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Compliance with Standard Protocol for the Diagnosis of Barrett's Oesophagus: Significance of The Complete Audit Cycle

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ABSTRACT

Background: The key to effective therapeutic endoscopic therapy is early dysplastic Barrett's oesophagus (BO) alteration detection. Oesophago-gastro-duodenoscopy (OGD) technical proficiency is quickly attained, but the diagnosis accuracy is still quite variable, especially in non-specialized endoscopic facilities.

Objective: We aimed to evaluate the quality of endoscopic diagnosis and the adherence to guidelines of BO in our unit. **Patients and Methods:** A retrospective cohort analysis was done for 436 eligible endoscopic reports after independent review for confirmation of BO. Cohorts represent the complete audit cycle during the period from 01/01/2018 till 01/07/2022. Group A represented first audit data, and group B represented re-audit data.

Results: A total eligible reports of 256 of BO in group A, and 180 reports in group B were reviewed. There was no significant difference between the groups regarding the age (62.7 ± 13.5 and 60.1 ± 15.1 years), male sex (68% and 70 %), and endoscopist specialty respectively. Surveillance was the most common indication (32.4% vs 35.5%), followed by Reflux (16.7% and 15%) in both groups respectively. Compliance with Prague, Paris, and Seattle protocol was significantly higher in group B (P value ≤0.05). Lack of awareness of the new guidelines, surgeon specialty, older age of the endoscopist, long segment of BO were the main factors of poor results in group A.

Conclusions: In the absence of local standard protocol for endoscopic diagnosis of BO, the adherence to the guidelines was poor. Compliance with the guidelines after implementing new recommendations results in better outcomes. It is important to complete the audit cycle to ensure that the quality improvement was achieved.

Keywords: Barrett's oesophagus, Barrett's surveillance, Prague Criteria, Seattle protocol, Paris classification, Adherence guidelines.

INTRODUCTION

The most significant risk factor for the emergence of adenocarcinoma is Barrett's oesophagus (BO), which is characterized as the presence of metaplastic columnar epithelium, which endoscopically manifests as salmon pink mucosa. Intestinal metaplasia (IM) is not necessary for the diagnosis of Barrett's oesophagus according to current British recommendations [1].

Current management of Barrett's oesophagus focuses mainly on surveillance to detect early low-risk neoplastic lesions suitable for advanced endoscopic therapies, Oesophagectomy is only still used in cases of high-risk and advanced carcinomas [2].

While it takes little time to become technically proficient in OGD, the grade of high-quality examination varies, and an unacceptable amount of endoscopies fail to detect cancer [3].

In a recent systematic review and meta-analysis by **Roumans *et al.*** [4] there was large variance between the studies regarding the adherence to Barrett's esophagus surveillance guidelines worldwide?

We noted a great variability between endoscopists in the description and reporting of BO in our unit, so we aimed to evaluate the quality of endoscopic diagnosis and the adherence to guidelines of BO in our unit.

PATIENTS AND METHODS

The population, intervention, comparator, outcomes, and study design (PICOS) framework were used to plan this study (Table1). We conducted our study between 01/01/2018 till 01/07/2022.

Table (1): PICOS criteria for the study

Parameter	Criteria
Population	A total of 436 reports, which mentioned word **Barrett's** weather as indication, findings, or final diagnosis were included in our study.
Intervention	Diagnostic OGD.
Comparators	**Group A**: first audit data. **Group B**: re-audit data.
Outcomes	Demographic data, indication for OGD, endoscopist specialty, compliance with Prague Criteria, Paris classification, and Seattle protocol were compared and statistically analyzed.
Study design	Retrospective cohort study between 01/01/2018 till 01/07/2022.

Population: A total of 436 reports which mentioned the word **Barrett's** weather as indication, findings, or final diagnosis were included.
Intervention: Diagnostic OGD.

Comparators: Group A: represented first audit data between 01/01/2018 and 31/03/2020. We chose this period as 6 months after the standards of the British Society of Gastroenterology (BSG) and Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS) were published in 2017 till the first COVID 19 national lockdown in March 2020. **Group B:** represented re-audit data between 01/04/2021and 01/07/2022, started 6 months after first audit to give

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enough time for implementation of the recommendations.

Outcomes: Demographic data, indication for OGD, endoscopist specialty, compliance with Prague criteria, Paris classification, and Seattle protocol were compared and statistically analyzed.

Ethical consent: Our local clinical governance unit approved the study. After explaining our research objectives. This study was conducted in compliance with the code of ethics of the world medical association (Declaration of Helsinki) for human subjects.

Statistical analysis:

A retrospective comparative cohort analysis was performed. Using IBM SPSS (Statistical Package for Social Science, IBM Corp., Armonk, NY) for Windows version 21. The gathered data were edited, coded, tabulated, and imported onto a PC. The mean and standard deviation (SD) were used to describe quantitative variables, whereas frequency was used to describe qualitative data. The groups were compared with relation to a qualitative variable using the Chi-square test. To compare the groups with reference to the quantitative variable in the parametric data, Student T-test and ANOVA were utilized. P value ≤ 0.05 was regarded as significant.

RESULTS

Demographic characteristics of patients & endoscopist: Table (2) summarized the study sample. 256 final reports in group A, and 180 reports in group B were included in our study containing Barrett's either as indication for surveillance, or mentioned as findings, or as final diagnosis after independent review for confirmation of BO. There was no significant difference between the groups regarding the age (62.7 ± 13.5 and 60.1 ± 15.1 years) and male sex (68% & 70 %), and endoscopist specialty respectively. The majority of OGDs were done by gastroenterologists (43% & 45%), surgeons (34% & 37.7%) then advanced nurse practitioner (ANP) (23% & 17.2%) in both groups respectively.

Table (2): Demographics and endoscopist specialty

Parameter	Group A	Group B
Total Reports with Barrett's	256	180
Age years (mean ± SD)	62.7 ± 13.5	60.1 ± 15.1
Male sex	174 (68%)	126 (70%)
Female sex	82 (32 %)	54 (30%)
Number of Reports by Gastro	110 (43%)	81 (45 %)
Number of Reports by Surgeons	87 (34%)	68 (37.7%)
Number of Reports by ANP*	59 (23%)	31 (17.2 %)

*ANP: Advanced Nurse Practitioner, Gastro: Gastroenterologists.

Indication for OGD: Table (3) summarized the indications for OGD. The main indication was BO surveillance (32.4% & 35.5%), followed by for reflux symptoms (16.7% & 15%) in both groups respectively.

Table (3): Indication for OGD

	Group A (256)	Group B (180)	P value
Surveillance	83 (32.4%)	64 (35.5%)	NS
Reflux	43 (16.7%)	27 (15%)	NS
Anaemia	26 (10.1%)	20 (11.1%)	NS
Abdo pain	22 (8.5%)	13 (7.2%)	NS
Dysphagia	18 (7%)	10 (5.5%)	NS
Dyspepsia	16 (6.25 %)	11(6.1%)	NS
Weight loss	13 (5%)	12 (6.6%)	NS
Others	35 (13.6)	23 (12.7%)	NS

Expressed in Number (Percentage)

Compliance with Prague, Paris, and Seattle protocol: Table (4) showed the number, and percentage of the OGD reports in which the Prague, Paris, and Seattle protocol were used. Group A had poor compliance with the guidelines & standards as the Prague classification was applied in only 34% of the reports as Circumferential and Maximum extent (CM) descriptors. None of the mucosal lesions found were described according to the Paris classification. The Seattle biopsy protocol was used in 54.8%. Re-auditing group B showed significant improvement in compliance with standard protocols.

Table (4): Compliance with Prague, Paris, and Seattle protocol

	Group A (256)	Group B (180)	P-Value
Prague Criteria			
Circumferential Extent **(C)**	87 (34 %)	126 (70%)	S
Maximum Extent **(M)**	85 (33.2%)	120 (66.6%)	S
Diaphragmatic Impression **(DI)**	15 (5.8%)	90 (50%)	HS
Level of Gastroesophageal Junction **(GOJ)**	72 (28.1%)	124 (68.8%)	S
Associated hiatus hernia **(HH)**	164 (64%)	144 (80%)	NS
Seattle Protocol			
4 quadrant biopsies	114/208 (54.8%)	153 (85%)	S
Level of Biopsy	64/227 (28.1%)	133 (73.8%)	HS
Paris classification	0	100 (55%)	HS

- Results presented in Number (percentage)
- S: significant if p value (≤ 0.05), HS: highly significant if p value (≤ 0.001), NS: non-significant.

Compliance with Prague Criteria & Seattle Protocol in Group A by endoscopist specialty: Table (5) summarized the performance of the endoscopists and showed that most of the cases were done by gastroenterologists, followed by surgeons, then ANP. The ANP endoscopies complied best with the standards of the Prague classification & Seattle biopsy protocol, with a highly significant difference to the other endoscopists, followed by the gastroenterologists, and lastly by the surgeons.

Table (5): Compliance with Prague Criteria & Seattle Protocol in Group A by endoscopist specialty

	Gastroenterologist	Surgeon	ANP
Number of cases performed	110/265	87/265	59/265
Diaphragmatic Impression (DI)	9/110 **(8.1%)**	6/87 **(6.8%)**	**0%**
Level of GOJ	17/110 **(15%)**	21/87 **(24.1%**	34/59 **(57% ***
Circumferential Extent (C)	40/106 **(37.7%)**	5/80 **(6.25%**	36/51 **(70% ***
Maximum Extent (M)	40/106 **(37.7%)**	5/80 **(6.25%**	34/51 **(66.6%)***
4 quadrant biopsies	42/89 **(47.1%)**	30/70 **(42.8%)**	42/49 **(85.7%) ***
Level of Biopsy	7/93 **(7.5%)**	11/79 **(13.9%)**	46/55 **(83.6%) ***

*P-Value: <0.001

Correlation between four quadrant biopsies (4QBx) and histopathology results:

There were highly significant negative histopathology results observed in group A regarding the reports where the Seattle protocol was not followed as compared to those where a four quadrants biopsy protocol was employed (Table 6). This was improved in group B as compliance with Seattle's protocol was 85% which minimized the risks of negative pathology and missed lesions.

Table (6): Correlation between four quadrant biopsies (4QBx) and histopathology results

		(4QBx)	Non- (4QBx)
Group A	Percentage	54.8%	45.2%
	Negative pathology	23.6%	51.5%*
Group B	Percentage	85%*	15%
	Negative pathology	18%	20%

*P- Value: <0.05

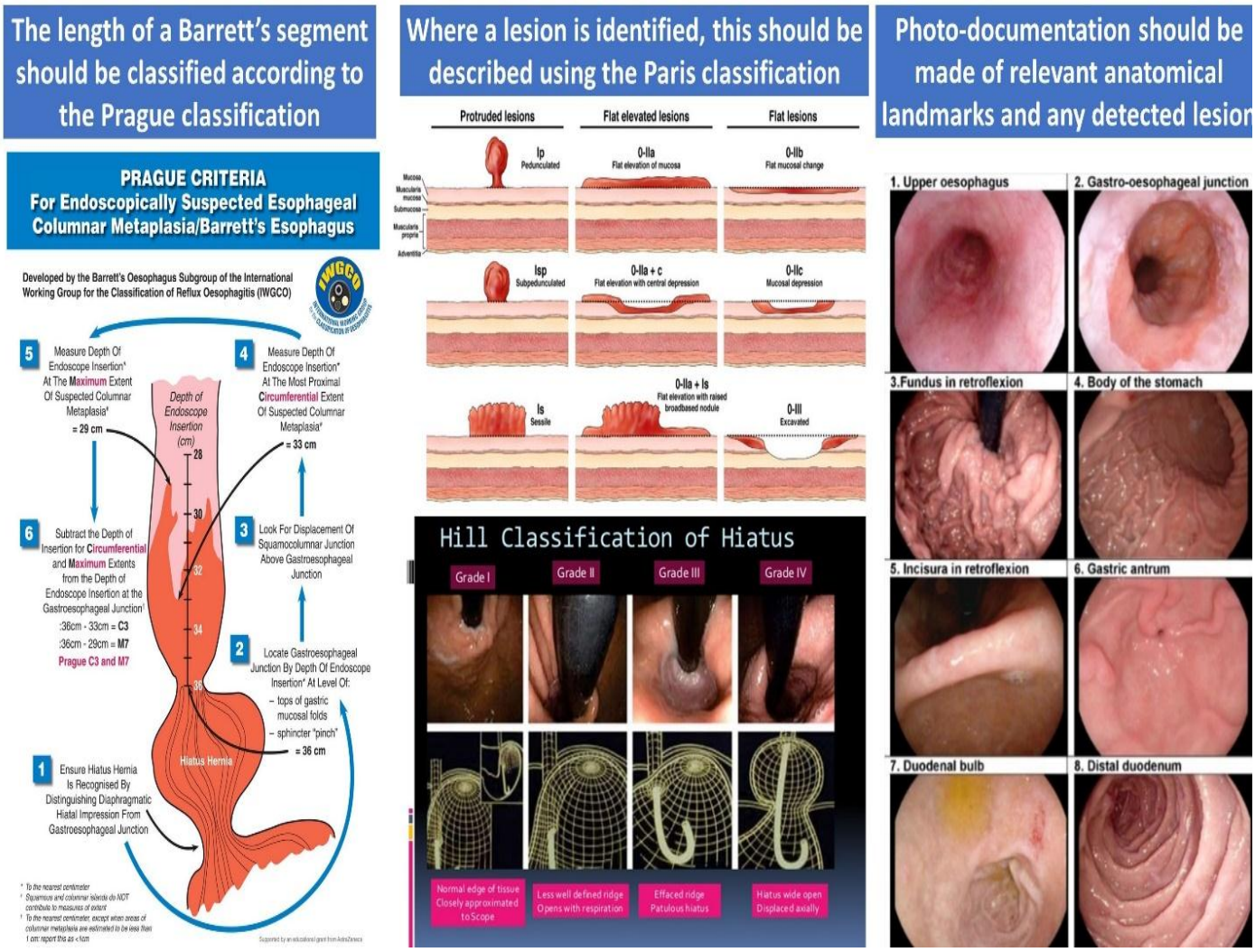

Figure (1): Illustrated guidelines for reporting Barrett's Oesophagus & OGD [3].

DISCUSSION

This study represents the complete audit cycle of a quality improvement project of our endoscopic practice of BO as there was a great variability of endoscopic description and reporting of BO in our unit. The results of the first audit were presented and published by the first author in October 2020 and showed poor compliance with the guidelines of BSG/AUGIS [5].

Performing endoscopy is variable across of the world, for which in most of the countries are done mainly by the gastroenterologists but in some countries like Ireland is considered main part of the job descriptions of any surgeon, but in other countries like UK and Egypt is not mandatory for the surgeons to learn endoscopies. This study was planned by the first author while he was working in Ireland on his sabbatical leave.

This retrospective cohort comparative study included a total number of 436 reports of BO, described by a total of 20 different endoscopists: ten surgeons, eight gastroenterologists, and two ANPs. There was no significant difference between the groups regarding the age (62.7 ± 13.5 and 60.1 ± 15.1 years) and male sex (68% and 70 %), and endoscopist specialty respectively.

The majority of OGDs were done by gastroenterologists (43% and 45%), surgeons (34% and 37.7%) then advanced nurse practitioner (ANP) (23% and 17.2%) in both groups respectively.

Group A showed poor compliance with Prague, Paris, and Seattle's protocol. The Barrett's segment's maximum length (M) and circumferential extent (C), as measured upon endoscope removal, are described in the Prague classification, which is one of the BSG/AUGIS-recommended quality criteria and is widely used with good inter-observer agreement [3, 6].

Although the main indication for OGD in both groups was Barrett's surveillance (32.4% and 35.5%), Prague classification as CM was used only in 34% in group A, with poor description of the gastroesophageal junction (GOJ) level, and diaphragmatic impression (DI) (28.1% and 5.8%) respectively. Other studies showed also that the Prague classification was poorly implemented, only in 34% of reports with the Danish national study [7], 43% in another British study [8], while it was not used in any of 28% reports who were suspecting Barrett's Oesophagus in other study reviewing 100 OGD reports for patients who were referred for consideration of anti-reflux surgery with a diagnosis of GERD [9].

Surprisingly none of the mucosal lesions in group A were described according to Paris classification, all were described as nodularity.

The Seattle approach, which comprises sampling the Barrett's segment using four quadrant biopsy specimens obtained at 2 cm intervals, was approved by BSG/AUGIS. Prior to the collecting of non-targeted biopsy specimens, suspicious regions should be scanned and biopsied [7]. In Group A the Seattle protocol was applied in 54.8% of the reports. There was a statistically significant difference ($P<0.05$) in the results of biopsy with higher negative results in reports, which did not follow Seattle protocol, which reflected the possibility of missed lesions.

Peters *et al.* [10] showed that non-adherence to the Seattle protocol resulted in a significant proportion of missed Barrett's during the surveillance due to the limited number of biopsies. On the other hand the rate of dysplasia detection was increased in study by **Abela *et al.*** [11] after the introduction of protocol biopsies, with increases in low grade dysplasia detection from 1.6 % to 18.9 %, and high-grade dysplasia detection from 0 % to 2.8 % [11].

Photo-documentation is recommended by the European Society of Gastrointestinal Endoscopy (ESGE) guidelines as they described eight anatomical landmarks (figure 1) to be included in any OGD report; the upper oesophagus, GOJ, fundus, gastric body, incisura, antrum, duodenal bulb and distal duodenum [12]. Results of another audit done by our unit showed that the most recorded photos in order were for retroflexion (95%), D2 (84%), GOJ (84%), antrum (72%), D1 (69%), body (19%), upper oesophagus (13%), and incisura (4%) [13].

Unawareness of the recommended Barrett's protocols was the main factor of poor outcome in group A as shown in a survey conducted before the study. In addition to other factors as older age of the endoscopists, surgeons endoscopists, non-Barrett's training. A recent meta-analysis showed that the better adherence to the Prague classification and the Seattle protocol was with shorter BO segments, university hospitals, dedicated surveillance programs, physicians compared to surgeons, awareness of the guidelines, and younger age of the endoscopists [4].

Suboptimal adherence to the guidelines and the variability in endoscopic reporting have been reported worldwide. A recent meta-analysis of 56 studies, with 14002 BO patients and 4932 endoscopists, between 1997- 2017, across Europe and North America showed large variance, and suboptimal adherence to the guidelines [4]. The same results from a multinational survey in Asia-Pacific region showed that just 6.3% of respondents consistently followed the Seattle procedure, and only 16.3% of respondents employed the Prague C and M criteria [14].

Ooi *et al.* [15] significantly found improvement in dysplasia detection rate from 18% on dedicated surveillance lists compared to 8% on non-dedicated lists when endoscopy was performed by specially trained endoscopists. In our study the surveillance represented only 32.4% of the indications which make establishment of dedicated lists for BO is less practical and may result in long waiters. So, we have established other simple, and easy recommendations.

Mortada and Fatima[5] recommended firstly, to increase the awareness of all current endoscopists

about the recommended diagnostic protocol of BO by circulating the guidelines, attending courses or lists with the compliant endoscopists. Secondly to ensure that newly joined/locum endoscopists are aware or trained in BO. Thirdly, they printed illustrated guidelines (figure 1) as a reference for the endoscopists. Lastly, they planned a re-audit after 6 months to ensure that the quality improvement has been achieved.

Re-audit as representing in group B showed significantly higher compliance with Prague Criteria, Paris & Seattle protocol as compared to group A (table 4). Paris classification wasn't used at all in group A as compared to 55% in group B. Applying four quadrants' biopsies was increased from 54.8% to 85% with the result of less negative pathology. Prague CM criteria was significantly increased from 34% to 70%.

Our study has the inherent limitations of retrospective analysis, but we succeeded in retrieving and reviewing all the endoscopic reports related to BO during that period with related pathology reports. Secondly, we did not include any data regarding the surveillance interval, because our intention was mainly to evaluate the description and reporting methods. The main strength of our study is that it represents the complete audit cycle, which ensures that quality improvement was achieved in our unit.

CONCLUSION

In the absence of local standard protocol for endoscopic diagnosis of BO, the adherence to the guidelines was poor. Compliance with the guidelines after implementing new recommendations results in better outcomes. It is important to complete the audit cycle to ensure that the quality improvement was achieved.

Authors Contributions:

- *Ahmed Elnabil-Mortada:* planned and developed the project with its two parts audit/reaudit cycle, data collection, presenting the audit, writing and final editing of the manuscript.
- *Sherif Shabana, Sherif Albalkiny & Mohamed Elsayed Seifalyazal:* data analysis and writing the manuscript.

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