Excellent agreement
Disease specific	Barrett’s esophagus	2C	100%	0%	0.000	Poor agreement
	Hiatus hernia	2C	100%	33%	0.000	Poor agreement
	Varices (according to size)	2C	100%	0%	0.000	Poor agreement
	Any Lesion (according to Paris classification)	2C	100%	0%	0.000	Poor agreement
	Gastric biopsy specimens	2C	80%	50%	0.799	Good agreement
Post procedure	PPI treatment	1A	98%	83%	0.785	Good agreement
	Auditing	3	98%	100%	1.000	Excellent agreement

Figure 1: Graph comparing the quality standard with established guidelines

would not miss to document. That documentation will be helpful for proper patient follow up as well as legal requirements. In our study, the endoscopist failed to document the pathological diseases of upper GI tract by using correct classifications and grading. Without proper documentation of those diseases, future endoscopists would have difficulties in decision making. A document with all common pathological conditions with relevant classifications will improve the quality of the endoscopy.

There was no proper consent form that was filled, prior to the procedure. The indication for each UGIE was not addressed. This is probably due to the heavy endoscopy lists which have colonoscopies, sigmoidoscopies, proctoscopies and many interventions. Thus, a pro-forma with sections for consent and indication will improve those deficiencies. In our unit, there was no exact time period allocated for the procedure although the appropriate time slot is 20 minutes. Time taken, varied from 2 minutes to 7 minutes. It was rarely performed beyond 10 minutes even for Barrett's oesophagus. Thus, there must be a slot to enter the time taken in the pro-forma. If a pathological lesion was identified, maximum 3-4 biopsies were taken. If there is a place for number of biopsies in our pro-forma, endoscopist will be encouraged to take more biopsies which will increase the quality of the procedure. Our study shows the requirement for a customized system for documentation of UGIE.

A complete UGIE report is an essential element of a quality endoscopy service. Narrative documentation is often associated with variations in the positive findings and other procedural details. We

suggest an electronic standardized UGIE report which will facilitate effective communication, successful practice, audit and quality improvement. Those can be never achieved using a narrative or written report which are usually written in clinic books.

Based on the results of our study, we would develop a proforma which would be piloted in our unit. This proforma, if found to be feasible, and achieving these same quality standards, could be recommended for use in centres in our country and other developing countries with similar resources.

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Author contributions

All authors contributed for the study equally.

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Availability of data and materials

Data will be available from the authors on request.

Ethics approval and consent to participate

Ethical clearance was obtained from the ethics review committee of the hospital.

Competing interests

Investigators or their family members will have no conflicts of interest related to the study. The study does not involve any financial remuneration for the investigators or participants.

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