Rola badań dodatkowych ze szczególnym uwzględnieniem endoskopii w ocenie ryzyka i leczeniu powikłań w grupie pacjentów operowanych z powodu otyłości chorobliwej

The role of diagnostic measures and methods, with particular emphasis on endoscopy in the risk assessment and treatment of complications in the group of patients operated on due to morbid obesity

Praca doktorska

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Gdańsk, rok 2022

Pragnę podziękować

mojej Promotor dr hab. n med. Monice Proczko-Stepaniak
za zaangażowanie, życzliwą pomoc i motywację do pracy naukowej,

dr Iwonie Marek i całemu zespołowi Pracowni Endoskopii
za nieocenione wsparcie,

oraz Rodzinie za to, że jest.

Spis treści

Indeks skrótów
BMI, body mass index, indeks masy ciała;
ERABS, enhanced recovery after bariatric surgery, kompleksowa formuła opieki okołooperacyjnej dla poprawy wyników leczenia bariatrycznego;
GERD-HRQL, GERD-Health-Related Quality of Life,
OAGB, one-anastomosis gastric bypass, wyłączenie żołądkowo-jelitowe na pętli omega;
%TWL, % total weight loss, % całkowita utrata masy ciała;

Słowa kluczowe
Otyłość, chirurgia bariatryczna, powikłania, endoskopia,

Streszczenie

Wstęp

Otyłość i choroby związane z otyłością, takie jak nadciśnienie tętnicze (NT), cukrzyca typu 2 (DM2), choroby sercowo-naczyniowe (ChSN), niealkoholowa stłuszczeniowa choroba wątroby (NAFLD) i dyslipidemia (DL) stały się jedną z głównych przyczyn zgonów w rozwiniętych i rozwijających się społeczeństwach[1,2]. W Polsce odpowiednio 68% mężczyzn i 53% kobiet ma BMI powyżej 25 kg/m2. Odsetek ludzi chorujących na otyłość (BMI>30 kg/m2) w dorosłej populacji sięga prawie 25%[3]. Chirurgia bariatryczna jest obecnie opcją leczenia z wyboru dla pacjentów chorujących na otyłość i chorobami z nią związanymi. Chirurgia bariatryczna zapewnia trwałą utratę masy ciała i ustąpienie chorób współistniejących związanych z otyłością[4–14]. Stale rosnąca liczba operacji bariatrycznych wykonywanych na świecie implikuje również wzrost ilości powikłań. Odpowiednia diagnostyka i leczenie powikłań mają zasadnicze znaczenie dla bezpieczeństwa pacjentów. Dlatego niezbędny jest właściwy dobór środków i metod diagnostycznych. Endoskopia odgrywa wiodącą rolę w leczeniu i wykrywaniu wczesnych i późnych powikłań chirurgii bariatrycznej[15–17].

Cele

Publikacja 1

Celem tego badania była ocena wpływu wczesnej interwencji endoskopowej na wyniki leczenia u pacjentów bariatrycznych (operowanych w ramach protokołu ERABS (enhanced recovery after bariatric surgery; kompleksowa formuła opieki okołooperacyjnej dla poprawy wyników leczenia bariatrycznego)). Celem pierwszorzędowym było porównanie wyników leczenia pacjentów, którzy przeszli interwencję endoskopową z powodu krwawienia do przewodu pokarmowego podczas pierwotnej hospitalizacji, a tymi, którzy zostali ponownie przyjęci z powodu powikłania pod postacią wczesnego (do 30 dni) krwawienia do przewodu pokarmowego.

Publikacja 2

Głównym celem tego badania była ocena wpływu całkowitego wstrzymania planowych operacji bariatrycznych („lockdown") z powodu pandemii COVID-19 na krótkoterminowe

wyniki (powikłania) i przebieg okołooperacyjny w grupie pacjentów poddanej leczeniu bariatrycznemu.

Publikacja 3

Pierwszorzędowym celem tego badania była ocena występowania obecności zmian histopatologicznych i makroskopowych w dolnym odcinku przełyku 2 lata po one-anastomosis gastric bypass (OAGB). Celem drugorzędowym było zbadanie przydatności kwestionariusza oceny jakości życia GERD-Health-Related Quality of Life (GERD-HRQL)[18] jako narzędzia przesiewowego do oceny nasilenia zmian o charakterze refluksowym oraz zbadanie wpływu aktywnego zakażenia H. pylori, cukrzycy typu 2, nadciśnienie tętniczego, niedoczynności tarczycy i przebytej cholecystektomii na występowanie zmian w przełyku.

Materiał i metody

Publikacja 1

Do tego retrospektywnego badania klinicznego włączono pacjentów, po operacji bariatrycznej wykonanej zgodnie z protokołem ERABS, poddanych wczesnemu (w ciągu 30 dni po operacji) leczeniu endoskopowemu z powodu krwawienia do przewodu pokarmowego. Zidentyfikowano 14 spośród 1431 operowanych pacjentów, a ich dane zostały wyodrębnione na potrzeby niniejszego badania. Oceniono typ krwawienia, lokalizację, technikę użytą do zatrzymania krwawienia, konieczność ponownej interwencji endoskopowej, stężenie hemoglobiny, ilość przetoczonych preparatów krwi i ich pochodnych oraz wyniki odległe (procent całkowitej utraty masy ciała (%TWL)). Pacjentów ponownie przyjętych do szpitala (grupa 2) z powodu krwawienia do przewodu pokarmowego porównano z pacjentami poddanymi interwencji endoskopowej podczas pierwotnego pobytu (grupa 1). Istotność statystyczną różnic przyjęto, jeśli wartości p była < 0.05.

Publikacja 2

Jest to retrospektywna analiza 158 pacjentów po operacjach bariatrycznych, którzy przeszli leczenie przed lub po pierwszym „lockdownie” z powodu pandemii COVID-19 w Polsce. Pacjentów podzielono na grupę przed i grupę po „lockdownie”, z których każda składała się z 79 pacjentów. Analizie poddano szczegółowe dane antropometryczne z okresu

przedoperacyjnego i operacji. Ponad to analizowano wyniki pooperacyjne: długość pobytu w szpitalu, powikłania według klasyfikacji Clavien-Dindo (CDC)[19,20], odsetek ponownych przyjęć do szpitala. Dodatkowo, dla każdego pacjenta obliczono comprehensive complication index (CCI)[21] wskazujący skumulowane obciążenie powikłaniami (www.accesssurgery.com). Normalność rozkładu analizowano za pomocą testu Shapiro–Wilka. Zmienne ilościowe analizowano za pomocą testu chi-kwadrat. Zmienne jakościowe analizowano za pomocą testu Kruskala-Wallisa lub testu U Manna–Whitneya. Wartość $p<0.05$ wskazywała na istotność statystyczną różnic.

Publikacja 3

Jest to analiza pacjentów operowanych (OAGB) w okresie od 1 stycznia 2016 r. do 31 grudnia 2017 r. u których zgodnie z protokołem badania zaplanowano wykonanie kontrolnej gastroskopii (GS) z biopsją z dystalnego odcinka przełyku dwa lata po operacji. Kryteria wykluczenia z badania były następujące: operacja bariatryczna inna niż OAGB, przebyta wcześniejsza operacja bariatryczna; brak uczestnictwa w nadzorze pooperacyjnym (lost to follow-up); przeciwwskazania do GS; nie stawienie się na zaplanowaną GS; odmowa wykonania GS, odmowa wykonania biopsji, GS nie wykonywane przez wyznaczonego lekarza; GS nieukończona. Wszyscy pacjenci przed GS wypełniali zwalidowany kwestionariusz GERD-HRQL. Objawy uznano za nieobecne u pacjentów z wynikiem GERD-HRQL wynoszącym 0, łagodne od 1 do 15, umiarkowane od 16 do 30 i ciężkim nasileniu od 31 do 50. Wszyscy pacjenci z potwierdzonym przedoperacyjnie przełykiem Baretta, ciężkim zapaleniem przełyku (klasyfikacja[22] Los Angles (LA) C lub D) nie zostali zakwalifikowani do OAGB. Normalność rozkładu analizowano za pomocą testu Shapiro-Wilka. Zmienne ilościowe analizowano za pomocą testu chi-kwadrat i przedstawione w medianach lub procentach. Zmienne jakościowe analizowano za pomocą testu Kruskala-Wallisa i testu U Manna–Whitneya i przedstawiono jako średnie z odchyleniami standardowymi. Wartość $p<0.05$ wskazywała na istotność statystyczną różnic.

Wyniki

Publikacja 1

Na podstawie analizowanych danych odsetek krwawień do przewodu pokarmowego u pacjentów operowanych w protokole ERABS w naszym ośrodku wynosił 0.97% (n = 14).

Odsetek wczesnych (do 30 dni) ponownych przyjęć z powodu krwawienia do przewodu pokarmowego wynosił 0.4% (n = 5), a ogólny odsetek wczesnych rehospitalizacji wynosił 0.91% (n = 13) w okresie objętym badaniem od czasu wdrożenia protokołu ERABS. Odstęp czasu między operacją a interwencją endoskopową był istotnie krótszy w grupie 1 w porównaniu z grupą 2 (p = 0.014). Stężenie hemoglobiny w surowicy przed endoskopią i długość pobytu w szpitalu były podobne w obu grupach (odpowiednio p = 0.658 i 0.403). W obserwacji odległej pooperacyjna utrata masy ciała (%TWL) pacjentów z grupy 2 była podobna do tej w grupie 1 (p = 0.298).

Publikacja 2

Grupa po „lockdownie" miała znacznie niższą operacyjną masę ciała (105.76 vs 114.25[kg]; p = 0,012) i BMI (36.99 vs 39.93[kg/m2]; p = 0.005) w porównaniu z grupą przed. Pierwotna długość hospitalizacji była istotnie dłuższa w grupie po „lockdownie" (3.04 vs 2.44[dni]; p = 0.001). Grupa po „lockdownie" miała znacząco niższy średni wynik CCI (1.90 vs 6.67; p = 0.046) i mniej wczesnych ponownych przyjęć po wypisie (0 vs 8.86; p = 0,007) niż grupa przed.

Publikacja 3

Od 1 stycznia 2016 r. do 31 grudnia 2017 r. w centrum bariatrycznym wykonano łącznie 760 operacji, wśród których OAGB stanowiło 211. 161 pacjentów wykluczono z badania, zgodnie z kryteriami wyłączenia. Pozostałych pięćdziesięciu pacjentów (43 kobiet i 7 mężczyzn), w średnim wieku 47.94 (28–72 [lata]; SD = 8.19), ze średnią przedoperacyjną masą ciała 121.25 (96-180 [kg]; SD = 17.84), ze średnim przedoperacyjnym BMI 43.7 (32.7–61.3 [kg/m2]; SD = 5.5), średnim operacyjnym BMI 37.42 (27.28–46.86 [kg/m2]; SD = 4.38) i średnią operacyjną masą ciała 103.91 (77-137 [kg]; SD = 13.96) zostało włączonych do badania. Dwadzieścia cztery osoby (48%) miały zapalenie przełyku stopnia A lub B wg klasyfikacji LA. Czterech pacjentów (8%) miało endoskopowe podejrzenie metaplazji przełyku (ESEM). 34/50 (68%) pacjentów miało różne zmiany histopatologiczne przełyku na podstawie przeprowadzonej GS, stwierdzono 4 przypadki przełyku Barretta. Kwestionariusz GERD-HRQL został wypełniony przez wszystkich uczestników raz przed GS. Średni wynik wyniósł 9 punktów (0–44; SD = 9.7).

Wnioski

Prezentowane prace pozwoliły na przekrojową analizę przydatność badań dodatkowych ze szczególnym uwzględnieniem endoskopii w diagnozowaniu i leczeniu powikłań po operacjach bariatrycznych.

Pierwsza publikacja dostarcza dowodów na to, że pacjenci operowani zgodnie z zaleceniami ujętymi w protokole ERABS, którzy są wypisywani do domu w 1. dobie po operacji i doświadczają powikłania pod postacią krwawienia do przewodu pokarmowego poza szpitalem, mogą być leczeni za pomocą interwencji endoskopowych równie skutecznie i bezpiecznie, jak pacjenci, u których to powikłanie wystąpiło podczas pierwotnego pobytu w szpitalu. Ponadto nasze badanie pokazuje, że takie postępowanie nie wpływa na długoterminowe wyniki leczenia (%TWL).

Druga publikacja przedstawia dość nieoczekiwane odkrycie, że istotnemu zmniejszeniu uległa ilość ponownych przyjęć (rehospitalizacji) do szpitala jak i obniżeniu uległ wskaźnik CCI w grupie pacjentów operowanych po „lockdownie" spowodowanym pandemią COVID-19. Należy jednak nadmienić, że jak pokazano w naszym badaniu, pacjenci operowani po „lockdownie" charakteryzowali się niższą średnią operacyjną masą ciała i średnim operacyjnym BMI, jednak z porównywalną wyjściową masą ciała i BMI, co teoretycznie mogło przyczynić się do obniżenia ryzyka wystąpienia powikłań.

Ostatnia publikacja dostarczyła wysokiej jakości dowodów na to, że pacjenci już dwa lata po OAGB są narażeni na ryzyko rozwoju przełyku Barretta. Co więcej raportowane przez pacjentów niskie wyniki w kwestionariuszu oceny dolegliwości (GERD-HRQL) w porównaniu do bardzo dużej ilości wykrytych zmian zapalnych w przełyku, potwierdzają tezę o występowaniu zjawiska bezobjawowego refluksu żółciowego po operacjach typu OAGB.

Podsumowując, właściwe wykrywanie i leczenie powikłań chirurgii bariatrycznej zależy od właściwego doboru badań dodatkowych, endoskopia ma pierwszoplanową rolę w diagnozowaniu i leczeniu powikłań.

Abstract

Introduction

Obesity and obesity-related diseases, such as hypertension (HA), type 2 diabetes (T2DM), cardiovascular diseases (CVD), non-alcoholic fatty liver disease (NAFLD) and dyslipidemia (DL) have become one of the leading causes of death in developed and developing societies[1,2]. In Poland, 68% of men and 53% of women, respectively, had a BMI greater than 25 kg/m^2. The rate of obesity (BMI>30 kg/m^2) in the adult population has reached almost 25%[3]. Bariatric surgery (BS) is currently the option of choice for patients with obesity and obesity-related diseases. BS provides sustained weight loss and the resolution of obesity-related comorbidities[4–14]. The rapidly growing number of BS worldwide imposes the number of complications. Proper management and detection of complications is essential for patients' safety. Therefore, proper selection of diagnostic means, and methods is essential. Endoscopy plays a leading role in management and detection of early and late post BS complications[15–17].

Aims

Publication 1

To evaluate the potential influence of early endoscopic intervention on bariatric patients' management pathway (patients operated under the ERABS (enhanced recovery after bariatric surgery)). The primary objective was to compare results between patients who underwent endoscopic intervention during the initial hospital stay and those who were readmitted following complications of early gastro-intestinal (GI) tract bleeding.

Publication 2

The primary aim of this study was to assess the influence of COVID-19 related national lockdown on the short-term outcomes (complications) and intraoperative course of bariatric patients.

Publication 3

The primary aim of the study was to evaluate the presence of esophageal GERD-related histopathological and macroscopical findings 2 years after OAGB. The secondary aims were to investigate the usefulness of the self-reporting GERD-Health-Related Quality of Life (GERD-HRQL) questionnaire[18] as a screening tool and investigate the influence of medical conditions (active H. pylori infection, type 2 diabetes mellitus (T2DM), hypertension (HA), hypothyroidism and previous cholecystectomy) on esophageal histopathology.

Material and methods

Publication 1

A clinical database was searched for patients undergoing early (within 2 weeks after surgery) endoscopic treatment because of GI tract bleeding following bariatric surgery under the ERABS protocol. 14 out of 1431 patients operated on were identified and their data were extracted for the purposes of this study. Patients readmitted to the hospital due to developing GI tract bleeding (group 2) were compared with patients undergoing endoscopic intervention during the initial stay (group 1), for the same purpose. Statistical significance was assumed if p-values were < 0.05.

Publication 2

This is a retrospective analysis of 158 bariatric surgery patients, who underwent bariatric procedures either prior to or after the first national COVID-19 lockdown in Poland. The patients were categorized as pre-lockdown group and the post-lockdown group, each comprising of 79 patients. The postoperative outcomes include length of hospital stay (LOS), Clavien–Dindo Classification (CDC)[19,20], rehospitalization rate were collected. Additionally, the comprehensive complication index (CCI)[21] indicates patient-specific cumulative complication burden was calculated (www.accesssurgery.com). The normality of distribution was analyzed using Shapiro–Wilk Test. The quantitative variables were analyzed using chi-square test. The qualitative variables were analyzed using the Kruskal Wallis test or Mann–Whitney U test. The statistical significance was assumed if P-value was <0.05.

Publication 3

Patients operated between 1st January 2016 to 31st December 2017 were schedule, two years after OAGB for upper endoscopy (UE) with a biopsy. In all cases, biopsies from the distal esophagus were obtained. The study exclusion criteria were as follows: bariatric surgery other than OAGB, previous bariatric surgery (LSG — laparoscopic sleeve gastrectomy, AGB — adjustable gastric banding, VGB — vertical banded gastroplasty); lost to follow-up, follow-up incomplete; contraindications for UE; not present for UE; refused UE; refused a biopsy; UE not performed by the dedicated physician; UE not completed. All patients, prior to UE, completed a validated GERD-HRQL questionnaire. Symptoms were considered as absent in patients reporting a GERD-HRQL score of 0, mild from 1 to 15, moderate from 16 to 30, and severe from 31 to 50. All patients were qualified for OAGB by multidisciplinary team (bariatric surgeon, bariatric nurse, dietitian, psychologist, and internal medicine specialist) after considering preoperative UE, abdominal and heart ultrasound, and nutritional status. All patients with confirmed Barrett esophagus (BE), severe esophagitis (Los Angles classification [22] (LA) C or D) were not qualified for OAGB.

Results

Publication 1

Based on the analyzed data, the percentage of GI bleeding in patients operated on under the ERABS protocol in our center was 0.97% (n = 14). The rate of early (up to 30 days) readmissions due to GI tract bleeding was 0.4% (n = 5) with an overall early readmission rate of 0.91% (n = 13) in the study period since the ERABS protocol was implemented. The time interval between surgery and endoscopic intervention was significantly shorter for group 1 in comparison to group 2 (p = 0.014). Serum Hb levels before endoscopy and the length of hospital stay were similar between the groups (p = 0.658 and 0.403, respectively). At long-term follow-up, the post-operative weight loss (%TWL) of patients in group 2 was like that in group 1 (p = 0.298).

Publication 2

The post-lockdown group had significantly lower operative weight (105.76 vs 114.25 [kg]; p = 0.012) and BMI (36.99 vs 39.93[kg/m2]; p = 0.005) compared to pre-lockdown group. The primary length of stay was significantly longer in the post-lockdown group (3.04 vs

2.44[days]; p = 0.001). The post-lockdown group had significantly lower mean CCI score (1.90 vs 6.67; p = 0.046) and less short-term readmissions post-discharge (0 vs 8.86; p = 0.007) than pre-lockdown group.

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Publication 3

Between 1st of January 2016 and 31st of December 2017 760 patients were operated on in bariatric center, among who, 211 OAGB were performed. 161 patients met our exclusion criteria. The remaining fifty patients (43 female and 7 male), with a mean age of 47.94 (28–72 years; SD = 8.19), a median preoperative weight of 121.25 (96-180[kg]; SD = 17.84), a median preoperative BMI of 43.7 (32.7–61.3[kg/m2]; SD = 5.5), a median operative BMI of 37.42 (27.28–46.86[kg/m2]; SD = 4.38) and a median operative weight of 103.91 (77-137 [kg]; SD = 13.96) were enrolled in the study. Twenty-four (48%) had grade A or B esophagitis. Four patients (8%) had endoscopically suspected esophageal metaplasia (ESEM). 34/50 (68%) patients had various histopathological esophageal changes, based on the conducted endoscopy, among which four cases of Barrett's esophagus were observed. The GERD-HRQL questionnaire was completed by all participants once during UE. The mean result was 9 points (0–44; SD = 9.7).

Conclusions

Presented studies provided a cross-section through the usefulness of additional tests with emphasis on endoscopy in detection and treatment of complications following bariatric surgery.

The first publication provides proof that patients who are discharged on the 1st postoperative day under the ERABS protocol and develop complications outside of the hospital can be managed with endoscopic interventions as effectively as those developing early complications during the initial hospital stay. Additionally, our study also shows that such management does not affect the long-term outcomes of bariatric surgery in terms of %TWL. Second publication presents an unexpected finding of improved treatment outcomes in the post-lockdown patients, with significantly fewer early readmissions, and lower CCI scores. As shown, in our study, the post-lockdown population group had a lower mean operative body weight and BMI, thus, contributing to the lowering of complication risk. The last publication provided high quality evidence that patients after OAGB are at the risk of development of BE. The majority of our cohort did not report any symptoms, none of patients reported severe GERD

symptoms (≥31 points in GERD-HRQL) and 3/50 (6%) moderate GERD symptoms (16–30 in GERD-HRQL), which in comparison to the histopathological results might confirms the thesis of the essential role of asymptomatic bile reflux following OAGB.

In conclusion, proper detection and treatment of post bariatric complications depends on a usage of wide spectrum of additional tests, questioners, endoscopy have a primary role in detection and treatment of complications.

Wstęp

Otyłość i choroby związane z otyłością, takie jak nadciśnienie tętnicze (NT), cukrzyca typu 2 (DM2), choroby sercowo-naczyniowe (ChSN), niealkoholowa stłuszczeniowa choroba wątroby (NAFLD) i dyslipidemia (DL) stały się jedną z głównych przyczyn zgonów w rozwiniętych i rozwijających się społeczeństwach[1,2]. W Polsce odpowiednio 68% mężczyzn i 53% kobiet ma BMI powyżej 25 kg/m2. Odsetek ludzi chorujących na otyłość (BMI>30 kg/m2) w dorosłej populacji sięga prawie 25%[3]. Chirurgia bariatryczna jest obecnie opcją z wyboru dla pacjentów chorujących na otyłość i chorobami z nią związanymi. Chirurgia bariatryczna zapewnia trwałą utratę masy ciała i ustąpienie chorób współistniejących związanych z otyłością[4–14]. Stale rosnąca liczba operacji bariatrycznych wykonywanych na świecie implikuje również wzrost ilości powikłań.

Obecnie uważa się, że nie da się w pełni wyeliminować występowania powikłań chirurgicznych jako takich, stąd też coraz większy nacisk kładziony jest na ich wczesne wykrywanie i właściwe leczenie. Powikłania chirurgii bariatrycznej stanowią bardzo niejednorodną i szeroką grupę przypadłości. Ich przyczyny są zwykle wieloczynnikowe i zależą między innymi zastosowanej techniki chirurgicznej, właściwego doboru i kwalifikacji pacjentów, zastosowaniu odpowiednich rodzajów operacji dostosowanych do potrzeb chorujących na otyłość pacjentów oraz przede wszystkim stałej kontroli pooperacyjnej.

Jednym z kluczowych narzędzi diagnostyczno-leczniczych na każdym etapie leczenia bariatrycznego pozostaje endoskopia[15–17].

Niniejszy przewód doktorski składa się z trzech prac oryginalnych. Wstęp do rozprawy doktorskiej stanowi praca pt. „*Endoscopic management of early GI tract bleeding in a group of bariatric patients undergoing a fast track protocol"* będąca próbą odpowiedzi na pytanie o bezpieczeństwo stosowania protokołu kompleksowej formuły opieki okołooperacyjnej dla poprawy wyników leczenia bariatrycznego (ERABS) w kontekście jednego z najczęściej występujących powikłań leczenia bariatrycznego – krwotoku do przewodu pokarmowego. Druga praca oryginalna pt. *„Influence of polish national COVID-19 lockdown on the patient characteristics and outcomes of bariatric surgery at a high-volume center – a cohort study"* to analiza porównująca wyniki leczenia pacjentów kwalifikowanych do chirurgicznego leczenia otyłości przed wybuchem pandemii COVID-19 z wynikami leczenia pacjentów operowanymi po wymuszonej przerwie związanej z krajowym "lockdownem". Do oceny częstości i ciężkości

powikłań zastosowano nowoczesny wskaźnik skumulowanej sumy powikłań CCI[21] (comprehensive complication index) oraz renomowaną klasyfikację Calvien-Dindo[19,20]. Główną część rozprawy doktorskiej stanowi praca pt. *„Evaluation of esophageal pathology in a group of patients 2 years after one-anastomosis gastric bypass (OAGB) – cohort study"* w której skupiono się na niezwykle istotnym problemie odległych powikłań pooperacyjnych u pacjentów którzy przeszli operację bariatryczną sposobem OAGB. Wyłączenie żołądkowo-jelitowe na pętli omega jest uznaną procedurą chirurgiczną, obarczoną jednak ryzkiem powstania refluksu żółciowego „de novo" lub progresji już istniejącego[23–30]. Teoretycznie operacja ta może prowadzić do zmian w obrębie dystalnego odcinka przełyku i rozwoju przełyku Barretta. W pracy tej wykorzystano wyniki badań endoskopowych (wykonanych przez autora) oraz wyniki histopatologiczne wycinków pobranych z dystalnej części przełyku, zgodnie z zaplanowanym algorytmem postępowania, u pacjentów 2 lata po OAGB.

Cele

Publikacja 1

Endoscopic management of early GI tract bleeding in a group of bariatric patients undergoing a fast track protocol. Celem pracy była ocena wpływu wczesnej interwencji endoskopowej na wyniki leczenia u pacjentów bariatrycznych (operowanych w ramach protokołu ERABS (enhanced recovery after bariatric surgery; kompleksowa formuła opieki okołooperacyjnej dla poprawy wyników leczenia bariatrycznego)). Celem pierwszorzędowym było porównanie wyników leczenia pacjentów, którzy przeszli interwencję endoskopową z powodu krwawienia do przewodu pokarmowego podczas pierwotnej hospitalizacji, a tymi, którzy zostali ponownie przyjęci z powodu powikłania pod postacią wczesnego (do 30 dni) krwawienia do przewodu pokarmowego. Ponad to, oceniono wpływ zastosowanej techniki uzyskania hemostazy oraz ilość interwencji endoskopowych potrzebnych do uzyskania hemostazy na wyniki leczenia.

Publikacja 2

Influence of polish national COVID-19 lockdown on the patient characteristics and outcomes of bariatric surgery at a high-volume center – a cohort study. Głównym celem tego badania była ocena wpływu całkowitego wstrzymania planowych operacji bariatrycznych

(„lockdown”) z powodu pandemii COVID-19 na krótkoterminowe wyniki (powikłania) i przebieg okołooperacyjny w grupie pacjentów poddanej leczeniu bariatrycznemu.

Publikacja 3

Evaluation of esophageal pathology in a group of patients 2 years after one-anastomosis gastric bypass (OAGB) – cohort study. Pierwszorzędowym celem tego badania była ocena występowania obecności zmian histopatologicznych i makroskopowych w dolnym odcinku przełyku 2 lata po OAGB. Celem drugorzędowym było zbadanie przydatności kwestionariusza oceny jakości życia GERD-Health-Related Quality of Life (GERD-HRQL)[18] jako narzędzia przesiewowego do oceny nasilenia zmian o charakterze refluksowym oraz zbadanie wpływu aktywnego zakażenia H. pylori, DM2, NT, niedoczynności tarczycy i przebytej cholecystektomii na obecność i częstość występowania zmian w dolnym odcinku przełyku.

Materiał i metody

Publikacja 1

Do tego retrospektywnego badania klinicznego włączono pacjentów, po operacji bariatrycznej wykonanej zgodnie z protokołem ERABS, poddanych wczesnemu (w ciągu 30 dni po operacji) leczeniu endoskopowemu z powodu krwawienia do przewodu pokarmowego. Protokół ERAB wprowadzono 1 stycznia 2015 roku (analizie poddano pacjentów operowanych pomiędzy 01/01/2015 a 01/01/2019). Zidentyfikowano 14 spośród 1431 operowanych pacjentów, a ich dane zostały wyodrębnione na potrzeby niniejszego badania. Oceniono typ krwawienia, lokalizację, technikę użytą do zatrzymania krwawienia, konieczność ponownej interwencji endoskopowej, stężenie hemoglobiny, ilość przetoczonych preparatów krwi i ich pochodnych oraz wyniki odległe (procent całkowitej utraty masy ciała (%TWL)). Pacjentów ponownie przyjętych do szpitala (grupa 2) z powodu krwawienia do przewodu pokarmowego porównano z pacjentami poddanymi interwencji endoskopowej podczas pierwotnego pobytu (grupa 1). Ponad to porównano wyniki leczenia pacjentów przy zastosowaniu pojedynczej techniki uzyskania hemostazy z grupą, u której użyto dwóch różnych technik hemostazy endoskopowej, oraz pacjentów wymagających powtarzanych interwencji endoskopowych (minimum 2) z grupą, która wymagała pojedynczej interwencji. Istotność statystyczną różnic przyjęto, jeśli wartości p była < 0.05.

Publikacja 2

Jest to retrospektywna analiza 158 pacjentów po operacjach bariatrycznych, którzy przeszli leczenie przed lub po pierwszym „lockdownie" z powodu pandemii COVID-19 w Polsce (12/03/2020 – 16/05.2020 (65 dni)). Pacjentów podzielono na grupę przed i grupę po „lockdownie", z których każda składała się z 79 pacjentów. Analizie poddano szczegółowe dane antropometryczne z okresu przedoperacyjnego i operacji. Ponad to analizowano wyniki pooperacyjne: długość pobytu w szpitalu, powikłania według klasyfikacji Clavien-Dindo (CDC)[19,20], odsetek ponownych przyjęć do szpitala. Dodatkowo, dla każdego pacjenta obliczono comprehensive complication index (CCI)[21] wskazujący skumulowane obciążenie powikłaniami (www.accesssurgery.com). Normalność rozkładu analizowano za pomocą testu Shapiro–Wilka. Zmienne ilościowe analizowano za pomocą testu chi-kwadrat. Zmienne jakościowe analizowano za pomocą testu Kruskala-Wallisa lub testu U Manna–Whitneya. Wartość $p<0.05$ wskazywała na istotność statystyczną różnic.

Publikacja 3

Jest to analiza pacjentów operowanych (OAGB) w okresie od 1 stycznia 2016 r. do 31 grudnia 2017 r. u których zgodnie z protokołem badania zaplanowano wykonanie kontrolnej gastroskopii (GS) z biopsją z dystalnego odcinka przełyku dwa lata po operacji. Kryteria wykluczenia z badania były następujące: operacja bariatryczna inna niż OAGB, przebyta wcześniejsza operacja bariatryczna (wykluczono pacjentów radykalizowanych bez względu na powód radykalizacji); brak uczestnictwa w pooperacyjnym nadzorze (lost to follow-up); pacjenci z niepełnym follow-up; przeciwwskazania do GS; nie stawienie się na zaplanowaną GS; odmowa wykonania GS, odmowa wykonania biopsji, GS nie wykonywane przez wyznaczonego lekarza (zgodnie z protokołem badania – dla zapewnienia porównywalnej jakości badań); GS nieukończona. Wszyscy pacjenci przed GS wypełniali zwalidowany kwestionariusz GERD-HRQL. Objawy uznano za nieobecne u pacjentów z wynikiem GERD-HRQL wynoszącym 0, łagodne od 1 do 15, umiarkowane od 16 do 30 i ciężkim nasileniu od 31 do 50. Wszyscy pacjenci z potwierdzonym przedoperacyjnie przełykiem Baretta, ciężkim zapaleniem przełyku (klasyfikacja[22] Los Angles (LA) C lub D) nie zostali zakwalifikowani do OAGB. Normalność rozkładu analizowano za pomocą testu Shapiro-Wilka. Zmienne ilościowe analizowano za pomocą testu chi-kwadrat i przedstawione w medianach lub procentach.

Zmienne jakościowe analizowano za pomocą testu Kruskala-Wallisa i testu U Manna–Whitneya i przedstawiono jako średnie z odchyleniami standardowymi. Wartość $p<0.05$ wskazywała na istotność statystyczną różnic.

Wyniki

Publikacja 1

Na podstawie analizowanych danych odsetek krwawień do przewodu pokarmowego u pacjentów operowanych w protokole ERABS w naszym ośrodku wynosił 0.97% (n = 14). Odsetek wczesnych (do 30 dni) ponownych przyjęć z powodu krwawienia do przewodu pokarmowego wynosił 0.4% (n = 5), a ogólny odsetek wczesnych rehospitalizacji wynosił 0.91% (n = 13) w okresie objętym badaniem od czasu wdrożenia protokołu ERABS. Odstęp czasu między operacją a interwencją endoskopową był istotnie krótszy w grupie 1 (średnio 25.78 [godzin]; SD= 12.51) w porównaniu z grupą 2 (średnio 43.20 [godzin]; SD= 6.57) (p = 0.014). Stężenie hemoglobiny w surowicy przed endoskopią (11.64 [g/dl]; SD= 2.92 vs 11.02 [g/dl]; SD= 1.05) i długość pobytu w szpitalu (4.78 [dni]; SD 1.92 vs 5.60 [dni]; SD= 1.14) były podobne w obu grupach (odpowiednio p = 0.658 i 0.403). W obserwacji odległej pooperacyjna utrata masy ciała (%TWL) pacjentów z grupy 2 była podobna do tej w grupie 1 (33.07; SD=7.1 vs 27.41; SD= 12.64; p = 0.298).

Publikacja 2

Grupa po „lockdownie" miała znacznie niższą operacyjną masę ciała (105.76 vs 114.25 [kg]; p = 0,012) i BMI (36.99 vs 39.93 [kg/m2]; p = 0.005) w porównaniu z grupą przed. Pierwotna długość hospitalizacji była istotnie dłuższa w grupie po „lockdownie" (3.04 vs 2.44 [dnia]; p = 0.001). Grupa po „lockdownie" miała znacząco niższy średni wynik CCI (1.90 vs 6.67, p = 0.046) i mniej wczesnych ponownych przyjęć (do 14 dni) po wypisie (0 vs 8.86, p = 0,007) niż grupa przed.

Publikacja 3

Od 1 stycznia 2016 r. do 31 grudnia 2017 r. w centrum bariatrycznym wykonano łącznie 760 operacji, wśród których OAGB stanowiło 211. 161 pacjentów wykluczono z badania, zgodnie z kryteriami wyłączenia (65 pacjentów przeszło wcześniejszą operację bariatryczną; 51 pacjentów nie zgłosiło się na zaplanowaną GS; 45 pacjentów uznano za „lost

to follow-up" lub nadzór pooperacyjnych był niekompletny). Pozostałych pięćdziesięciu pacjentów (43 kobiet i 7 mężczyzn), w średnim wieku 47.94 (28–72 [lata]; SD = 8.19), ze średnią przedoperacyjną masą ciała 121.25 (96-180 [kg]; SD = 17.84), ze średnim przedoperacyjnym BMI 43.7 (32.7–61.3 [kg/m2]; SD = 5.5), średnim operacyjnym BMI 37.42 (27.28–46.86 [kg/m2]; SD = 4.38) i średnią operacyjną masą ciała 103.91 kg (77-137 kg; SD = 13.96) zostało włączonych do badania. Dwadzieścia cztery osoby (48%) miały zapalenie przełyku stopnia A lub B wg klasyfikacji LA (20 pacjentów stopnia A). Czterech pacjentów (8%) miało endoskopowe podejrzenie metaplazji przełyku (ESEM). 34/50 (68%) pacjentów miało różne zmiany histopatologiczne przełyku na podstawie przeprowadzonej GS, stwierdzono 4 przypadki przełyku Barretta. Wszystkie przypadki przełyku Barreta zostały ocenione w protokole patomorfologicznym jako zmiany niedysplastyczne. Kwestionariusz GERD-HRQL został wypełniony przez wszystkich uczestników raz przed GS. Średni wynik wyniósł 9 punktów (0–44; SD = 9.7). Przebyta wcześniejsza cholecystektomia (9 pacjentów) miała wpływ na występowanie zmian w przełyku pod postacią przewlekłego aktywnego/nieaktywnego zapalenia (p= 0.05), pacjenci obciążeni cukrzycą typu 2 mieli częściej zmiany o charakterze nadżerek (erosions) i zmian reaktywnych w dystalnym przełyku w porównaniu z grupą nie chorującą na cukrzycę typu 2 (odpowiednio p= 0.015 i p= 0.022). Aktywna infekcja H.pylori nie miała wpływu na obecność zmian mikroskopowych w przełyku (p= 0.923) i zmian zapalnych (p= 0.164).

Wnioski

Prezentowane prace pozwoliły na przekrojową analizę przydatność badań dodatkowych ze szczególnym uwzględnieniem endoskopii w diagnozowaniu i leczeniu powikłań po operacjach bariatrycznych.

Pierwsza publikacja dostarcza dowodów na to, że pacjenci operowani zgodnie z zaleceniami ujętymi w protokole ERABS, którzy są wypisywani do domu w 1. dobie po operacji i doświadczają powikłania pod postacią krwawienia do przewodu pokarmowego poza szpitalem, mogą być leczeni za pomocą interwencji endoskopowych równie skutecznie i bezpiecznie, jak pacjenci, u których to powikłanie wystąpiło podczas pierwotnego pobytu w szpitalu. Ponadto nasze badanie pokazuje, że takie postępowanie nie wpływa na długoterminowe wyniki leczenia (%TWL).

Druga publikacja przedstawia dość nieoczekiwane odkrycie, że istotnemu zmniejszeniu uległa ilość ponownych przyjęć (rehospitalizacji) do szpitala jak i obniżeniu uległ wskaźnik

CCI w grupie pacjentów operowanych po „lockdownie" spowodowanym pandemią COVID-19. Wydawać by się mogło, ze blisko dwumiesięczna „przerwa" może mieć wpływ na wyniki operacji" Należy jednak nadmienić, że jak pokazano w naszym badaniu, pacjenci operowani po „lockdownie" charakteryzowali się niższą średnią operacyjną masą ciała i średnim operacyjnym BMI, z zaznaczeniem, że wyjściowe parametry BMI i masy ciała były podobne w obu grupach, co teoretycznie mogło przyczynić się do obniżenia ryzyka wystąpienia powikłań.

Ostatnia publikacja dostarczyła wysokiej jakości dowodów na to, że pacjenci już dwa lata po OAGB są narażeni na ryzyko rozwoju przełyku Barretta. Co więcej raportowane przez pacjentów niskie wyniki w kwestionariuszu oceny dolegliwości (GERD-HRQL) w porównaniu do bardzo dużej ilości wykrytych zmian zapalnych w przełyku, potwierdzają tezę o występowaniu zjawiska bezobjawowego refluksu żółciowego po operacjach typu OAGB. Szczególnym nadzorem endoskopowy należy również objąć pacjentów po cholecystektomii i z współistniejąca cukrzycą typu 2 (stanowiącą jedno z głównych wskazań do OAGB), gdyż chorzy ci są narażeni na rozwój zmian zapalnych w dystalnym odcinku przełyku.

Podsumowując, właściwe wykrywanie i leczenie powikłań chirurgii bariatrycznej zależy od właściwego doboru badań dodatkowych, endoskopia ma pierwszoplanową rolę w diagnozowaniu i leczeniu powikłań.

Cykl prac wchodzących w skład rozprawy doktorskiej i dane bibliometryczne

Cykl składa się z trzech prac oryginalnych opublikowanych w międzynarodowych czasopismach naukowych umieszczonych na Liście Filadelfijskiej. Łączny Impact Factor (IF) cyklu to 5.771. Łączna punktacja MNiSW to 210 punktów.

a) Szymański Michał, Marek Iwona, Hellmann Andrzej, Patel Agastya, Bigda Justyna, Kaska Łukasz, Proczko-Stepaniak Monika

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   Videosurgery and Other Miniinvasive Techniques 2021: 16 (1): 139-144

   https://doi.org/10.5114/wiitm.2020.99146

   Czasopismo umieszczone na Liście Filadelfijskiej, wskaźnik IF: 1.195
   Punktacja MNiSW: 70 punktów

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   „Influence of polish national COVID-19 lockdown on the patient characteristics and outcomes of bariatric surgery at a high-volume center – a cohort study"

   Obesity Research & Clinical Practice 2021 (15) 406-408

   https://doi.org/10.1016/j.orcp.2021.06.012

   Czasopismo umieszczone na Liście Filadelfijskiej, wskaźnik IF: 2.288
   Punktacja MNiSW: 70 punktów

c) Szymański Michał, Marek Iwona, Wilczyński Maciej, Janczy Agata, Bigda Justyna, Kaska Łukasz, Proczko-Stepaniak Monika

   „Evaluation of esophageal pathology in a group of patients 2 years after one-anastomosis gastric bypass (OAGB) – cohort study"

   Obesity Research & Clinical Practice

   https://doi.org/10.1016/j.orcp.2021.12.001

   Czasopismo umieszczone na Liście Filadelfijskiej, wskaźnik IF: 2.288
   Punktacja MNiSW: 70 punktów

Endoscopic management of early GI tract bleeding in a group of bariatric patients undergoing a fast track protocol

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Videosurgery Miniinv 2021; 16 (1): 139–144
DOI: https://doi.org/10.5114/wiitm.2020.99146

Abstract

Introduction: *Enhanced recovery after bariatric surgery (ERABS) and other fast track protocols are currently being implemented in bariatric surgery. This approach has several benefits. However, early complications may occur and require urgent re-hospitalization and management. Gastrointestinal (GI) bleeding following bariatric surgery remains one of the most serious complications requiring endoscopic treatment.*
Aim: *To evaluate the potential influence of early endoscopic intervention on bariatric patients' management.*
Material and methods: *A clinical database was searched for patients undergoing endoscopic treatment because of GI tract bleeding following bariatric surgery under the ERABS protocol. 14 out of 1431 patients operated on were identified and their data were extracted for the purposes of this study. Patients readmitted to the hospital due to developing GI tract bleeding (group 2) were compared with patients undergoing endoscopic intervention during the initial stay (group 1), for the same purpose.*
Results: *We found no statistically significant differences in hemoglobin level or length of hospital stay before endoscopy between groups. Based on the analyzed data, the percentage of GI bleeding in patients operated on under the ERABS protocol in our center is 0.97% (n = 14). The rate of early (up to 30 days) readmissions due to GI tract bleeding is 0.4% (n = 5) with an overall early readmission rate of 0.91% (n = 13) in the study period since the ERABS protocol was implemented.*
Conclusions: *Long-term effects (% total weight loss, %TWL) of bariatric surgery do not depend on the need of early endoscopic intervention and rehospitalization. Endoscopic intervention is a safe treatment modality, not associated with risk of reoperation or complications.*

Key words: *obesity, endoscopy, enhanced recovery after bariatric surgery, enhanced recovery after surgery, gastrointestinal tract bleeding.*

Introduction

The enhanced recovery after bariatric surgery (ERABS) protocol is a feasible concept, which is safely implemented globally in several bariatric centers with acceptable morbidity and mortality outcomes [1–4]. Moreover, such fast track protocols are also claimed to be cost effective. These programs of perioperative care allow patients to be discharged from the hospital as soon as functional recovery is achieved, thereby reducing the length of hospital stay. However, this in turn results in some complications occurring outside the hospital which remain unnoticed or require urgent re-hospitalization and management [5].

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Early postoperative gastro-intestinal (GI) tract hemorrhage is defined as bleeding occurring from the GI tract within 2 weeks after surgery [6]. Endoscopy plays an important role in early management and diagnosis of such postoperative complications following bariatric surgery [7]. It is most commonly indicated when symptoms such as hematemesis, melena and/or a drop in hemoglobin level occur, indicating potential GI tract bleeding [8]. Endoscopic management of acute bleeding in the early postoperative period is often challenging due to the altered post-operative anatomy and the risk of disrupting the stapler line [9].

To the best of our knowledge, evidence regarding the occurrence of early GI tract bleeding, its endoscopic management and long-term influence on weight loss in patients managed under ERABS or other fast track protocols is lacking. We present a single center experience in the field of early endoscopic interventions following bariatric surgery performed in accordance with the ERABS protocol.

Aim

To evaluate the potential influence of early endoscopic intervention on bariatric patients' management pathway. The primary objective was to compare results between patients who underwent endoscopic intervention during the initial hospital stay and those who were readmitted following complications of early GI tract bleeding.

Material and methods

A prospectively maintained clinical database of patients operated on at the hospital was searched for patients who underwent bariatric surgery under the ERABS protocol. Data of patients operated on between 1.01.2015 and 1.01.2019 were collected.

Data collection

The following data were extracted: demographic information (age, sex), type of bariatric surgery, length of primary hospital stay (LOS), location and type of bleeding (Forrest classification [10]), type of technique used to achieve hemostasis, total number of endoscopic interventions per patient, number of reoperations, number of early readmissions (within 30 days), basic laboratory parameters, intensive care unit (ICU) stay, late readmission rate (within 6 months) and long-term effect of bariatric intervention (%TWL).

Study design

Patients were divided into two groups: group 1 (occurrence of GI tract bleeding during initial hospital stay) and group 2 (readmission due to GI tract bleeding). Statistical analysis was performed to compare the groups.

ERABS intervention

In accordance with the enhanced recovery after surgery (ERAS) protocol, the pathway utilized in the management of patients undergoing bariatric surgery included preoperative preparation, and standardized intraoperative and postoperative care. The preoperative preparation included patient counselling, liver-shrinking diet for 2 weeks and smoking cessation for at least 2 weeks before the surgery. The patients were orally administered pantoprazole (40 mg), paracetamol (1000 mg), metoclopramide (10 mg) and gabapentin (300 mg) on the day of the surgery. All patients were also preoperatively screened by a multidisciplinary team (consisting of a surgeon, anesthesiologist and nutritionist). During the surgery, an optimized anesthetic protocol with restrictive fluid therapy and low dose opioid anesthesia was utilized. The surgical team included a dedicated bariatric team of a scrub nurse, anesthesiologist and a surgeon. The postoperative care involved early full mobilization of the patient within 4 h after the surgery and multimodal, non-opioid analgesia. The patients were discharged on postoperative day one if specific criteria were fulfilled: good tolerance of liquid diet, adequate pain control on oral analgesia, adequate mobilization and stable hemoglobin level (Hb). Additionally, the patients were prescribed pantoprazole (40 mg) for 3 months after laparoscopic sleeve gastrectomy (LSG), and for 6 months after one anastomosis gastric bypass (OAGB) and Roux-en-Y gastric bypass (RYGB).

Endoscopic technique

All endoscopic procedures were performed by an endoscopist and nurse with experience in the field of upper GI tract interventions. The procedures were performed using Pentax EG-3490K or EG29-i10 endoscopes in a dedicated endoscopic suite.

Statistical analysis

Assumptions of normality and equality of variances of the collected variables were assessed using the Shapiro-Wilk test and Leven's tests, respectively. Student's *t*-test and Pearson's correlation coefficient were used to evaluate the differences and relationships between the variables. For analysis of categorical variables, Fisher's exact test was used. Statistical significance was assumed if *p*-values were < 0.05. Statistical analysis was performed using Statistica 12.5 (StatSoft).

Results

Between 1st January 2015 and 1st January 2019, 1431 patients underwent bariatric surgery in accordance with the ERABS protocol at our center. Of these, 14 (6 males, 43%) patients requiring endoscopic interventions in the postoperative period were included for analysis in this study. The mean age of the included cohort was 44.7 years (range: 28–61). The patients underwent three types of bariatric surgery: OAGB (11 patients), LSG (2 patients) and RYGB (1 patient). The indications for gastroscopy were as follows: hematemesis (*n* = 12, 86%), decrease in serum Hb level (*n* = 13, 93%) and hypovolemic shock (*n* = 2, 14%). The time interval between surgical procedure and bleeding complications ranged from 4 to 40 h (mean = 28 h). The endoscopic intervention was performed after a mean time of 32 h after the surgery (range: 8–48 h). Details are presented in Table I. The majority of the patients (*n* = 10, 71%) were found to have active, oozing bleeding (Forrest classification 1b) upon endoscopic intervention. The most common site of bleeding was the gastro-jejunal anastomosis in 12 (86%) patients. Of the 2 patients who underwent LSG, 1 was observed to have multifocal bleeding (esophagus and stapler line) and the other to have isolated stapler line bleeding.

In all cases, an injection of epinephrine solution with osmotically active medium (glucose, Voluven) was initially used to achieve hemostasis. If necessary, extra hemostatic clips were used (Olympus, Cook). The technique used to achieve hemostasis (use of one method (epinephrine injection OR hemostatic clips) or a combined method (epinephrine

Table I. Patients' baseline characteristics

Type of surgery	Number of patients	Age	Hematemesis	Time to bleeding	Time to endoscopy	Forrest scale	LOS	Total number of interventions
LSG	2	59 (71–61)	100%	4–36 h	8–48 h	1b–2b	4–9	2–3
OAGB	11	42.5 (28–52)	82% (*n* = 9)	10–41 h	12–48 h	1b = 63%	3–7	1–2
RYGB	1	41	100%	40 h	48 h	2a	7	1

Table II. Comparison of technique of endoscopic hemostasis used

Parameter	One method (*n* = 8)			Combined method (*n* = 6)			*P*-value
	Mean	Range	SD	Mean	Range	SD	
Age [years]	40.63	28–57	8.67	48.67	43–61	6.92	0.087
Follow-up [months]	17.63	3–31	10.00	13.67	8–24	6.71	0.420
Time before endoscopy [h]	27.50	8.00–48.00	15.18	38.00	24.00–48.00	9.03	0.160
Hb level preOP [g/dl]	13.44	10.40–16.70	2.13	14.43	12.60–15.30	0.94	0.309
Hb level preGastro [g/dl]	11.59	8.20–15.50	2.70	11.20	7.00–12.70	2.12	0.777
BMI pre OP [kg/m^2]	37.25	31.00–41.00	3.41	38.00	34.00–43.00	3.35	0.689
BMI during follow-up [kg/m^2]	28.36	22.80–36.80	4.52	30.83	29.50–32.60	1.03	0.218
LOS [days]	4.75	3–7	1.39	5.50	4–9	2.07	0.432
%TWL [%]	32.03	8.93–43.82	11.43	29.74	21.30–38.16	6.53	0.670

injection AND hemostatic clips)) did not have any significant influence on BMI during follow-up, LOS or %TWL (Table II). The patients requiring additional endoscopic intervention were significantly older than those who achieved hemostasis with single endoscopic intervention (p = 0.015). The need for repeated endoscopic intervention did not affect %TWL (p = 0.429) (Table III).

None of the patients included in this study required surgical re-intervention or ICU admission. Two patients required blood transfusion (a total of 14 units of packed red blood cells and 3 units of frozen fresh plasma was used). There were no deaths during the study period with a mean follow-up period of 15.93 months.

Patients were divided into two groups. Group 1 (n = 9) included patients who developed hemorrhage during the initial hospital stay and were compared to the patients in group 2 (n = 5), who required readmission because of upper GI tract bleeding. The patients in group 1 had the following comorbidities: diabetes mellitus (DM) (n = 3) and hypertension (HA) (n = 5). In group 1, two additional patients were receiving rivaroxaban (Xarelto) prior to surgery due to cardiological comorbidities (atrial fibrillation and mitral valve replacement, respectively), which was switched to low molecular weight heparin during the perioperative period. In group 2, concomitant comorbidities such as DM (n = 1) and HA (n = 3) were also present. There was 1 active smoker in each group. In both groups, none of patients had obstructive sleep apnea syndrome. The time interval between surgery and endoscopic intervention was significantly shorter for group 1 in comparison to group 2 (p = 0.014). Serum Hb levels before endoscopy and the length of hospital stay were similar between the groups (p = 0.658 and 0.403, respectively). At long-term follow-up, the post-operative weight loss (%TWL) of patients in group 2 was similar to that in group 1 (p = 0.298) (Table IV).

Discussion

To the best of our knowledge, this is the first article addressing the issue of early re-admission due to GI tract bleeding following bariatric surgery among patients treated in accordance with the ERABS protocol. In the community of bariatric surgery, the causes and frequencies of re-admission following discharge are a topic of ongoing discussion [11]. Potential risk factors for prolonged hospital stay as well as early re-admissions, such as intraoperative adverse events and low oral fluid intake on the day of surgery, have been identified [12]. Furthermore, the incidence of GI tract bleeding after LSG and RYGB has been well documented. Early upper GI hemorrhage has been mostly reported after laparoscopic RYGB (1–4%) with bleeding lesions being often identified at the gastrojejunostomy staple lines and rarely at the jejunojejunostomy, in the gastric pouch, or bypassed stomach [13]. The majority of patients included in this study who underwent laparoscopic OAGB developed bleeding from the gastrojejunostomy site (n = 11, 100%). Some studies have reported concerns over implementation of pre-operative ERABS recommendations [14]. However, in our center, the recommendations are optimally executed, and we did not find any specific comorbidities or preexisting conditions that may affect readmission rate.

Based on the analyzed data, the percentage of GI bleeding in patients operated on under the ERABS protocol in our center was 0.98% (n = 14). Between implementing the ERABS protocol in January 2015 to January 2019, the rate of readmissions due to GI

Table III. Impact of repeated endoscopic interventions on the results of treatment

Parameter	Re-scope						*P*-value
	No (n = 9)			Yes (n = 5)			
	Mean	Range	SD	Mean	Range	SD	
Age	40.11	28–48	6.39	51.20	43–61	8.14	0.015
BMI pre OP [kg/m^2]	37.89	31.00–43.00	3.92	37.00	34.00–39.00	1.87	0.243
BMI during follow-up [kg/m^2]	29.88	22.80–36.80	3.97	28.60	25.00–31.00	3.07	0.646
LOS [days]	4.67	3.00–7.00	1.32	5.80	4.00–9.00	2.17	0.547
%TWL [%]	29.50	8.93–43.67	10.17	33.84	24.26–43.82	8.01	0.429

Table IV. Comparison of studied groups

Parameter	Group 1 (n = 9)			Group 2 (n = 5)			P-value
	Mean	Range	SD	Mean	Range	SD	
Age [years]	44.89	28.00–61.00	10.71	42.60	38.00–48.00	3.65	0.656
Follow-up [months]	17.89	8.00–28.00	7.13	12.40	3.00–31.00	10.90	0.273
Time before endoscopy [h]	25.78	8.00–48.00	12.51	43.20	36.00–48.00	6.57	0.014
Hb level preOP [g/dl]	14.32	10.40–16.70	1.92	13.04	11.50–14.50	1.10	0.198
HB level pre Gastro [g/dl]	11.64	7.00–15.50	2.92	11.02	9.20–11.90	1.05	0.658
BMI pre OP [kg/m^2]	38.56	34.00–43.00	2.79	35.80	31.00–41.00	3.63	0.137
BMI during follow-up [kg/m^2]	30.02	25.00–36.80	3.57	28.34	22.80–32.00	3.82	0.425
LOS [days]	4.78	3.00–9.00	1.92	5.60	4.00–7.00	1.14	0.403
TWL [%]	33.07	21.30–43.82	7.10	27.41	8.93–43.67	12.64	0.298

tract bleeding was 0.4% (n = 5) with an overall readmission rate of 0.91% (n = 13). Several studies have reported readmission rates ranging from 1.87% to 14.46% when implementing the ERABS protocol [15–22]. There is still a lack of reliable data on long-term treatment outcomes in patients with GI tract bleeding. Our study demonstrates that endoscopic treatment is a safe method for managing GI tract bleeding occurring in the post-bariatric surgery period. It provides proof that patients who are discharged on the 1st postoperative day under the ERABS protocol and develop complications outside of the hospital can be managed with endoscopic interventions as effectively as those developing early complications during the initial hospital stay. Additionally, our study also shows that such management does not affect the long-term outcomes of bariatric surgery in terms of %TWL.

However, this study has several limitations. The number of patients included in both groups is small. Our data also lack homogeneity as the patients included in the study underwent three different types of bariatric procedures (LSG, OAGB and RYGB). Furthermore, the mean follow-up period was relatively short (15.93 months, range: 8–31 months). Despite these limitations, our study does provide an essential input to the current discussion on patient safety under fast track protocols such as ERABS.

Conclusions

Endoscopic management of postoperative bleeding complications in patients undergoing bariatric surgery in accordance with the ERABS protocol is feasible and safe. Furthermore, the time of occurrence of bleeding complications as well as the method of hemostatic management does not seem to influence long-term outcomes of bariatric surgery.

Conflict of interest

The authors declare no conflict of interest.

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Received: 20.03.2020, **accepted:** 15.05.2020.

Obesity Research & Clinical Practice 15 (2021) 406–408

Contents lists available at ScienceDirect

Obesity Research & Clinical Practice

journal homepage: www.elsevier.com/locate/orcp

Influence of polish national COVID-19 lockdown on the patient characteristics and outcomes of bariatric surgery at a high-volume center—A cohort study

ARTICLE INFO

Keywords
Bariatric
Surgery, COVID-19
Lockdown
Outcomes

ABSTRACT

Introduction: As a result of the COVID-19 pandemic, the health care systems around the world have been overburdened resulting in significant reduction of planned surgical procedures such as bariatric surgeries. The primary aim of this study is to assess the influence of the COVID-19 national lockdown in Poland on the short-term outcomes and intraoperative course of bariatric patients in a high volume IFSO certified bariatric center.

Material & methods: This is a retrospective analysis of 158 bariatric surgery patients, who underwent bariatric procedures either prior to or after the first national lockdown in Poland. The patients were categorized as pre-lockdown group and the post-lockdown group, each comprising of 79 patients.

Results: The post-lockdown group had significantly lower operative weight (105.76 vs 114.25, p = 0.012) and BMI (36.99 vs 39.93, p = 0.005) compared to pre-lockdown group. The primary length of stay was significantly longer in the post-lockdown group (3.04 vs 2.44, p = 0.001). The post-lockdown group had significantly lower mean CCI score (1.90 vs 6.67, p = 0.046) and less short-term readmissions post-discharge (0 vs 8.86, p = 0.007) than pre-lockdown group.

Conclusion: The post-lockdown group was found to have lower body weight and BMI on the day of the operation than those operated prior to the lockdown. These findings are conflicting to previous research assessing weight changes during lockdowns. Since the qualification criteria and order of operations were similar and pre-defined for both groups, possible explanations for these findings are higher patient motivation due to COVID-19 fears and longer preparation period due to elective surgery postponement. We encourage bariatric centers globally to assess the effect of national lockdowns on the patient profiles as well as the psychological and behavioral impact on the bariatric cohort.

Introduction

In 2020, the SARS-COV2 virus spread around the world causing a global pandemic.

To curb the spread of the virus, many countries have instituted nation-wide lockdowns, which has negatively impacted patients being prepared for bariatric surgery [1–3]. Our clinic, a high volume IFSO (International Federation for the Surgery of Obesity and Metabolic Disorders) certified bariatric center, performs around 400 bariatric surgeries annually. During the 1st Polish lockdown (12/03/2020 to 16/05/2020 (65 days)), all the elective non-oncological surgeries were entirely postponed. The primary aim of this study is to assess the influence of COVID-19 related national lockdown on the short-term outcomes and intraoperative course of bariatric patients.

Material & methods

This is a cohort study including 158 patients, who underwent bariatric surgery at the Department of General, Endocrine and Transplant Surgery, Medical University of Gdansk, Poland. All patients were qualified in accordance to IFSO and Bariatric Chapter of the Association of Polish Surgeons guidelines [4,5]. These patients were divided into two groups – pre-lockdown group (79 patients operated from 1st January 2020 until 12th March 2020) and post-lockdown group (additional 79 patients operated between 16th May 2020 until the same number of patients as pre-lockdown group were recruited). The patient charts were retrospectively reviewed to collect data. The postoperative outcomes include length of hospital stay (LOS), Clavien–Dindo Classification (CDC) [6,7], rehospitalization rate were collected. Additionally, the comprehensive complication index (CCI) indicates patient-specific cumulative complication burden was calculated (www.accesssurgery.com). The normality of distribution was analyzed using Shapiro–Wilk Test. The quantitative variables were analyzed using chi-square test. The qualitative variables were analyzed using the Kruskal Wallis test or Mann–Whitney U test. The statistical significance was assumed if P-value was <0.05. Statistical analysis was performed using SPSS Statistics 25.0 (IBM Inc., Armonk, NY, USA).

Results

The mean age of patients in the pre-lockdown and post-lockdown group was 42.77 and 41.18 years, respectively (p = 0.335). The majority of patients in both groups were females (76.12% vs 79.75%, p = 0.598). The post-lockdown group had significantly lower mean operative weight (105.76 vs 114.25, p = 0.012) and BMI (36.99 vs 39.93, p = 0.005). However, groups were similar with regards to maximum BMI, weight, and height. The groups were also similar in prevalence of different comorbidities (Table 1).

https://doi.org/10.1016/j.orcp.2021.06.012
Received 25 June 2021; Accepted 28 June 2021
Available online 1 July 2021

Table 1
Prevalence of comorbidities in pre-lockdown and post-lockdown group. (COPD = chronic obstructive pulmonary disease, GERD = gastroesophageal reflux disease, OSAS = obstructive sleep apnea syndrome, PCOS = polycystic ovary syndrome).

	Pre-lockdown (*N* = 79)		Post-lockdown (*N* = 79)		*p-value*
	N	%	*N*	%	
Hypertension	38	48.10%	26	32.91%	0.152
COPD/Asthma	7	8.86%	11	13.92%	0.317
Diabetes melitus II	15	18.99%	17	21.52%	0.692
Cardiological disorders	4	5.06%	5	6.33%	0.731
GERD	16	20.25%	11	13.92%	0.291
OSAS	10	12.66%	7	8.86%	0.441
Active/<6 months nicotine addiction	22	27.85%	15	18.99%	0.189
Insulin resistance	12	15.19%	11	13.92%	0.822
Dyslipidemia	8	10.13%	8	10.13%	1.000
Chronic kidney failure	2	2.53%	0	0.00%	0.155
Depression	3	3.80%	6	7.59%	0.303
Hypothyroidism	16	20.25%	22	27.85%	0.264
Joint & bones	12	15.19%	9	11.39%	0.482
PCOS	1	1.27%	3	3.80%	0.311
Anticoagulants prior to surgery	5	6.33%	2	2.53%	0.246

The characteristic of surgeons, types of operations and complications is presented in Table 2. The LOS was found to be significantly longer in the post-lockdown group (3.04 vs 2.44, p = 0.001). The mean CCI score was significantly lower in the post-lockdown (1.90 vs 6.67, p = 0.046). However, there was no difference in CDC. Patients in pre-lockdown group required more readmissions within 14 days of discharge (0% vs 8.86, p = 0.007). Fourteen patients in the pre-lockdown group experienced postoperative complications vs eight in post-lockdown group.

Discussion

Contrary to contemporary literature [8], our analysis shows that the post-lockdown cohort have lower body weight and BMI on the day of the operation than those operated prior to the lockdown. However, the burden of comorbid conditions remained similar, regardless of the period. A possible explanation is the change in attitude of patients towards their own safety and health concerns. However, recent survey studies have associated national lockdowns periods with poorer weight control, reduced physical activity, and increased binge eating [9,10]. Since the qualification criteria for bariatric surgery at our institution did not change it is difficult to ascertain the cause of reduced operative BMI and weight. Furthermore, there were no patients lost-to-follow up during the lockdown period, with all patients undergoing surgery as scheduled listed in our pre-determined institutional operation list, apart from patients who were diagnosed with COVID-19 or refused operation due to fear of SARS-COV-2. Our study presents an unexpected finding of improved treatment outcomes in the post-lockdown patients, with significantly fewer early readmissions, and lower CCI scores. As shown, in our study, the post-lockdown population group had a lower mean operative body weight and BMI, thus, contributing to the lowering of complication risk [11]. Regardless of better outcomes, the post-lockdown required longer hospital stays probably due the safety and epidemiological protocols instituted during the ongoing pandemic.

The findings of our study are limited in terms of their generalizability. Additionally, our findings may be construed as a result of "cherry-picking" easier and slimer patients during the initial resumption post-lockdown, however, in order to accurately determine the impact of the lockdown on bariatric patients a pre-requisite for our study was to determine patient order according to our institutional operative list. Furthermore, it is possible that some complications in the pre-lockdown group were related to COVID-19. During the period prior to the first lockdown, there was limited awareness and understanding regarding the severity of the novel coronavirus.

In conclusion, our retrospective analysis found the post-lockdown patients to have significantly lower operative BMI and weight as well as better postoperative outcomes compared to the pre-operative group. The findings of our study are contradictory to reports regarding weight changes during the lockdown period.

Ethical statement

All procedures performed in studies involving human participants

Table 2
Details regarding operative management and complications. (LSG = laparoscopic sleeve gastrectomy, OAGB = one anastomosis gastric bypass, RYGB = Roux-en-Y gastric bypass, IFSO = International Federation for the Surgery of Obesity and Metabolic Disorders, GS = general surgery, CCI = comprehensive complication index).

		Pre-lockdown (*N* = 79)		Post-lockdown (*N* = 79)		*p*-value
		N	%	*N*	%	
Type of surgery	LSG	45	70.31%	60	75.95%	0.220
	OAGB	16	25.00%	11	13.92%	
	RYGB	1	1.56%	5	6.33%	
	Band removal	2	3.13%	3	3.80%	
Operator	IFSO certificated	46	58.23%	50	63.29%	0.076
	GS specialist	30	37.97%	20	25.32%	
	Resident	3	3.80%	9	11.39%	
Operation time	[Minutes]	61.14	±20.88	56.76	±18.54	0.159
Readmission <14 days	No	72	91.14%	79	100.00%	*0.007*
	Yes	7	8.86%	0	0.00%	
Readmission 15–30 days	No	77	97.47%	79	100.00%	0.155
	Yes	2	2.53%	0	0.00%	
Complications >30 days	No	72	91.14%	77	97.47%	0.086
	Yes	7	8.86%	2	2.53%	
Clavien Dindo classification <30 days	No	65	82.28%	73	92.41%	0.094
	I	1	1.27%	2	2.53%	
	II	5	6.33%	2	2.53%	
	IIIa	6	7.59%	0	0.00%	
	IIIb	1	1.27%	2	2.53%	
	IV	1	1.27%	0	0.00%	
	V	0	0.00%	0	0.00%	
CCI		6.67	±17.06	1.90	±8.07	*0.046*

were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Due to the retrospective nature of the study, it did not require Bioethics Committee approval.

Conflict of interests

Drs. Michał Szymański, Maciej Wilczyński, Monika Łącka, Agastya Patel, Justyna Bigda, Łukasz Kaska, Monika Proczko-Stepaniak have no interests do declare.

CRediT authorship contribution statement

Michał Szymański: Conceptualization, Formal analysis, Investigation. **Maciej Wilczyński:** Conceptualization, Methodology, Writing - original draft. **Monika Łącka:** Data curation, Writing - original draft. **Agastya Patel:** Writing - original draft, Writing - review & editing. **Justyna Bigda:** Writing - original draft. **Łukasz Kaska:** Writing - original draft. **Monika Proczko-Stepaniak:** Project administration, Supervision, Writing - review & editing.

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Original Article

Evaluation of esophageal pathology in a group of patients 2 years after one-anastomosis gastric bypass (OAGB) — Cohort study

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ARTICLE INFO

Keywords:
Bariatric surgery
OAGB
Barrett's esophagus
Endoscopy

ABSTRACT

Background: One-anastomosis gastric bypass (OAGB) is a well established surgical procedure for morbid obesity. There are ongoing speculations and a debate regarding biliary reflux (BR) following OAGB. Studies considered OAGB as a risk for symptomatic and asymptomatic BR and marginal ulceration. The aim of the study was to evaluate the rate of gastroesophageal reflux disease (GERD) and esophagitis in microscopic and macroscopic evaluations among post OAGB patients diagnosed by means of upper endoscopy (UE) with a mucosal biopsy, and to assess the influence of comorbidities and medical history on endoscopic findings.
Methods: Patients operated between 1st January 2016 to 31st December 2017 were schedule, two years after OAGB for UE with a biopsy. In all cases, biopsies from the distal esophagus were obtained. All patients received a validated GERD-Health-Related Quality of Life questionnaire to assess their current symptoms.
Results: Fifty patients were finally enrolled in the study. Twenty-four (48%) had grade A or B esophagitis. Four patients (8%) had endoscopically suspected esophageal metaplasia (ESEM). 34/50 (68%) patients had various histopathological esophageal changes, based on the conducted endoscopy, among which four cases of Barrett's esophagus were observed.
Conclusions: Despite the high rates of esophagitis in our cohort, most of the patients did not report any symptoms which confirm the thesis of the essential role of asymptomatic bile reflux following OAGB. Theoretically, chronic bile reflux can degenerate Barrett's esophagus into esophageal cancer.

Introduction

One-anastomosis gastric bypass (OAGB) was approved by the International Federation for the Surgery of Obesity (IFSO) as a standalone bariatric procedure in 2018 [1]. Since its original invention by Rutledge in 1997 [2], it has had as many propagators as critics [3–5]. Significant weight loss, a relatively short course of procedure and a low early complication rate are assets of the procedure. On the other hand, an existing risk of marginal ulcerations, a worsening of preexisting/de novo gastroesophageal reflux disease (GERD), and asymptomatic bile reflux (BR), as well as a risk of malnutrition [6–9] have been reported.

Complications such as GERD and BR have been recently addressed in the literature [10–13]. The reported rate of BR following OAGB ranges from 0,6 to 14% [14,15]. No reports of Barrett's esophagus (BE) following OAGB are currently available [16].

There is a consensus on the risk of esophageal cancer following OAGB. The majority of experts (86%) felt that OAGB did not increase the risk of gastric and esophageal cancers, and should not be considered a carcinogenic procedure [17]. A study conducted by Bruzzi et al. [18] on a rat OAGB-model shows no pre-cancerous lesions after a short 16-week follow-up.

However, there is a theoretical risk of asymptomatic BR following

Abbreviations: OAGB, one-anastomosis gastric bypass; GERD, gastroesophageal reflux disease; BR, bile reflux; BE, Barrett's esophagus; GERD-HRQL, GERD-Health-Related Quality of Life; T2DM, type 2 diabetes mellitus; HA, hypertension; FU, follow-up; UE, upper endoscopy; IFSO, International Federation for the Surgery of Obesity; LSG, laparoscopic sleeve gastrectomy; AGB, adjustable gastric banding; VGB, vertical banded gastroplasty; HS, Heartburn Score; RS, Regurgitation Score; ESEM, endoscopically suspected esophageal metaplasia.

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https://doi.org/10.1016/j.orcp.2021.12.001
Received 24 October 2021; Received in revised form 21 November 2021; Accepted 12 December 2021

Please cite this article as: Michał Szymański, *Obesity Research & Clinical Practice*, https://doi.org/10.1016/j.orcp.2021.12.001

OAGB which could lead to BE and esophageal cancer.

Obesity is one of the main risk factors of GERD, which is one of the most common recognizable gastrointestinal diseases [19]. GERD occurrence is strictly combined with obesity and one of the therapeutic options is the reduction of excessive body weight [20].

Therefore, the primary aim of the study was to evaluate the presence of esophageal GERD-related histopathological and macroscopical findings 2 years after OAGB.

The secondary aims were to investigate the usefulness of the self-reporting GERD-Health-Related Quality of Life (GERD-HRQL) questionnaire [21] as a screening tool, and investigate the influence of medical conditions (active H. pylori infection, type 2 diabetes mellitus (T2DM), hypertension (HA), hypothyroidism and previous cholecystectomy) on esophageal histopathology.

Materials and methods

Study design

This is a retrospective analysis of prospectively collected data on patients operated between 1st of January 2016 to 31st of December 2017 in a bariatric center. All procedures performed in studies involving human participants were in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments. The study design and protocol were approved by the University Ethics Committee (NKBBN/289/2018). Written informed consent was obtained from all participants.

From 1st of January 2018 to 31st of December 2019, all patients who attended a routine post-OAGB follow-up (FU) were referred for ambulatory upper endoscopy (UE) with a biopsy. All patients under the supervision of an outpatient department were operated on at a high-volume bariatric center. The qualification for OAGB was in accordance with the International Federation for the Surgery of Obesity (IFSO) guidelines and recommendations of the Bariatric Chapter of the Association of Polish Surgeons [22].

The study exclusion criteria were as follows: bariatric surgery other than OAGB, previous bariatric surgery (LSG — laparoscopic sleeve gastrectomy, AGB — adjustable gastric banding, VGB — vertical banded gastroplasty); lost to follow-up, follow-up incomplete; contraindications for UE; not present for UE; refused UE; refused a biopsy; UE not performed by the dedicated physician; UE not completed.

All patients, prior to UE, completed a validated GERD-HRQL questionnaire. Symptoms were considered as absent in patients reporting a GERD-HRQL score of 0, mild from 1 to 15, moderate from 16 to 30, and severe from 31 to 50.

All patients were qualified for OAGB by multidisciplinary team (bariatric surgeon, bariatric nurse, dietitian, psychologist, and internal medicine specialist) after considering preoperative UE, abdominal and heart ultrasound and nutritional status. All patients with confirmed BE, severe esophagitis (Los Angles classification [23] (LA) C or D) were not qualified for OAGB.

Surgical technique

A laparoscopic approach was used to reach the abdominal cavity. A long, narrow gastric pouch (16−18 cm) was designed starting from a point near crow's foot to the point laterally to the angle of His with a 34-Fr or 36-Fr bougie tube using a stapler technique. Gastrojejunostomy was then performed mean 180 cm distally to the ligament of Treitz using a V-loc suture to the reinforced back wall of the anastomosis, followed by a 30-mm linear stapler and a V-loc suture for stapler entry closure. A leak test was performed at the end of the procedure using a diluted methylene blue solution. Mostly, one drain was positioned in the vicinity of the anastomosis.

Endoscopy protocol

UE was performed in a dedicated outpatient endoscopy suite, after at least a 6 h period of fasting. Two endoscopists with experience in bariatric endoscopy conducted the study. The gastroscope tip was covered with lidocaine gel and lidocaine mouth spray was used. The examination was performed on patients lying on the left-hand side. Esophagitis was recorded according to the LA classification. Evidence of BE was evaluated according to the Prague C&M classification [24]. We separately recorded the presence or absence of bile in the esophagus. In all cases, biopsies from the distal esophagus were taken. In all cases, a mucosal sample from the gastric pouch was taken for the rapid urease test (H.p. Swift Test, Instytut Żywności i Żywienia, Poland) to screen for H. pylori; the result was obtained after 30 min. The remaining specimens were fixed in 10% buffered formalin, and transferred to the Department of Pathomorphology. After processing, the specimens were stained with hematoxylin–eosin and modified Giemsa stain. The microscopic examination was performed with full access to the patients' history and results of UE.

Statistical analysis

The normality of distribution was analyzed through the Shapiro-Wilk Test. The quantitative variables were analyzed using the chi-square test and presented in medians, interquartile ranges or percentages. The qualitative variables were analyzed using the Kruskal Wallis test and Mann–Whitney *U* test and presented as means with standard deviations. The statistical significance was assumed if the p-value was <0.05. The statistical analysis was performed using SPSS Statistics 25.0 (IBM Inc., Armonk, NY, USA).

Results

Between 1st of January 2016 and 31st of December 2017 760 patients were operated on in bariatric center, among who, 211 OAGB were performed. 161 patients met our exclusion criteria (65 had previous bariatric surgery, mostly LSG; 51 did not present for UE; 45 were lost to follow-up or had incomplete follow-up) therefore these patients were not considered in the study. The remaining fifty patients (43 female and 7 male), with a mean age of 47.94 (28–72 years; SD = 8.19), a median preoperative weight of 121.25 kg (96−180 kg; SD = 17.84), a median preoperative BMI of 43.7 (32.7–61.3 kg/m^2; SD = 5.5), a median operative BMI of 37.42 (27.28–46.86 kg/m^2; SD = 4.38) and a median operative weight of 103.91 kg (77−137 kg; SD = 13.96) were enrolled in the study. The following comorbidities were observed in the study group preoperatively (see Table 1).

UE esophageal macroscopic abnormalities and histopathological findings

Twenty patients (40%) had grade A esophagitis and four patients (8%) had grade B esophagitis, whereas no patient resulted in grade C or D. Four patients (8%) had endoscopically suspected esophageal metaplasia (ESEM). None of the patients had a biliary stagnation in a distal esophagus.

19 (38%) patients had a chronic inactive/active inflammation, 6 (12%) had erosions in a distal esophagus. We observed 4 cases of BE, which were all nondysplastic. 3 (6%) patients had reactive changes. Acanthotic changes were observed in 2 (4%) patients.

Secondary outcomes

Eighteen patients (36%) were tested positive for H. pylori infection. Active H. pylori infection had no influence on the presence of microscopic esophageal lesions ($p = 0.923$) and esophagitis ($p = 0.164$) in the study group.

Previous cholecystectomy (9 patients — 18%) significantly increased the incidence of chronic active / inactive inflammation in our cohort

Table 1
Prevalence of comorbidities. T2DM = type 2 diabtes mellitus; HA = Hypertension; OSAS = obstructive sleep apnea syndrome; GERD = gastroesophageal reflux disease; COPD = chronic obstructive pulmonary disease.

		(*n* = 50)
T2DM	*N*	19
	%	38.00%
HA	*N*	24
	%	48.00%
OSAS	*N*	4
	%	8.00%
Hypothyroidism	*N*	9
	%	18.00%
Active/<6 months nicotine addiction	*N*	2
	%	4.00%
COPD/Asthma	*N*	3
	%	6.00%
GERD	*N*	6
	%	12.00%
Cardiac disorders	*N*	3
	%	6.00%

(66.67% to 31.71%; p = 0.05).

The GERD-HRQL questionnaire was completed by all participants once during UE. The mean result was 9 points (0–44; SD = 9.7). The Heartburn Score (HS) mean result was 5 (0–25; SD = 5.5) and the Regurgitation Score (RS) mean result was 3 (0–19; SD = 4.5).

Results over 13 points in both RS and HS were statistically significantly correlated with the occurrence of reflux esophagitis (p = 0.033 and p = 0.007, respectively) in the biopsy results.

Erosions and reactive changes were more frequent in patients with preexisting T2DM (26.32% to 3.23%; p = 0.015 and 15.79% to 0%; p = 0.022, respectively). We observe a correlation between preexisting hypothyroidism and the occurrence of histopathological lesions. Erosions and chronic active/inactive inflammation were more frequent (33.33% to 7.32%; p = 0.03 and 77.78% to 29.27%; p = 0.007, respectively). There was no correlation between preexisting HA and occurrence of esophageal lesions.

In our cohort we observed 9 cases of hiatal hernia preoperatively. Mean GERD-HRQL result in this subgroup was 2 points (0–8; SD = 2.76).

Discussion

In the presented study, we evaluated post OAGB patients mainly in the context of BE and GERD-related esophageal changes.

The decrease of BMI from a mean preoperative BMI of 43.7+/-5.5 kg/m^2 to a mean follow-up BMI of 22.01 +/− 4.28 kg/m2 (p < 0.05) and %TWL of 25.79 +/− 9.11 after a mean follow-up of 28+/−4 months, confirms the effectiveness of OAGB as a hypoabsorptive surgical procedure [25–27].

24/50 (48%) patients have esophagitis (only grade A and B) among whom 3/50 (6%) were confirmed to have reflux esophagitis in the final pathological report, which is a surprisingly higher result in comparison to the published studies [13,16,28–31]. However, in some of the listed publications, only asymptomatic patients were considered. In our cohort 6 (12%) patients have preoperatively GERD. We observed no remission of GERD among those patients. The prevalence of de-novo esophagitis is 18/50 (36%).

The recent paper by Sebastianelli et al. [32] proves that sleeve gastrectomy has been associated with higher risk of BE. There is a lack of information regarding incidents of BE following OAGB; in our cohort, 8% patients were diagnosed with BE, 2 years after OAGB.

Several studies established the prevalence of BE in an unselected population between 1–5.6% (1–2% in Europe) [33–35]. The most important risk factors for BE, such as male gender and older age, are non-dominant factors in our cohort, which might be proof of OAGB as a standalone risk factor for BE, which requires further studies.

The high rate of H. pylori infection among OAGB patients is surprising, while all patients, prior to surgery, underwent eradication when necessary. Based on preoperative UE protocols 17 H. pylori tests were obtained in a study group, among which 5 (29,4%) were positive. However only stool tests were conducted to confirm eradication priori to OAGB. Further prospective studies are needed to address this issue.

The majority of our cohort did not report any symptoms, none of patients reported severe GERD symptoms (≥31 points in GERD-HRQL) and 3/50 (6%) moderate GERD symptoms (16–30 in GERD-HRQL), which in comparison to the histopathological results might confirms the thesis of the essential role of asymptomatic BR following OAGB. In our series, limited to relatively small sample, GERD related histopathological findings were poorly related to GERD-HRQL results. This makes us believe that usefulness of GERD-HRQL as a screening tool is poor, while most of patients reported a lack of symptoms. However, we need to emphasize that GERD-HRQL was obtain from the subjects only 2 years after OAGB. What is more, we cannot omit the fact that almost half of the patients (24/50 48%) in our sample continued to take PPI at least once a week, which is far beyond our postoperative recommendation (up to 1 year following OAGB).

Previous cholecystectomy increases the presence of chronic inflammation and erosion in the distal esophagus in long-term observation following OAGB. This fact was also confirmed previously in patients with not altered anatomy [36], which makes us believe that this group required careful UE FU. Patients with preexisting T2DM were more likely to develop LA—A esophagitis and erosions. OAGB is a well-established metabolic procedure proposed mainly for bariatric patients with T2DM [37], which in our opinion makes this group in need of careful endoscopic FU. We observed a correlation between preexisting hypothyroidism and the occurrence of esophageal pathology, in our opinion it is an incidental finding.

Preexisting moderate and large hiatal hernias could possibly influence occurrence of GERD symptoms postoperatively [38]. In our cohort we observed 9 subjects with small and moderate hiatal hernias. What is surprising all patients, postoperatively reported a mean result of 2 points in GERD-HRQL. Further studies addressing this issue should be conducted to obtained histopathological samples.

All in all, 34/50 (68%) patients had various histopathological esophageal changes, based on the conducted endoscopy. Chronic symptomatic and asymptomatic BR can induce the degeneration of BE to adenocarcinoma. In patients with mixed reflux (acid and biliary), treatment of the acid component of the reflux with proton-pump inhibitors improves symptoms but does not provide long-term protection from Barrett's lesions [39]. The risk of developing esophageal adenocarcinoma in BE ranged from 0.1% (without dysplasia) to 19% (with high grade dysplasia) per year [40–43]. Only two cases of gastric cancer following OAGB were observed (one in the gastric remnant and one in the gastric pouch) [44,45]; however, in one case there was a lack of preoperative endoscopy. One case of esophageal cancer was diagnosed [45] two years after OAGB; the patient was a smoker. To sum up, we can conclude that the risk of malignancy after bariatric surgery is low [46].

The fact that this is a single center study is one of the main limitations of the study. What is more, 161 patients were excluded due to our exclusion criteria, which is rather a large number. Among whom, 51 patients referred to UE did not present for examination. Rate of non-attendance was 50% (51/101). In published studies non-attendance at endoscopy rate was lower than a rate of 20% [47–49], however in one study non-attendance rate, which was associated with low socio-economical status, was higher than 40% [50]. There are no studies addressing issue of non-attendance at endoscopy among post bariatric population. Finally, there were no routine biopsies of distal esophagus obtained during preoperative UE. Which could possibly affect our results. Further studies are needed.

To conclude, OAGB provided good weight loss and comorbidity improvement; however, endoscopic FU should be obligatory in all symptomatic patients. Screening in asymptomatic patients should be planned based on preexisting comorbidities such as T2DM. Based on our data, the first cases of BE were diagnosed two years after surgery. Although the mean follow-up is 24 months, it requires further long-term studies to fully asses the impact of OAGB on the distal esophagus.

Conclusion

Patients undergoing OAGB are at risk of the development of BE, therefore careful endoscopic follow-up is crucial. Despite the benefits of the metabolic and bariatric effects of OAGB, there is an overwhelming risk of BE.

Funding

There are no financial conflicts of interest to disclose.

Conflict of interest

The authors declare that they have no conflict of interest.

CRediT authorship contribution statement

Michał Szymański: Conceptualization, Methodology, Project administration, Resources, Validation, Visualization, Writing - original draft. **Iwona Marek:** Conceptualization, Methodology, Project administration, Resources. **Maciej Wilczyński:** Writing - review & editing, Software. **Agata Janczy:** Writing - review & editing, Software. **Justyna Bigda:** Supervision. **Łukasz Kaska:** Supervision. **Monika Proczko-Stepaniak:** Conceptualization, Supervision, Writing - review & editing.

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