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Association of Body Mass Index and Gastroesophageal Reflux Disease and Its Complications Such as Hiatus Hernia, Reflux Esophagitis and Barrett's Esophagus, a Retrospective Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author SS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors ZZ and HS managed the analyses of the study. Authors YYL and YCK managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Obesity is a fast-emerging epidemic in the Asia-Pacific region especially in Malaysia. According to National health and morbidity survey of 2015, obesity in Malaysians make up 17.7% of the population out of these 30% are overweight. Gastroesophageal reflux diseases are being affected greatly by obesity.

Objectives: To determine the association between GERD complications such as hiatus hernia,

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reflux esophagitis and Barrett's esophagus with bodv mass index via esophagogastroduodenoscopy (OGDS) in The school of medicine, University Sains Malavsia. Methods: Study included retrospective analysis of 127 GERD patients with GerdQ questionaire scoring system treated by OGDS. The patients were divided into 2 groups according to their body mass index (BMI) comprising of Group 1 i.e. Normal BMI group with BMI less than 22.9 kg / (m2) (54 patients) and Group 2 comprising of obese patients with the BMI more than 23 kg / (m2) (73 paients). The clinical factors (age, gender, ethinicity, weight, height, BMI and GerdQ questionaire scoring) and OGDS findings (hiatus hernia, reflux esophagitis and Barrett's esophagus) were analyzed. OGDS films were classified as Hiatus hernia, reflux esophagitis and Barrett's esophagus. Results: The mean age of the patients were 43.91 years old. Obesity as in BMI > 30 kg/m2 were statistically significant association with Hiatus hernia and statistically significant association with reflux esophagitis. However, obesity was statistically insignificant association with Barrett's esophagus. Obese patient also showed statistically insignificant association with Barrett's esophagus endoscopically Circumferential of metaplasia and Maximum extend of metaplasia (M). The risk prediction shows statistically significant association between Body Mass Index with reflux esophagitis based. Those in obese group had 3.6 times higher Odds to get reflux esophagitis symptoms compared to those in normal BMI group. **Conclusion:** Obese patient had association with hiatus hernia and reflux esophagitis, but not for

Conclusion: Obese patient had association with hiatus hernia and reflux esophagitis, but not for the Barrett's esophagus. The risk prediction association between Body Mass Index is with reflux esophagitis based in obese group had 3.6 times symptoms compared to those in normal BMI group. In obese patient with GERD symptoms LRYGB was suggested as it is more effective procedure for alleviating the symptoms of GERD as it plays a role in significant weight loss without altering the anatomy of the LES and increasing intragastric pressure.

Keywords: Gastroesophageal reflux disease; Barrett's esophagus; esophagogastroduodenoscopy; morbidity.

1. INTRODUCTION

Obesity is a fast-emerging epidemic in the Asia-Pacific region, with numbers paralleling the rising global prevalence within the past 30 years. The landscape of gut diseases in Asia has been drastically changed by obesity, especially the gastroesophageal reflux disease (GERD) [1, 2]. It is a common digestive disorder that affects the lower esophageal sphincter (LES) that has been linked to obesity [3]. The symptoms are heartburn and regurgitation which causes the mucosal damage. Oesophago gastroduodenoscopy (OGDS) procedure is one of common procedure in Malaysia usually done by surgeons or gastroenterologist [4]. It is normally done as an outpatient procedure in patient with GERD symptoms [4].

Malaysia, known as Asia's fattest country, recorded an increase in its obesity rate in year 2015, with the latest statistics showing that the overweight and the obese make up nearly half of its 30 million population. According to the National Health and Morbidity Survey of 2015, obese Malaysians make up 17.7% of the population while those who are categorized as overweight make up 30% [5-7]. The obesity

prevalence have increased drastically from 4.4% in 1996 to 17.7 per cent in 2015.

Lee and coworkers suggested that central obesity is an important factor in the aetiology of reflux and does this by the increased abdomino-thoracic pressure gradient inducing hiatus hernia and increasing the rate of flow of reflux when sphincter opens. Hence, resulting severe erosive oesophagitis and Barrett's oesophagus [8-13].

Therefore, the present study aimed to examine the association between GERD and its complication such as hiatus hernia, reflux esophagitis and Barrett's esophagus with body mass index via esophagogastroduodenoscopy in School of Medical Sciences, Health Campus, University Sains Malaysia.

2. METHODOLOGY

A list of patients with Gastroesophageal reflux disease with GerdQ questionnaire scoring system in School of Medical Sciences, Health Campus, University Sains Malaysia from January 2014 to Mei 2017 were obtained from the record in the endoscopy room. Patients who fulfilled the inclusion and exclusion criteria in the study. Inclusion criteria was based on the selection of patients diagnosed with gastroesophageal reflux disease and an esophagogastroduodenoscopy (OGDS)

Exclusion criteria were based on the selection of Patients who were diagnosed with gastroesophageal reflux disease but without having GerdQ questionnaire scoring system. Patients with incomplete or missing data documentation and patient without esophagogastroduodenoscopy (OGDS).

Parameters related to age, gender, ethinicity, weight, height, BMI and disease condition were recorded.

Two gastroentrologists were used to analyse the OGDS pictures. Findings of hiatus hernia (Hill Grading), reflux esophagitis (Los Angeles classification) and Barrett's oesophagus (Prague Classification) according to it severity were graded.

Patients were divided into two groups according to the body mass index based on WHO (ASIAN population classification) as Non obese patients with normal BMI (less than 22.9 kg / m2) in group 1 andObese patients with more than 23 kg/m2) in group 2.

Data was analyzed using SPSS-24software. All numerical variables were described using mean and standard deviation, whereas all categorical variables were described using frequency and percentage. Chi-square test was used to determine the association between the study variables. If assumption of chi-square test was not met. Fisher exact test result was applied.

3. RESULTS

There were no statistical significant association between gender (p=0.067) and ethnicity (p=0.170) with BMI. Significantly, out of the total population studied 64.4% of male were obese and 84.9% Malay ethnicity were obese.

Based on chi square result, there were no significant association between this two variables as shown in Table 3. However, we can see that 58.2% of obese patient were categorized for 50% of likelihood of GERD group and 71.4% patient were categorized for 89% likelihood of GERD as illustrated in Fig. 2.

Table 4 showed the result of association analysed by chi square test between Body Mass Index (BMI) with Hiatus hernia based on Hill's Grading. There were statistically significant association (p<0.05). However, we can see only 8.2% of obese patient were categorized in Hill's Grade 1 group and 32.9% patient were categorized in Hill's Grade 4 group.

Table 5 showed that there were statistically significant association (p=0.08) analysed by Fisher's Exact test between Body Mass Index (BMI) with reflux esophagitis based on LA classification. From there the highest frequency were under normal BMI group of no reflux esophagitis was 81.5%. However, we can see 32.9% of obese patient were categorized in LA Grade A and 11% in LA grade B

From Table 6, it shows that Body Mass Index (BMI) and Barrett's oesophagus histologically proven were statistically insignificant.

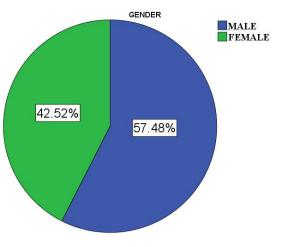


Fig. 1. Distribution of gender using pie chart

Variables	Mean (SD)	N (%)	
Gender	, <i>i</i>		
Male		73 (57.5)	
Female		54 (42.5)	
Ethnicity			
Malay		102 (80.3)	
Chinese		24 (18.9)	
Indian		1 (0.8)	
Age	43.91(14.93)		
Weight	68.12(23.61)		
Height	160.12(12.88)		
BMI group	, <i>i</i>		
Normal (BMI < 22.9 kg/m2)		54 (42.5)	
Obese (BMI > 23 kg/m2)		73 (57.5)	
GERDQ		· · ·	
0-2 (0% GERD)		8 (6.3)	
3-7(50% GERD)		55 (43.3)	
8-10 (79% GERD)		43 (33.9)	
11-18 (89% GERD)		21 (16.5)	
BE Histology			
No Barrett's Esophagus		121 (95.3)	
Barrett'sesophagus		6 (4.7)	
BE Endo C			
C0		109 (85.8)	
C1		1 (0.8)	
C2		11 (8.7)	
C3		6 (4.7)	
BE Endo M			
MO		109 (85.8)	
M1		6 (4.7)	
M2		6 (4.7)	
M3		2 (1.6)	
M5		4 (3.1)	
Hiatus Hill			
HILL'S GRADE 1		12 (9.4)	
HILL'S GRADE 2		40 (31.5)	
HILL'S GRADE 3		45 (35.4)	
HILL'S GRADE 4		30 (23.6)	
Reflux esophagitis LA			
No		84 (66.1)	
LA A		31 (24.4)	
LAB		10 (7.9)	
LAD		2 (1.6)	

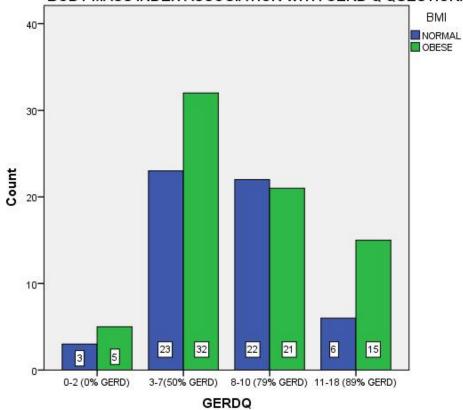
Table 1. Descriptive statistic of socio-demographic of patients included in the study (n=127)

Table 2. Association of Sociodemographic with Body Mass Index (BMI)

Variables	E	P-value		
	Normal N (%)	Obese N (%)	Chi-square (df)	_
Gender				
Male	26 (48.1%)	47(64.4%)		0.067
Female	28 (51.9%	26 (35.6)	3.348 (1)	
Ethnicity				
Malay	40 (74.1%)	62 (84.9%)		0.170
Non Malay	14 (25.9%)	11 (15.1%)	2.314 (1)	

Variables	Gerd Q Questionnaire					
	0-2 0% GERD N (%)	3-7 50% GERD N (%)	8-10 79% GERD N (%)	11-18 89% GERD N (%)	Chi-square (df)	
BMI						
Normal	3 (37.5%)	23 (41.8%)	22 (51.2%)	6 (28.6%)	3.080 (3)	0.380
Obese	5 (62.5%)	32 (58.2%)	21 (48.8%)	15 (71.4%)		

Table 3. Association of Body	y Mass Index ((BMI) with Gerd	Q Questionaire
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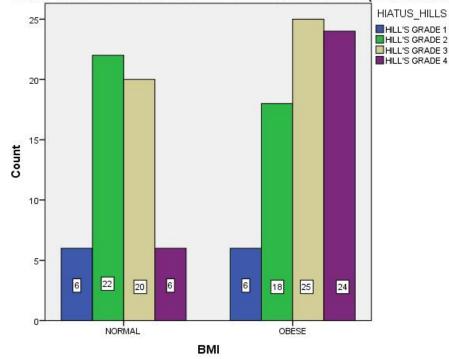




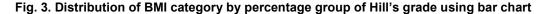


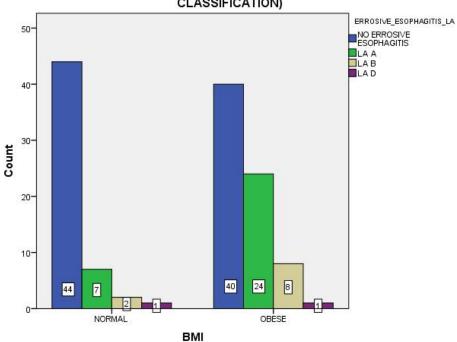
Variables	Hiatus hernia (Hill's Grading)					
	Hill's Grade 1 N (%)	Hill's Grade 2 N (%)	Hill's Grade 3 N (%)	Hill's Grade 4 N (%)	Chi-square (df)	-
BMI						
Normal	6 (11.1%)	22 (40.7%)	20 (37.0%)	6 (11.1%)	9.117 (3)	0.028
Obese	6 (8.2%)	18 (24.7%)	25 (34.2%)	24 (32.9%)		

Table 7 showed that there were statistically insignificant association analysed by Fisher's Exact test between Body Mass Index (BMI) with Barrett's oesophagus endoscopically based on Prague classification of Circumferential of metaplasia (C). Comparison of distribution of different group of Barrett's Esophagus of Circumferential of metaplasia (C) by BMI group was illustrated in Fig. 6. The bar graph showed that the distribution was monopolied by C0 in both group of BMI (normal and obese)



BODY MASS INDEX ASSOCIATION WITH HIATUS HERNIA (HILL'S GRADING)





BODY MASS INDEX ASSOCIATION WITH EROSIVE ESOPHIGITIS (LA CLASSIFICATION)

Fig. 4. Distribution of BMI category by percentage group of Erosive Oesophagitis based (LA classification) using bar chart

Variables	Reflux esophagitis based (LA classification)						*P-value
	No R.E N (%)	LA Grade A N (%)	LA Grade B N (%)	LA Grade C N (%)	LA Grade D N (%)	Fisher's exact test	
BMI							
Normal	44 (81.5%)	7 (13.0%)	2 (3.7%)	0 (0%)	1(1.9%)	10.689	0.08
Obese	40 (54.8%)	24(32.9%)	8(11.0%)	0 (0%)	1(1.4%)		
		*/	-isher freeman l	lalton test			

Table 5. Association of E	Body Mass Index	(BMI) with Reflux	Oesophagitis (I	LA classification)
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 Table 6. Association of Body Mass Index (BMI) with Barrett's Oesophagus based (Histologically proven)

Variables	Barrett's esophag	*P-value	
	No Barrett's Esophagus	Barrett's Esophagus	
BMI			
Normal	51 (94.4%)	3(5.6%)	
Obese	70(95.9%)	3(4.1%)	0.699
	*Fishe	er's Exact test	

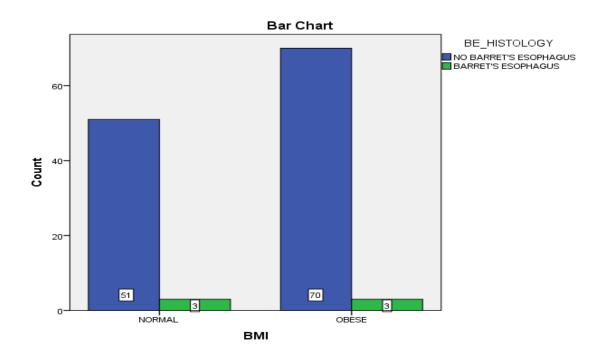
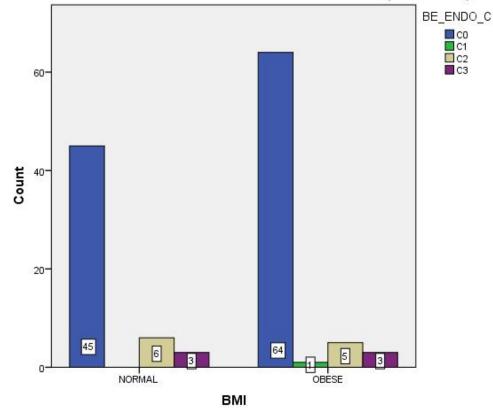


Fig. 5. Distribution of BMI category by percentage group of Barrett's Esophagus based (Histologically proven) using bar chart

 Table 7. Association of Body Mass Index (BMI) with Barrett's Oesophagus based (Prague Classification) of Circumferential of Metaplasia (C)

Variables	Barrett	t's Oesopha	agus of Circu	nferential o	of Metaplasia (C)	*P-value
C 0 C 1 C 2 C 3 Fisher's exact test						
BMI						
Normal	45 (83.3%)	0 (0%)	6 (11.1%)	3(5.6%)		0.774
Obese	64 (87.7%)	1(1.4%)	5(6.8%)	3(4.1%)	1.682	



BODY MASS INDEX ASSOCIATION WITH BARRET'S ESOPHAGUS (ENDOSCOPIC) PRAGUE C

Fig. 6. Distribution of BMI category by percentage group of Barrett's Oesophagus (Prague Classification) of Circumferential of Metaplasia (C) using bar chart

From the present study, there were no significant association analysed by Fisher's Exact Test between Body Mass Index (BMI) and Barrett's oesophagus endoscopically (Table 8). Fig. 7 showed the distribution of patients with different type of Barrett's Oesophagus of Maximum extend of metaplasia (M) by two groups of BMI (obese and normal). Therefore, it can be concluded that M0 was highest for both normal and obese patients. From the present study (Table 9), based on simple logistic regression there were no association between BMI and hiatus hernia.

An association between BMI and Reflux (Table 10) was observed (p<0.05).Those in obese group have 3.6 times higher Odds to get reflux esophagitis symptoms compared to those in normal BMI group as shown in Table 10.

Table 8.	Association of Body Mass Index (BMI) with Barrett's Oesophagus based (Prague	
	Classification) of Maximum extend of Metaplasia (M)	

Variables	Barrett's Oesophagus of Maximum extend of metaplasia (M)						*P-value
	M 0	M 1	M 2	М 3	M 5	Fisher's exact test	
BMI							
Normal	45(83.3%)	3 (5.6%)	2 (3.7%)	2 (3.7%)	2 (3.7%)		0.618
Obese	64(87.7%)	3 (4.1%)	4 (5.5%)	0 (0%)	2 (2.7%)	3.052	

Variable	В	OR (95% CI)	P value	
BMI	0.333	1.40 (0.42,4.59)	0.583	

Table 9. Risk prediction association between Body Mass Index (BMI) with hiatus hernia based
(hill's grading)



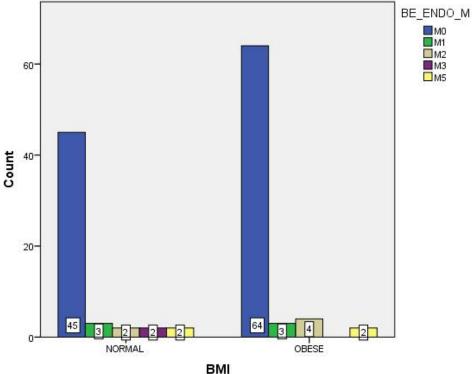


Fig. 7. Distribution of BMI category by percentage group of Barrett's Oesophagus based (Prague Classification) of Maximum extend of metaplasia (M) using bar chart

 Table 10. Risk prediction association between body mass index (BMI) with reflux Oesophagitis based (LA Classification)

Variables	В	OR (95% Cl)	P value	
BMI	1.289	3.6 (1.59,8.3)	0.002	

Table 11. Risk prediction association between body mass index with Barrett's oesophagus based (Histology with or without endoscopically proven)

Variables	В	OR (95% CI)	P value	
BMI	- 0.352	0.70 (0.26,1.91)	0.490	

4. DISCUSSION

According to the National Health and Morbidity Survey of 2015, Malaysia is known as Asia's fattest country, recorded an increase in its obesity rate in year 2015. The latest statistics showing that the overweight and the obese make up nearly half of its 30 million population. In which obese and overweight Malaysians make up 17.7% and 30% respectively. The obesity Sarmukh et al.; AJRS, 4(3): 18-31, 2020; Article no.AJRS.61308

prevalence have increased drastically from 4.4 % in 1996 to 17.7 % in 2015. Obesity is an increasing problem worldwide. It is predicted that by the year 2020, 77.6% of men will be overweight and 40.2% obese; the corresponding predictions for women are 71.1% overweight and 43.3% obese.

Obesity is associated with many diseases like heart disease, diabetes mellitus, non alcoholic fatty liver disease and Gastroesophageal reflux disease (GERD). GERD is a common gastrointestinal disorder in most countries including Malaysia. The etiopathogenesis of gastroesophageal reflux can be multifactorial such as impaired gastric emptying and oesophageal clearance, etc.). Based on literature, the risk factor in GERD patients include age, obesity, lifestyle (alcohol and cigarette smoking). A few studies have reported the association between body mass index and GERD, with hallmark symptoms of heartburn and acid regurgitation [14,15,16] and its complications such as hiatus hernia , reflux esophagitis and Barrett's oesophagus [17].

Based on present study, there were no statistical significant association between gender and ethnicity with BMI. About 64.4% of male and 84.9% Ethnic Malay were obese. This can be due to the study was conducted in Kelantan and the main ethnicity are Malay.

Several studies have demonstrated the validity and reliability of GERD Q questionnaire to identify and to diagnose of gastroesophageal reflux disease [18, 19, 20, 21]. Recent GERDQ questionnaire system has been used [22]. We used a structured Malay language questionnaire which was translated from GERDQ questionnaire.

Indigenously modified questionnaire specifically for Malay population developed by Lee et al., was used. It included questions on severity of symptoms of gastroesophageal reflux disease duration of 1 week. The total score was then divided into 4 categories based on the likelihood of GERD. A) 0 -2 points carries 0 % of likelihood of GERD, B) 3 -7 points carries 50 % of likelihood of GERD, C) 8 -10 points carries 79 % of likelihood of GERD and D) 11-18 points carries 89% of likelihood of GERD.

There were no significant association between this two variables. However, we can see that 58.2% of obese patient were categorized for 50% of likelihood of GERD group and 71.4% patient were categorized for 89% likelihood of GERD.

However, Jacobson et al., in a prospective study in Nurses' Health Study (NHS) cohort were of opinion that BMI was associated with GERD symptoms in both normal weight and overweight group. Weight loss in nurses was associated with a reduce risk of GERD symptoms [23, 24].

Use of interobserver was able to establish satisfactory, precise and valid endoscopic regonition and grading to reduce the bias [24]. Hiatus hernia is a condition involving herniation of the contents of the abdominal cavity, most commonly the stomach, through the diaphragm into the mediastinum. The oesophagus enters the abdomen through the diaphragmatic hiatus, anchored at the level of the esophagogastricjunction by the phrenoesophageal membrane, which also fills the potential space within the hiatus. The hiatus is vulnerable to visceral herniation because it is directly subject to pressure stress between the abdomen and the chest. In the United States, hiatus hernia was listed as a primary or secondary cause of hospital admissions in 142 of 10 000 inpatients between 2003 and 2006 [25]. The major risk factor for development of hiatus hernia is Age and obesity [26, 27, 28].

The association between the Body Mass Index (BMI) with Hiatus hernia were statistically significant. However, it was seen that only 8.2% of obese patient were categorized in Hill's Grade 1 group and 32.9% patient were categorized in Hill's Grade 4 group. The results were consistent with the theory of increase of intraabdominal pressure due to obesity. Beside that, in obese patient the hiatus hernia causes decrease in the effectiveness of the lower esophageal sphincter function and impaired effective esophageal acid clearance [29].

Abraham et al., were of opinion that the overweight and obese patients were significantly more likely to have reflux esophagitis than a normal BMI patient (OR 6.26; 95% CI 3.82-10.28) [30,31].

LA classification system, developed by the International Working Group for classification of Oesophagitis with support of World Organization of Gastroenterologywas observed a validated tool to describe the reflux esophagitis by grades of severity. [32].

4.1 The Los Angeles Classification of Reflux Oesophagitis by Lundell L, et al.

- **Grade A** : One (or more) mucosal break no longer than 5 mm that does not extend between the tops of two mucosal folds
- **Grade B:** One (or more) mucosal break more than 5 mm long that does not extend between the tops of two mucosal folds
- Grade C: One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but which involve less than 75% of the circumference
- **Grade D:** One (or more) mucosal break which involves at least 75% of the oesophageal circumference

The association between the Body Mass Index with reflux esophagitis was statistically significant (p < 0.05).

From there the highest frequency of normal BMI patients were under group of no erosive oesophagitis 81.5%. However, we can see 32.9% of obese patient were categorized in LA Grade A and 11% in LA grade B. This could be due to the mechanisms result in reflux oesophagitis such as increase in intra-abdominal pressure, increased intragastric pressure, greater lower oesophageal sphincter (LES) relaxation, an abnormal diaphragmatic pinchcock, and a delayed acid clearance. These mechanisms explain why obese people are predisposed to reflux gastric contents.

The association between the Body Mass Index (BMI) with Barrett's oesophagus histologically proven were statistically not significant. Barrett's oesophagus for both group of BMI was equally same. This could be due to lack of routine biopsy samples in GERDs patients.

There were statistically no significant association between Body Mass Index (BMI) and Barrett's oesophagus endoscopically based on Prague classification of Circumferential of metaplasia (C) and Maximum extend of metaplasia (M) is significant. In present study, the only risk prediction association between Body Mass Index (BMI) is with Reflux oesophagitis based (LA Classification). Those in obese group have 3.6 times higher Odds to get reflux oesophagitis symptoms compared to those in normal BMI group. However, there were no risk prediction association between Body Mass Index (BMI) with Hiatus Hernia and Barrett's oesophagus in which (p=0.583) and (p=0.490) which is more than α = 0.05 respectively.

Maureen et al. conducted a systemic review regarding the surgical decision making in GERD patients. Surgical correction which are also known as the anti-reflux operations such as minimally invasive gastroesophageal fundoplication is the gold standard in GERD [36].The aim of this surgical procedure is to create an effective barrier to reflux at the gastroesophageal junction and thus attempt to improve physiologic and mechanical issues that may be involved in the pathogenesis of GERD. They have incooperate the guidelines written by the American Society for Gastrointestinal and Endoscopic Surgeons (SAGES) into this study. There are three types of fundoplication, 1) Nissen which is total (360°) wrap, 2) Dor partial anterior (180-200°) wrap and 3) Toupet partial posterior (270°) wrap fundoplication. Nissen fundoplication is proven to be very effective in controlling reflux over long periods of time. However, this procedure is only improve reflux symptoms in normal BMI patient [35].

In morbidly obese patients with GERD symptoms the procedure of choice is bariatric procedure. A meta analysis on Bariatric surgery from year 1990 till 2003 involving total of 22,094 patients was analysed from a total of 136 fully extracted studies. The surgical procedures were grouped into 5 categories: 1) gastric bypass (principally Roux-en-Y), 2) gastric banding, 3) biliopancreatic diversion or duodenal switch 4) gastroplasty (principally vertical banded gastroplasty) and 5 other (biliary intestinal bypass, ileogastrostomy, jejunoileal bypass, and unspecified bariatric). They have concluded that bariatric surgery is most effective and efficient means of achieving significant and sustainable weight loss in severely obese patients [36].

We would like to discuss the effectiveness of bariatric surgery in obese patient with GERD symptoms. Bariatric procedure can be grouped into 2 main categories which is 1) primarily restrictive procedure such as Laparoscopic sleeve gasterectomy (LSG) and 2) primarily malabsorptive procedure such as Laparoscopic Roux en Y Gatric Bypass (LRYGB).

Juan et al., conducted a retrospective case series in 15 patients who underwent laparoscopic sleeve Gatrectomy (LSG) in University of Santiago, Chile between year 2003 till 2012. They have analyzed the clinical data for 24 hour pH monitoring, oesophageal manometry and clinical outcome. They concluded that LSG can cause GERD symptoms to be worsen. This was due to the hypothesis shows that LSG causes a lower gastric compliant which increases the intragastric pressure and eventually cause increased oesophagus-gastric pressure gradient. Besides that, the decreased LES resting pressure, non-resolution of a hiatal hernia and narrowing in the gastric angle (angle of His) are all contributing factor to higher reflux symptoms in post operative LSG patients [37].

Meanwhile, in Pittsburgh Medical Center in Pennsylvania, USA, conducted a prospective study involving 57 patients between Feb 1999 till April 2001. The patients with body mass index (BMI) > 35 kg/m2 with GERD symptoms who underwent LRYGB were included in this study. LRYGB causes a reduction in the gastric content, preventing the bile reflux to the gastric pouch and decrease in the intra-abdominal pressure due to the weight loss. They concluded that post operative LRYGB, the GERD symptoms in the obese patient was improved and well controlled. They suggested that the antireflux mechanism of this surgery is a combination of acid reflux reduction [38].

5. CONCLUSION

In our obese patient with GERD symptoms we suggest for LRYGB as it is more effective procedure for alleviating the symptoms of GERD as it plays a role in significant weight loss without altering the anatomy of the LES and increasing intragastric pressure.

CONSENT

It is not applicable.

ETHICAL APPROVAL

The study protocol was reviewed and approved by the Human Research and Ethics Committee, School of Medical Sciences, Health Campus, University Sains Malaysia. as well as the Medical Review and Ethic Committee (MREC), Ministry Of Health Malaysia. The data of patients were obtained by retrospective study of patient's medical records.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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