SCIENTIFIC ARTICLE

Performance measures and quality standards in lower gastrointestinal endoscopy in Sri Lanka: a prospective observational study

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Abstract

Introduction

Lower gastrointestinal endoscopy(LGIE) is the gold standard diagnostic tool in evaluating large bowel mucosal pathology. Guidelines have been developed to ensure the quality of the procedure with regard to patient safety and diagnostic accuracy. There is lack of data regarding quality of LGIE in Sri Lanka.

Objective

Aim of this study is to assess the quality of LIGE performed in a tertiary care center in Sri Lanka by comparison with the standard quality indicators.

Material and Methods

A prospective observational study was carried out in a tertiary care centre in Sri Lanka. Data of 210 patients who underwent LGIE by four experienced endoscopists (Both Colonoscopy and Flexible sigmoidoscopy) were recorded. Variables assessed were selected from quality indicators given in the guidelines of American Society of Gastroenterologists and European Society of Gastrointestinal Endoscopy. Data was compared with pre, intra and post procedure standard quality targets using the one sample proportion test to evaluate the hypothesis related to the indicators and calculating the p values

Results

All pre-procedure measures and 6 out of 7 intra procedure measures did not reach the target goals. Although majority of post-procedure targets were achieved, overall quality of the endoscopy in relation to all 3 categories falls below the recommended minimum standards.

Conclusion

The quality of LGIE with-regard to all the aspects falls below the expected standards indicating poor quality of LGIE performed in a Sri Lankan tertiary care setting. Majority of the failures are due to lack of awareness and training rather than lack of resources. Using a standard protocol based pro-forma, improved education of endoscopy staff on guidelines and maintaining an electronic database will increase the quality of LGIE.

Introduction

Despite advancement of radiological imaging, lower gastrointestinal endoscopy (LGIE) remains the 'gold standard' investigation for assessment of large bowel pathology. However lower gastrointestinal endoscopy is not without its drawbacks which include risk of serious complications such as bowel perforation and low but non-negligible miss rate of colorectal cancers [1]. Several studies have shown that colonoscopy is less effective in preventing deaths due to proximal colon cancer which is likely attributed to quality factors of endoscopy. [2-7].

There is a growing interest to increase quality standards of endoscopic examinations to minimize diagnostic errors, reduce complications and unnecessary health care costs from repeated procedures[8].

Many professional bodies have published recommendations on performance measures for LGI endoscopy . Of these, guidelines developed by the American society of Gastroenterologists (ASGE), American Gastrointestinal Society (AGS) and The European Society of Gastrointestinal Endoscopy (ESGE) with regards to quality assurance are widely accepted. These performance measures are well-defined, reliable, and simple tools which have proven impact on clinical outcomes. They also have susceptibility for improvement, and applicability to all levels of endoscopy services.

Standard guidelines assess quality standards and performance measures belonging to several key domains, pre-procedure measures, completeness of the procedure, performance

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measures for diagnostic and therapeutic accuracy, complications and post procedure follow-up.

Adherence to guidelines help to minimize diagnostic errors and reduce associated morbidity and mortality [9,10]. In addition, these guidelines have focused on the accuracy of endoscopic report documentation and ESGE has developed the minimal standard terminology for gastrointestinal endoscopy (MST)[11]. Recommendations for image documentation have also been introduced recently.

Currently Sri Lanka lacks a national endoscopy data base. We could not find any studies that has evaluated the quality of performed LGIE in Sri Lankan context. Principle objective of this study was to assess the quality of the lower GI endoscopy procedures with aim to develop a proforma(checklist) which suits Sri Lankan setting.

Methodology

This is a prospective observational study conducted at a tertiary care centre in Sri Lanka. Ethical clearance was obtained from the ethical review committee of the institution. Patients >16 years, who undergo diagnostic LGIE (Both colonoscopy and flexible sigmoidoscopy) were included in the study after obtaining informed written consent. Patients undergoing LGIE for emergencies and assessment of anastomotic site after rectal surgeries were excluded. Study was carried out over a period of 8 months starting from December 2019. All the data was collected by trained health professionals. All procedures were performed by four experienced endoscopists who have received adequate amount of training and perform more than 150 colonoscopies per a year[12,13]. Endoscopists were aware of a study being conducted, but not the components assessed.

Fourteen components, were chosen from the two guidelines (American Society of Gastroenterologists and European society of gastrointestinal endoscopy) by four specialists attached to the unit, based on relevance and feasibility. Selected components included pre, intra and post procedure variables. Each component has recommended minimum performance target according to the standard guidelines. A pre-tested proforma was used to collect the data. Variables studied were compared with standard performance targets and level of adherence to the standard values were assessed using the one sample proportion test (one sample Z test for proportions) and one sample t test with testing the hypothesis related to the indicators. Statistical analysis was done using SPSS software by obtaining the p values and confidence intervals (one tailed and two tailed) at 5 % significance level with normal approximation method.

Results

A total of 210 procedures were recorded. (colonoscopy=138; sigmoidoscopy=72). Out of 210 patients, 115(54.8%) were males and 95(45.2%) were females. Age range of the study population was between 17 to 82 years. Descriptive analysis of study population is shown in Table 1 and Table 2 shows the indications for the procedures. Quality standards were assessed under 3 categories; pre, intra and post- procedure measures, which are demonstrated in Table 3 to 5.

Table 1. Demography of the study population (N = 210)

Variable	Number	Percentage (%)
Sex		
Male	115	54.8
Female	95	45.2
Age		
17-20 years	6	2.85
20-29years	19	9.05
30-39 years	31	14.7
40-49years	47	22.4
50-59 years	51	24.3
60-69 years	43	20.5
70-79years	8	3.8
80-82 years	5	2.4

Table 2. Indications for the procedures [N=210]

Indication	Number	Percentage (%)
Rectal bleeding	56	26.7
Altered bowel habits	58	27.6
Unexplained Iron deficiency anaemia (Negative upper GI endoscopy)	6	2.8
Unexplained loss of appetite/weight	8	3.8
Surveillance after resection of large bowel malignancy	11	5.2
Surveillance after polyp resection	6	2.8
Surveillance of Inflammatory bowel disease/polyposis coli for malignancy	4	1.9
Chronic abdominal pain or discomfort	61	29.1

Table 03. Comparison of assessed pre-procedure quality indicators and recommended target values

	Pre-procedure indicators				
	Variable	**Performance target**	**Sample proportion**	**P value**	**Lower bound at 95% significance level**
1	Colonoscopy is performed for a standard indication (and documented)	> 80%	0.7095	0.99	0.6579
2	Informed consent is obtained	> 98%	0.7476	1.00	0.6983
3	Pre-procedure history and examination are performed and documented	> 98%	0.8904	1.00	0.8550
4	Risk for adverse events is assessed and documented	>98%	0.4714	1.00	0.4147
5	Sedation plan is documented	>98%	0	—	—
6	Team pause is conducted and documented	>98%	0	—	—

Table 04. Comparison of assessed intra-procedure quality indicators and recommended target values

	Intra-procedure indicators				
	Variable	**Performance target**	**Sample proportion**	**P value**	**Lower bound at 95% significance level**
1	Procedure note documents the quality of preparation	>98%	0.584	1.00	0.5219
2	Doses/Routes of administration of medications are documented	>98%	0.076	1.00	0.0483
3	Bowel preparation is adequate	>90%	0.7523	1.00	0.6984
4	Caecal intubation rate	≥90% ≥95% for screening	0.8809	0.850	0.8377
5	Adenoma detection rate	≥25%	0.3380	0.003	0.2839
6	Withdrawal time - measured	>98%	0	—	—
7	Withdrawal time minimum >6 min (in a negative colonoscopy)	>6 min	2 minutes and 30 seconds (Average)	0.2752	CI (2.337, 2.463)

Table 05. Comparison of assessed post-procedure quality indicators and recommended target values

	Post-procedure Indicators				
	Variable	**Performance target**	**Sample proportion**	**P value**	**Lower bound at 95% significance level**
1	Incidence of perforation	<1:500 <0.002	0 (No perforation)	—	—
2	(i)post-polypectomy significant bleeding	<1%	0 (No significant bleeding)	—	—
	(ii)Frequency in which post-polypectomy bleeding is managed without surgery	≥90%	100%	—	—
3	Appropriate recommendation for timing of repeat colonoscopy is documented and provided	≥90%	0.6476	1.0	0.5896

Informed written consent was obtained in only 74.8%(N=157,) of cases. Although rest of the procedures were performed after obtaining a written consent it was not taken describing all the relevant risks and were not satisfactorily documented. Risk factors for adverse effects such as presence of allergies, being on antiplatelets and anticoagulants assessed and documented in only 47.1%(N=99) cases. Only 71% percent of procedures had a proper indication and in 4% no indication was documented. A team pause was not conducted in any of the cases. Use of sedative drugs were documented in only 7.6%(N=16) cases. Even when documented, medication name, dose and route were not properly written.

In 86% of cases of sigmoidoscopy, the scope negotiated the splenic flexure and caecal intubation rate was 88.3% (recommended >90%). Although equipment for photo documentation was available, it was not used to confirm caecal intubation or to demonstrate the lesions identified. In 65.4% of cases of colonoscopy with failed caecal intubation the scope did not reach at least up to the splenic flexure, of which 15.8% examinations were limited to the sigmoid colon. Poor bowel preparation accounted for majority of procedure failures (53.7%). Pain (34.5%) and anatomical difficulties accounted for rest of the failed procedures.

Proper bowel preparation was achieved only in 75.4% of cases. The median duration of colonoscopy (without biopsy or polypectomy) was 12 min. Only 11.4% of colonoscopies had withdrawal time of >6 minutes. Withdrawal time was not actively measured in any of the cases. None of the procedure documentations included all aspects assessed by LGIE and majority (68%) of documentations included less than 50% of aspects of assessment.

Major complications in terms of bleeding, bowel perforation, cardiopulmonary complications, ICU care or prolonged hospital stay, were not encountered. No deaths were recorded as a direct result of LGIE.

Discussion

This study evaluated the process of LGIE quality with regards to 3-time scales; pre-procedure, intra-procedure, and post procedure.

*Pre-proced*ure quality indicators

In this study, only 70.9% (p=0.99, CI=0.6579;lower bound at 95% significance level) of patients had LGIE for a standard indication which is below the expected standard of 80%. Performing LGIE for a standard indication reduces the patient risk, work-load, financial burden as well as facilitates arriving at a more significant diagnosis [14,15]. This is particularly important for a resource poor setting like Sri Lanka. This fact is further emphasized by findings of another Sri Lankan study by Samarakoon et al which showed compliance with standard indications provided in guidelines enhances maximum utilization of limited resources while maintaining quality and safety of endoscopy[16].

Informed written consent was obtained only in 74.6% of cases (expected in ≥98%, p=1.00, CI-0.6983). In a study in UK involving both patients and medical negligence specialists, showed that 48% of solicitors and 38% of patients expect that patients should be told of even very uncommon risks. In addition all the solicitors and patients stated that patients understanding should be rechecked after the consent[17]. However, our study shows that approximately 25% of patients lacks even a proper written consent. Main reason for this is lack of a proper consent form which include all possible risks and complications. This demonstrates poor concern with regard to ethical and legal aspects of LGIE in Sri Lankan setting.

Proper assessment and documentation of history and examination findings (p=1.00, CI-0.8550) as well as the risk for adverse events (p=1.00, CI-0.4147) fall far below expected targets. ASGE recommends that proper history and directed physical examination is vital to identify abnormalities of major organ systems; history of adverse events related to sedation or anesthesia; medication associated issues such as allergies and use of anti-thrombotic drugs. Although guidelines emphasize the risk assessment of sedation related adverse events by an established method such as ASA score, in this study group this was only carried out for high-risk patient categories such as those with heart disease.

ASGE recommends to conduct a 'Team pause' prior to commencement of any endoscopic procedure; in-order to confirm that the correct patient is undergoing the correct procedure. However, none of the LGIE were proceeded by a team pause.

It is a major failure that none of the pre-procedural quality indicators met the recommended minimum standards. Non-compliance with these criteria shows a major drawback in relation to patient safety and requires immediate attention.

Intra-procedure quality indicators

Intra-procedure measures principally assess the technical aspects of LGIE including completeness of the examination and all therapeutic interventions employed.

Adenoma detection rate (ADR) is a vital quality measure in colonoscopy. Several large scale studies have shown that colonoscopy cohorts followed for up to 3 years after the procedure with late detection of colorectal cancers (CRC) were mainly attributable to missed adenomas [18-19]. A study conducted in the US revealed that higher ADR were associated with lower risks of developing interval and advanced-stage colorectal malignancy. In fact, it showed a 5% reduction in interval colorectal cancer for each 1% increase in ADR. In both genders higher ADR were linked with a decreased risk for colon cancers[20].

Although guidelines do not specifically provide a recommendation regarding ADR for flexible sigmoidoscopy (FS) ; this study also included adenomas detected by FS when calculating ADR. Calculated adenoma detection rate in this study was 33.8% which exceeds the recommended target (p=0.003, CI=0.2839). Since screening colonoscopies are not carried out to detect colorectal cancer in public hospital system in Sri Lanka, we measured ADR in symptomatic patients. Although the achieved value is not an ADR by definition as the patients are symptomatic it can be considered as a fair surrogate measure of adenoma detection. This is the only indicator that met the recommended target out of intra-procedure quality measures.

Caecal intubation rate, which measures completeness of LGIE, is recommended to be ≥90% (with photographic evidence). Failed caecal intubation results in not only increased risks of interval proximal CRCs but higher financial costs, as the examination must be rescheduled [21]. In a German study, Brenner et al. showed that there is a direct association between interval colon cancers and completeness of the previous negative colonoscopy[22]. Our study showed adjusted caecal intubation rate (after excluding procedures with poor bowel preparation and other reasons which hinders advancing the scope due to risk of perforation) of 88.1%(p=0.850) which is close to the expected value but does not meet the required target. Caecal intubation should be documented in writing as well as with photo or video evidence. However, none of the cases in this study were photo or video graphically documented. ESGE recommends to carry out an audit to determine the cause if caecal intubation rate of an endoscopy service is suboptimal .These audits can identify causes of incomplete colonoscopy and assess each endoscopists performance, which in turn provide a valuable feedback to help maintain their technical skills above the minimum required level.

Despite flexible sigmoidoscopy(FS) being widely used; there is lack of standard guidelines to define landmarks to assess completeness of FS. Most widely used end point is reaching the splenic flexure although some endoscopists aim only to reach just beyond sigmoid colon. However, it is mandatory that standards are set in future to assess completeness of FS to ensure their quality.

In this study, quality of bowel preparation was assessed using the Boston Bowel Preparation Scale, where bowel preparation is considered adequate if BBPS score ≥2 in each 3 segments of colon (however for sigmoidoscopy, a value of 2 or more was considered adequate since only the left colon is evaluated)[23]. Only 75.2% (N=158, p=1.00), cases had adequate bowel preparation which is far below the expected rate of 90%. Poor bowel preparation is associated with reduced caecal intubation rate, reduced detection of polyps and increased risk of perforation, apart from substantial economic burden of repeated examinations [2-3].

The probable cause of poor bowel preparation in the study population could be prolonged waiting time between the end of the preparation and the commencement of the procedure. A meta analysis of multiple randomized trails have identified this interval as the most important factor governing the quality of bowel preparation. It has shown that preparation quality is inversely related to the waiting time [24]. Therefore it is necessary to implement measures to increase the quality of bowel preparation in Sri Lankan setting particularly by minimizing the undue waiting time . The above meta-analysis by Kilgore et al.also demonstrated that poor quality due to prolonged waiting time can be overcome by utilizing split dose regimen for bowel preparation. Considering the high patient load per session and practical difficulty in reduction of waiting time Sri Lankan setting utilizing split dose regimen , may be a more practical solution.

Documentation of bowel preparation status was only done in 58.4% procedures. (N=123, p=1.00). This study also found that non-standardized terms such as 'poor' and 'good' to describe the bowel preparation status were used in the documentation. However this need to be avoided and an objective validated method such as Boston bowel preparation score should be followed in order to minimize inter-observer variability.

There is an extremely poor compliance in relation to documentation of the medications utilized during procedures. Although the required minimum is 98% , only 7.6% (N=16, p=1.00) procedure notes mentioned the used medications accurately.

Another important quality measure that falls behind required target is maintaining an adequate withdrawal time. Although the recommended minimum withdrawal time is 6 minutes(for a negative colonoscopy), mean withdrawal time of a negative colonoscopy in the study is 2.5 minutes(p=0.2752, CI-2.337-2.463). In large scale study, Shaukat et al showed that shorter withdrawal time is an independent risk factor for lower ADR and interval CRC due to missed lesions[25]. A randomized controlled trail which utilized tandem colonoscopies to compare adenoma detection rates and adenoma miss rates (AMR) between 3-minute and 6-minute withdrawal time demonstrated that regardless of expertise, a shorter withdrawal time is linked with low ADR rate and high AMR[26]. Therefore, mean withdrawal time of 2.5min is not acceptable and requires urgent attention of the endoscopists to avoid missing lesions.

In addition, none of the procedures had withdrawal time measured or documented. High patient load per session, not being aware of the recommended withdrawal time and its importance could be the reasons for this. Mean duration for a negative colonoscopy in this study was 12 minutes. In contrast, ESGE guidelines recommends minimum of 30 minutes for a routine colonoscopy slot. However, with the high patient load and lack of endoscopic facilities in Sri Lankan setting allocation of such a time slot may not be practical.

Post-procedure quality indicators

Post procedure complications such as significant post polypectomy bleeding or perforation was not encountered in this study. There were no admissions due to endoscopy related complications over a 30 day follow up period. Therefore, these indicators met the required targets.

Proper documentation of each LGIE is of utmost importance since the report is utilized in planning further patient care. ASGE and ESGE recommends that documentation should follow Minimum Standard Terminology (MST) when reporting endoscopic findings [27]. None of LGIE reports met assessed criteria and 68% failed to have at least 50% of mandatory documentation aspects.

Not being aware of the importance of documentation, not having a computer-based documentation system and lack of time can be considered as the causes for poor quality in documentation. Therefore, it is important to educate endoscopists regarding MST in order to achieve required standard in documentation.

Conclusions

In conclusion, out of 5 pre-procedure indicators, none reached expected targets. Considering that all pre-procedural indicators being non-technical and not depending on quality of facilities available, guidelines can be easily implemented by educating health-care workers and by using a proforma.

Out of 7 intra-procedure quality indicators, ADR was the only measure which exceeded the required target. Since it is considered as one of the most crucial indicators this can be considered as a positive aspect. Failure of adherence to recommended withdrawal time, poor assessment and documentation of bowel preparation are major drawbacks and can be improved by proper education of endoscopists. Split dose regimen of bowel cleansing will be more suited in achieving required level of bowel preparation in overcrowded Sri Lankan setting. In addition, regular audits are required to assess the performance indicators such as Caecal intubation rate, ADR and complication rate of individual endoscopists to determine whether their skill levels are maintained above the recommended level.

In post procedure measures, poor quality of documentation is a major failure identified in this study and it can be improved with increasing the awareness regarding MST.

In summary, most of the quality measures can be improved by re-education of endoscopy staff regarding guidelines and quality indicators, as failures are due to lack of awareness rather than lack of resources. As a follow up, we plan to develop a proforma based on the criteria that were assessed. This will be piloted in a future and could be recommended for endoscopy centers throughout the country, provided it is successful in achieving the standards.

Preferences

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