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INCIDENCE AND RISK OF GALLSTONES IN A COHORT OF OBESE PATIENTS AFTER LAPAROSCOPIC POST SLEEVE GASTRECTOMY

Running Title: Incident of gallstones post sleeve gastrectomy

Hind Ahmed Alnassar [1*], Sufana Amer Alotaibi [1], Mohammed Saleh Alwadai [2], Sara Ahmed Makhdum [3], Zahra'a Abdullah Assmary [4], Mojahid Hani Attar [4], Aziz Ibrahim Barno [5], Rana Rasheed Al-Rasheed [5], Abdullah Abdulmonem Alzarra [6], Afrah Muhaisen Allehabi [7], Yaseen Mohammed Haddadi [8], Amal Nasser Alqahtani [2]

[1] General Surgery Department, King Fahad University Hospital, Al-Khobar, Saudi Arabia
[2] College of Medicine, King Khalid University, Abha, Saudi Arabia
[3] College of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia
[4] College of Medicine, Umm Al-Qura University, Mecca, Saudi Arabia
[5] King Fahad Medical Research Center, King Abdulaziz University, Jeddah, Saudi Arabia
[6] College of Medicine, Imam Abdulrahman bin Faisal University, Dammam, Saudi Arabia
[7] College of Medicine, Taif University, Taif, Saudi Arabia
[8] College of Medicine, Jazan University, Jazan, Saudi Arabia

Abstract:
Background: *Laparoscopic sleeve gastrectomy has become the treatment of choice by many surgeons, nowadays. The gallstones incidence in sleeve gastrectomy is reported in many studies with still no definite risk factor determined for its causes.* ***Methods:*** *A retrospective study was conducted in King Fahad University Hospital in Al-Khobar, Saudi Arabia. The included patients were [mention glimpse of inclusion criteria]. A detailed personal and history of diseases was obtained from each patient. Incidence and 95% confidence interval were calculated. Cox regression analysis was used to predict risk factors associated with high risk of gallstone formation.* ***Results:*** *The incidence of gallstone after sleeve gastrectomy was 3.81% which was the same as symptomatic gallstones. there was significant increase in BMI in patients who developed gallstone more than patients with no gallstones group [p-value = 0.02]. However, the rate of change of BMI did not increase the risk for gallstone formation. Furthermore, the risk factors associated with time to develop gallstones was being single, high BMI, preoperative lipase HR = 1.05, SE = 0.02, P-value =0.018], cholesterol, LDL and postoperative total bilirubin, LDL and HDL.* ***Conclusion:*** *The risk factors associated with time to develop gallstones were marital status, BMI, preoperative lipase, cholesterol, LDL and postoperative total bilirubin, LDL and HDL.*

Keywords: *Gallstones, laparoscopic sleeve gastrectomy, bariatric surgery, obesity*

*** Corresponding author:**
Hind Ahmed Alnassar,
General Surgery Department,
King Fahad University Hospital,
Al-Khobar, Saudi Arabia
Email: hend.alnassar@yahoo.com

QR code

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INTRODUCTION:

Bariatric surgery is the treatment of choice for patients with morbid obesity BMI>40 Kg/m^2 or obesity [BMI>30 Kg/m^2] with co-morbid conditions [1-4]. The comorbid conditions accompanying obesity includes hypertension, cancer, diabetes mellitus, dyslipidaemia, cardiovascular disorders, osteoarthritis and gallstones [5]. However, the complications accompanying these surgeries still limit the use of bariatric surgery [6].

There are many techniques of Bariatric surgeries including the gastric banding, gastric bypass and sleeve gastrectomy [7]. Despite no gold standard for treatment, the laparoscopic sleeve gastrectomy is considered the most common type used nowadays with many surgeons considering it as the main surgery for morbid obesity [8, 9]. The laparoscopic sleeve gastrectomy achieved a remarkable weight loss results compared to gastric bypass and less complications than gastric banding [10-12]. Lager et al. reported that the laparoscopic sleeve gastrectomy was associated with less risk of operative and post-operative complications than Roux-en-Y Gastric Bypass [13]. Another study by Barzin et al. found that in Iranian obese patients, sleeve gastrectomy had less complication than Roux-en-Y Gastric Bypass but non-significant [9]. Another multicentre retrospective study found that sleeve gastrectomy had less complications than Roux-en-Y Gastric Bypass despite the higher weight loss with gastric bypass [14, 15]. However, other studies found that the weight loss among both types of surgery are the same clinical trial. In addition, Gehrer et al. found that the LSG was associated with less nutritional deficiency, hernias and intestinal obstruction [16]. That's why, there is an exponential increase of laparoscopic sleeve gastrectomy [LSG] worldwide with many surgeons considering it as the standard treatment of obesity due to safer and easier techniques [8, 9].
Efforts are directed towards decreasing the complications of the Laparoscopic sleeve gastrectomy to make it a suitable choice for a wider population [17]. More research is now directed towards identification of the risk factors and prediction of complication to address it early and prevent them. There are two types of complications either acute complication including bleeding and leak [18]. Increasing stapler firing was found to decrease the risk of leakage and other techniques was found to decrease the risk of haemorrhage [19, 20]. The chronic complications include the stricture, gastro-oesophageal reflux and gallstone formation [18].

Gallstone formation after laparoscopic LSG is well documented and was diagnosed in about 11.2% of cases. Despite the reported range from 3.8 to 5.8%, other studies had found a high incidence of gallstone. The gallstones were found either during the operation or after the operation. The period of appearance of gallstones ranges from six to twelve months. The dilemma after the diagnosis was the cholecystectomy surgery after the LSG. Many papers recommended other treatment modalities even starting with medical treatment for gallstones after the LSG to decrease incidence of gallstones [21, 22].

That's why many studies in literature had investigated the risk factors predisposing for the gallstone formation. Body mass index was considered the most important predictor for the gallstone formation [21-24]. Moreover, the rate of weight loss was considered the highest risk factor for the gallstone formation [25]. However, there is still controversial evidence regarding this point as other studies found no effect on gallstone formation [23, 26]. Other disputed risk factor include age, sex, preoperative cholesterol level. However, no specific risk factors are determined [21, 22, 24, 27, 28].
For these aforementioned reasons, this study was conducted to stand on the incidence and risk factor of post laparoscopic sleeve gastrectomy.

METHODS:

This study is a part of retrospective cohort in King Fahad University Hospital in Al-Khobar, Saudi Arabia from May 2015 to June 2016 that was approved by the IRB committee of the hospital on January 2015.

Patient recruitments

All the patients consented orally on their approval to be part of this research with their identity to be anonymous. All the procedures were conducted based on the declaration of Helsinki.
The patients were only included in cohort if they approved to enrol in the follow up program after the sleeve gastrectomy, while patients with pre-existing gallstones were excluded from the study.

Detailed history from each patient was obtained including marital status, nationality, history of diseases and previous cholecystectomy. Pre-operative and post-operative total bilirubin, Amylase, Lipase, Alkaline phosphatase, Cholesterol, Triglycerides, LDL, HDL and haemoglobin A1C were obtained. Ultrasound and lab tests were performed 1 week before the operation, 1 week post operatively, 1 month post operatively, 3 month post operatively, 6 month post operatively, 1 year post operatively and 2 year month post operatively.
Diagnosis of gallbladder stone after the surgery

depended on the presence of symptoms of gallstones which is confirmed using ultrasound

Statistical techniques

We used Shapiro-Wilk test for continuous variables to check the normality distribution. The results were presented as mean ± standard deviation for continuous variables that were normally distributed or as median and interquartile range [IQR] for continuous variables whose distribution was not normal. Categorical variables were presented as frequencies and percentages. Wilcoxon rank test was used to detect the difference in non-parametric groups. The missing data were imputed by K nearest neighbors using K = 5.

BMI change was calculated by the BMI change at the end of the study minus the BMI at the start of the study.

Incidence was calculated based on CDC guidelines. The 95% confidence interval was calculated by mid P-exact test.

We used a cox regression analysis to predict risk factors for gallstones occurrences. The results were expressed as hazard ratio and 95% confidence interval. All analyses were conducted in R 3.3.4

RESULTS

Patients characteristics

The mean age of study participants was 31.82 years [SD = 8.91]; approximately 71% of the participants were females. The mean body mass index before the surgery was 47.7 Kg/m^2 [SD = 7.72] and most of the participants were Saudis [152]. The cohort included 20 patients had diabetes mellitus, 17 patients had hyperlipidaemia, 16 patients had hypertension and 10 patients had cholecystectomy Table 1

There was no significant difference between pre-operative and post-operative lab test except for total bilirubin and alkaline phosphatase Table 2.

Comparison between the patients who had gallstones after the surgery and those who had not revealed no significant difference between the two groups except in BMI Table 3.

There was significant increase in BMI in gallstone groups more than patients with no gallstones group [p-value = 0.02]. There was no significant difference between the two groups regarding the laboratory tests. The median duration for the patients to develop gallstones was 13.34 months [SD = 8.9].

Incidence of gallstones after laparoscopic sleeve gastrectomy

The incidence of gallstones in post sleeve gastrectomy was 3.81 per 100 patients per year [IR = 0.0381, 95% CI [1.76 – 7.23]]. The incidence of symptomatic gallbladder stones was the same as all cases was symptomatic.

The relationship between the change of BMI and gallstone formation

There was no difference between the weight loss in the gallstone group and no gallstone group [P-value = 0.8] Fig 1.

The weight loss in the gallstone group was not considered rapid weight loss buy it was rather gradual weight loss [P-value = 0.78] Fig 2

The risk factors associated with time to develop gallstones post laparoscopic sleeve gastrectomy patients

Multivariate cox regression analysis revealed that the most common risk factors associated with the occurrence of gallstones are marital status, BMI, preoperative lipase, cholesterol, LDL and postoperative total bilirubin, LDL and HDL. Being single decreased the risk to 0.11

[HR = 0.11, SE = 1.05, P-value = 0.04]] compared to married. Furthermore, BMI was found to increase the risk of gallstone development after LSG [HR = 1.20, SE = 0.06, P-value = 0.003]]. Preoperative laboratory tests were not associated with increased risk except Lipase [HR = 1.05, SE = 0.02, P-value =0.018], Cholesterol [HR = 0.83, SE = 0.06, P-value =0.0005], LDL [HR = 1.16, SE = 0.05, P-value =0.005]. In addition, Post-operative total bilirubin [HR = 0.001, SE = 4.29, P-value = 0.004], Post-operative LDL, Post-operative HDL significantly predicted the decreased risk of the gallstones [HR = 0.90, SE = 0.04, P-value =0.018], [HR = 0.79, SE = 0.08, P-value =0.005] respectively. Other factors like age, sex and duration of LSG did not increase the risk of the gallstones Table 4.

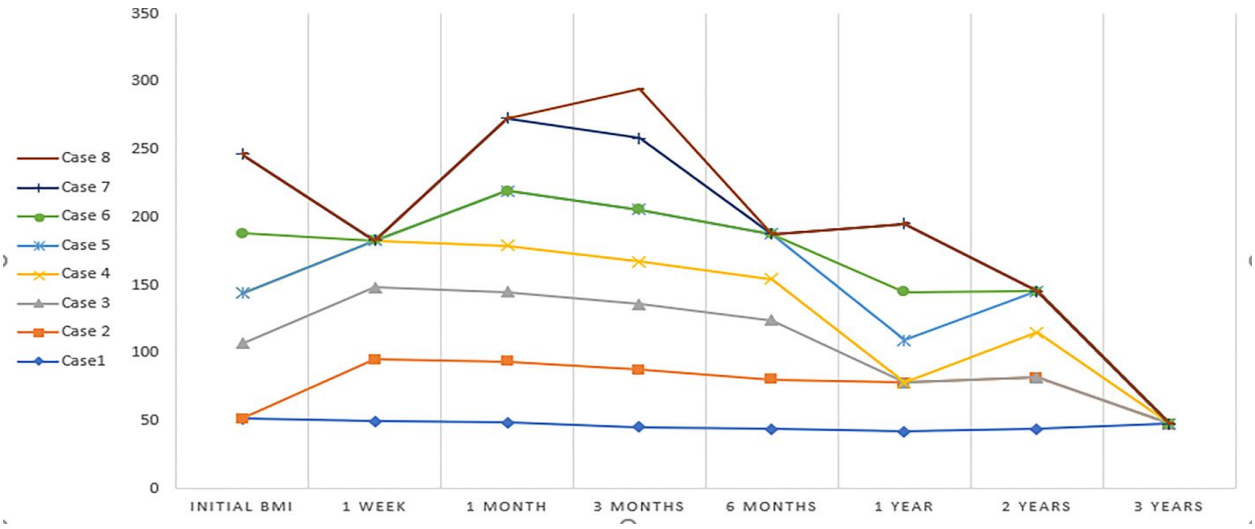

Fig 1 showing the difference of change of BMI between both groups.

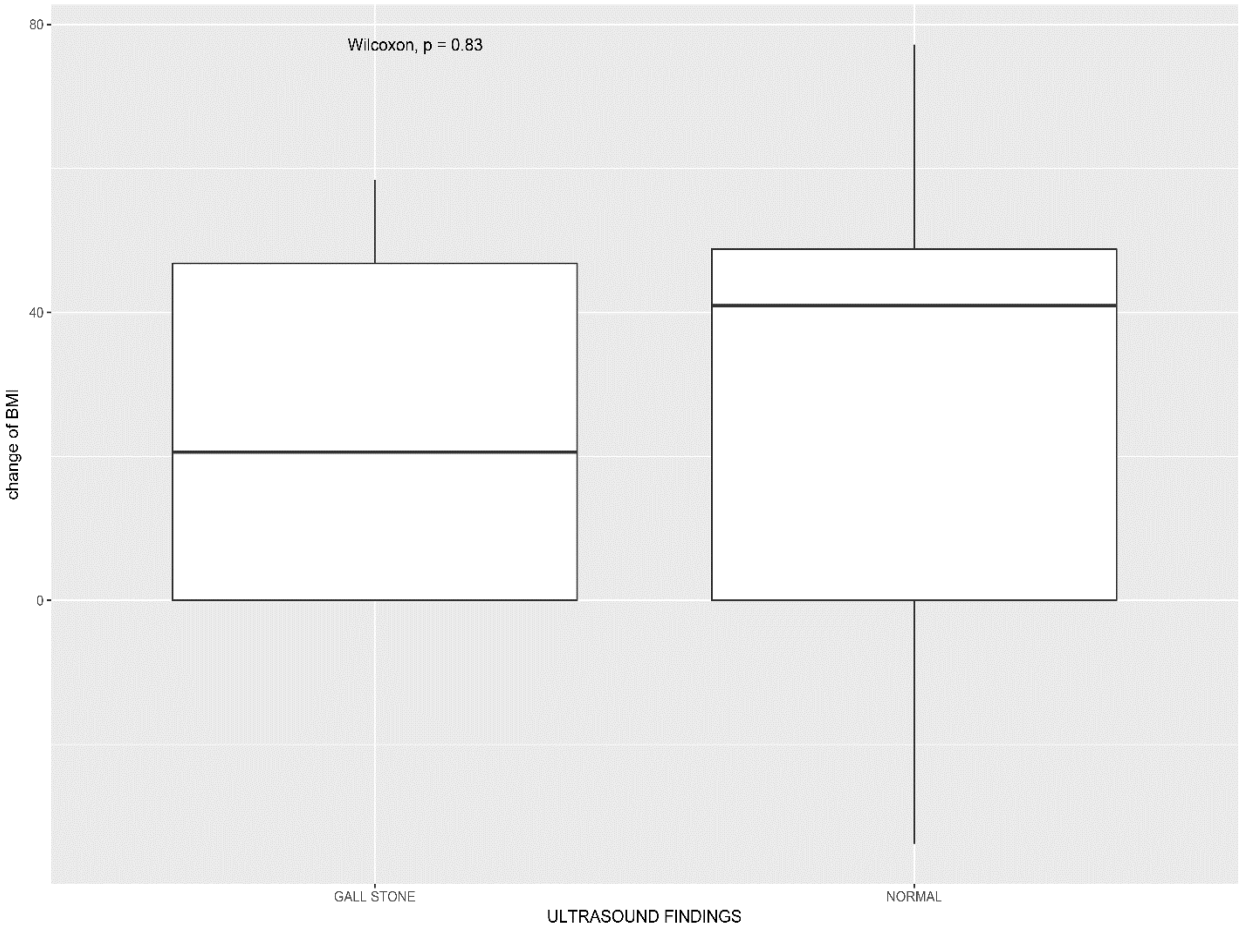

Fig 2 showing the rate of weight loss at each point of follow-up in the eight cases who had gall stones

Table 1: The baseline characteristics of the cohort population

		Overall
n		174
Age [mean [sd]]		31.82 [8.91]
Sex [%]	FEMALE	123 [70.7]
	MALE	51 [29.3]
Marital status [%]	MARRIED	77 [44.3]
	SINGLE	97 [55.7]
Nationality [%]	EGYPT	10 [5.7]
	JORDAN	4 [2.3]
	KUWAIT	1 [0.6]
	NON-SAUDI	1 [0.6]
	PALESTINE	1 [0.6]
	SAUDI	152 [87.4]
	SUDAN	1 [0.6]
	SYRIA	3 [1.7]
	YEMEN	1 [0.6]
BMI [mean [sd]]		47.70 [7.72]
Diabetes mellitus [%]	NO	153 [88.4]
	YES	20 [11.6]
Hyperlipidaemia [%]	NO	157 [90.2]
	YES	17 [9.8]
Hypertension [%]	NO	156 [90.7]
	YES	16 [9.3]
Previous cholecystectomy [%]	NO	162 [94.2]
	YES	10 [5.8]

Table 2: comparison between preoperative and postoperative laboratory tests

	Pre-operative	**Post-operative**	**P-value**
total bilirubin [mean [SD]]	0.41 [0.41]	0.60 [0.56]	<0.0001
Amylase [mean [SD]]	49.32 [36.14]	52.37 [34.57]	0.38
Lipase [mean [SD]]	89.96 [53.45]	147.83 [137.15]	0.13
Alkaline phosphatase [mean [SD]]	91.69 [25.11]	84.49 [32.76]	0.001
Cholesterol [mean [SD]]	187.87 [37.68]	184.87 [37.57]	0.76
Triglycerides [mean [SD]]	118.88 [69.21]	99.15 [56.25]	0.077
LDL [mean [SD]]	124.10 [32.07]	118.02 [37.21]	0.50
HDL [mean [SD]]	43.37 [10.58]	47.59 [19.77]	0.10
HBA1C [mean [SD]]	6.65 [1.96]	6.32 [1.03]	0.85

Table 3: Comparison between patients who developed gall stones and those who did not

		No gall stones	Gall stones	p
n		166	8	
Age [mean [SD]]		31.96 [8.89]	30.81 [9.16]	0.58
Sex [%]	FEMALE	110 [71.9]	13 [61.9]	0.492
	MALE	43 [28.1]	8 [38.1]	
Maritalstatus [%]	MARRIED	66 [43.1]	11 [52.4]	0.572
	SINGLE	87 [56.9]	10 [47.6]	
Nationality [%]	EGYPT	9 [5.9]	1 [4.8]	0.354
	JORDAN	4 [2.6]	0 [0.0]	
	KUWAIT	1 [0.7]	0 [0.0]	
	NON-SAUDI	1 [0.7]	0 [0.0]	
	PALESTINE	1 [0.7]	0 [0.0]	
	SAUDI	133 [86.9]	19 [90.5]	
	SUDAN	0 [0.0]	1 [4.8]	
	SYRIA	3 [2.0]	0 [0.0]	
	YEMEN	1 [0.7]	0 [0.0]	
BMI [mean [SD]]		47.18 [7.27]	51.47 [9.83]	0.016
Diabetes mellitus [%]	NO	134 [88.2]	19 [90.5]	1
	YES	18 [11.8]	2 [9.5]	
Hyperlipidaemia [%]	NO	136 [88.9]	21 [100.0]	0.224
	YES	17 [11.1]	0 [0.0]	
Hypertension [%]	NO	136 [89.5]	20 [100.0]	0.265
	YES	16 [10.5]	0 [0.0]	
Previous cholecystectomy [%]	NO	144 [95.4]	18 [85.7]	0.203
	YES	7 [4.6]	3 [14.3]	
total bilirubin [median [IQR]]		NA [NA+ NA]	5.00 [5.00+ 5.00]	NA
Amylase [median [IQR]]		42.00 [27.50+ 56.00]	47.00 [43.00+ 49.00]	0.471
Lipase [median [IQR]]		100.50 [57.50+ 126.25]	22.00 [20.00+ 126.00]	0.262
Alkaline phosphatase [median [IQR]]		90.00 [73.00+ 103.75]	91.00 [75.50+ 105.25]	0.815
Cholesterol [median [IQR]]		185.00 [166.50+ 205.50]	169.00 [155.50+ 190.50]	0.133
Triglycerides [median [IQR]]		103.00 [65.00+ 144.00]	117.00 [87.00+ 128.50]	0.659
LDL [median [IQR]]		124.00 [106.00+ 145.75]	111.50 [91.75+ 129.25]	0.143
HDL [median [IQR]]		42.00 [35.50+ 50.00]	38.50 [37.25+ 45.50]	0.479
HBA1C [median [IQR]]		6.10 [5.62+ 6.77]	6.55 [6.03+ 7.07]	0.945
post-operative Amylase [median [IQR]]		48.00 [39.75+ 58.25]	34.50 [24.25+ 47.00]	0.18
post-operative Lipase [median [IQR]]		120.00 [83.00+ 170.75]	94.00 [17.00+ 98.00]	0.239
post-operative alkaline phosphatase [median [IQR]]		78.50 [65.00+ 96.75]	78.00 [72.00+ 96.50]	1
post-operative cholesterol [median [IQR]]		180.00 [164.50+ 222.00]	172.50 [134.75+ 198.00]	0.423
post-operative triglycerides [median [IQR]]		94.00 [59.50+ 129.00]	72.00 [61.75+ 94.75]	0.775
post-operative LDL [median [IQR]]		121.00 [97.50+ 146.00]	96.00 [88.75+ 137.75]	0.3
post-operative HDL [median [IQR]]		49.00 [36.75+ 58.00]	30.00 [25.00+ 40.00]	0.051
post-operative HBA1C [median [IQR]]		6.05 [5.73+ 6.38]	6.70 [6.10+ 7.30]	0.8

Table 4: the results of cox proportional regression analysis

	Hazard ratio	standard error	P-value
Age	0.99	0.07	0.87962
male	5.40	1.01	0.09648
Single	0.11	1.05	0.03554
Jordan	0.00	27300.00	0.99946
Kuwait	0.00	171000.00	0.99992
Non-Saudi	0.00	86100.00	0.99988
Palestine	0.00	86100.00	0.9998
Saudi	0.03	1.97	0.08393
Sudan	0.00	5.85	0.10289
Syria	0.00	20200.00	0.99901
Yemen	0.00	137000.00	0.99989
BMI	1.20	0.06	0.00267
Diabetes mellitus	4.35	2.79	0.59835
Hyperlipidaemia	0.00	8150.00	0.99819
Hypertension	0.00	5940.00	0.99265
Post-operative TOTAL BILIRUBIN	0.00	4.29	0.00455
Post-operative AMYLASE	0.97	0.05	0.61891
Post-operative LIPASE	0.99	0.01	0.54055
Post-operative ALKALINE PHOSPHATASE	1.02	0.03	0.61143
Post-operative CHOLESTEROL	1.04	0.03	0.20987
Post-operative TRIGLYCERIDE	1.00	0.02	0.99768
Post-operative LDL	0.90	0.04	0.01843
Post-operative HDL	0.79	0.08	0.00529
Post-operative HBA1C	0.32	2.07	0.58495
Length of post-operative stay	1.27	0.39	0.53871
Length of hospital stay	1.22	0.27	0.45553
Total bilirubin	0.56	0.51	0.2495
Amylase	1.21	0.10	0.05626
Lipase	1.05	0.02	0.01815
Alkaline phosphatase	1.01	0.03	0.61574
Cholesterol	0.83	0.06	0.00057
Triglyceride	1.00	0.01	0.59032
LDL	1.16	0.05	0.00497
HDL	1.20	0.09	0.05313
HBA1C	0.12	1.44	0.14509
Intra-operative complication	12.90	2.73	0.34911
Length of operation [min]	1.02	0.01	0.05585

DISCUSSION:

This study was set out to recognize the incidence of gallstones after sleeve gastrectomy and the risk factors associated with it. Per our results, the incidence of gallstone after sleeve gastrectomy was 3.81% which was the same as symptomatic gallstones. there was significant increase in BMI in patients who developed gallstone more than patients with no gallstones group [p-value = 0.02]. Furthermore, the risk factor associated with time to

develop gallstones was marital status, BMI, preoperative lipase, cholesterol, LDL and postoperative total bilirubin, LDL and HDL.
The gallstone formation after the laparoscopic sleeve gastrectomy is mainly due to rapid weight loss after the surgery [24, 27, 29, 30]. The cholethiasis formation itself is increased in females, more than 40 years and obese [31]. These risk factors were also found to be associated with increased risk of gallstone formation in bariatric surgery [24, 27, 29, 30].

In this study, the incidence of symptomatic gallstones was 3.8% which is considered the same as Ming et al., which had approximately the same mean BMI as in this study [30]. Another study reported incidence of 2.8% of post-operative gallstone formation which is less than our study [21]. Lalor et al. reported the incidence of gallbladder stone formation of 0.7% [32]. The usual range of the incidence of gallstones formation is 3.8-5.8% [21]. Generally, the low reported incidence of the gallstone in this study may be explained by explained patients' incompliance to follow-up and short follow-up duration [21]. Other studies had similar incidence to our study [30, 33, 34] meanwhile Sioka et al. had higher incidence of 5.8% [28].Furthermore, another study had incidence rate of 22.9% which explained its high incidence on the diagnosis of gallstones. In this study, they performed ultrasound for all patients which induced a high false positive. Unlike our study, we performed ultrasound only for patients with symptoms suggestive of biliary disease. Another main difference between each study is the duration for gallstone formation. Deitel et al and Amaral et al. had reported that patients developed gallstones after 16 months of LSG [27, 33]while Ming et al. reported that the time to form gallstone was 21 months [30]. In our study, the interval between LSG and post-operative gallbladder stone was 13 months. It is reported that gallbladder stones usually develop in the first six months to one year after sleeve gastrectomy [27, 33]. In our study, we followed the patients for three years and had the highest incidence in the first year after LSG. All the patients in our cohort had symptoms of gallstones, unlike other studies that showed that the symptomatic gallbladder represents a portion of the whole patients [22, 24, 27, 33, 35]. Asymptomatic gallbladder is considered a dilemma for surgeons for its treatment and its effects [22, 24, 27, 28, 33, 35].

In our study, we used a cox proportional hazard regression to include the time to gallstones in consideration. In our study, BMI was found to be a main risk factor for the gallstone formation. The BMI has always been a risk factor for gallstone formation whether after bariatric surgery or not [27, 31, 36, 37]. It is also postulated that the rate of weight loss was also associated with increased incidence of gallstone formation [25, 28]. In our study there was no difference between the change of BMI between cases who had gallstones and those had not. Similarly, Shiffman et al. and De Oliveira et al has found that BMI or the rate of weight loss was not associated with gallstone formation [23, 25, 38]. The same was found in Manatsathit et al. who reported the cause of this controversial results was different follow-up times and the measurement scales of the rate of weight loss [26]. It was not possible for us to measure the BMI change at each follow-up point because not all cases were followed at the same time. Age, gender, previous history of diseases in our study was not associated with the gallstone formation. Surprisingly, these factors are risk factors for formation of gallstone itself [31] however, it was reported in many studies that these factors did not affect the risk of gallstones after LSG [21-24, 35, 39]. Marital status in our study was one of the factors that increased incidence of gallbladder stone. However, this issue was never addressed in literature. Another thing that also not addressed much in literature is preoperative and postoperative laboratory tests. In this study, the preoperative lipase and cholesterol was major determinant of the gallstone formation after sleeve gastrectomy. It was found in another study that using of anti-cholesterol drugs significantly decreased the gallstone formation after sleeve gastrectomy [22]. There is no enough evidence on the relationship between preoperative lipase and gallstone formation in LSG. Bera et al. found that serum lipase was not related to the gallstone diseases. Post operative LDL and HDL seemed to decrease the risk to the gallstone formation while preoperative LDL increased the risk for gallstone formation [40]. The increased risk in gallstones in patients with high LDL was proven in many studies [21, 31, 41]. However, the protective effect after surgery still needs more investigation. Literature search did not explain this effect. More investigations are needed to understand this effect.

In conclusion, the incidence of gallstone after sleeve gastrectomy was 3.81%. There was significant increase in BMI in patients who developed gallstone more than patients with no gallstones group. However, the rate of weight change did not increase the risk for gallstone formation. Furthermore, the risk factors associated with time to develop gallstones was marital status, BMI, preoperative lipase, cholesterol, LDL and postoperative total bilirubin, LDL and HDL.

Conflict of interest
None

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