Zastosowanie wybranych technik małoinwazyjnych
w leczeniu patologicznej otyłości

Selected miniinvasive techniques in the treatment of
morbid obesity

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Lista skrótów

%EWL - procentowy ubytek nadmiernej masy ciała (ang. % excess weight loss)

AGB - regulowana opaska żołądkowa (ang. adjustable gastric band)

BAROS - system oceny i przedstawiania wyników leczenia chirurgicznego otyłości (ang. bariatric analysis and reporting outcomes system)

BMI - wskaźnik masy ciała (ang. body mass index)

BPD-DS - wyłączenie żółciowo-trzustkowe z przełączeniem dwunastnicy (ang. biliopancreatic diversion - duodenal switch)

BSCG - Bariatrycznie-Naukowa Grupa Badawska (Bariatric Scientific Collaborative Group)

EAES - Europejskie Towarzystwo Chirurgii Endoskopowej (European Association for Endoscopic Surgery)

LAGB - założenie regulowanej opaski żołądkowej w technice laparoskopowej (ang. laparoscopic adjustable gastric banding)

LSG - laparoskopowa rękawowa resekcja żołądka (ang. laparoscopic sleeve gastrectomy)

NAGB - założenie nierregulowanej opaski żołądkowej (ang. non-adjustable gastric band)

NIH - Narodowy Instytut Zdrowia Stanów Zjednoczonych (National Institute of Health)

NOTES - operacje przez naturalne otwory ciała (ang. natural orifice transluminal endoscopic surgery)

RYGB - ominienie żołądkowo-jelitowe (ang. Roux-en-Y gastric bypass)

SAGES - Amerykańskie Towarzystwo Chirurgów Endoskopowych i Przewodu Pokarmowego (Society of American Gastrointestinal and Endoscopic Surgeons)

SG - rękawowa resekcja żołądka (ang. sleeve gastrectomy)
SILS - operacje laparoskopowe z pojedynczego dostępu
(ang. single incision laparoscopic surgery)
WHO - Światowa Organizacja Zdrowia (ang. World Health Organization)

Abbreviations

% EWL - % excess weight loss
AGB - adjustable gastric banding
BAROS - bariatric analysis and reporting outcomes system
BMI - body mass index
BPD-DS - biliopancreatic diversion - duodenal switch
BSCG - Bariatric Scientific Collaborative Group
EAES - European Association for Endoscopic Surgery
LAGB - laparoscopic adjustable gastric banding
LSG - laparoscopic sleeve gastrectomy
NAGB - non-adjustable gastric banding
NIH - National Institute of Health
NOTES - natural orifice transluminal endoscopic surgery
RYGB - Roux-en-Y gastric bypass
SAGES - Society of American Gastrointestinal and Endoscopic Surgeons
SG - sleeve gastrectomy
SILS - single incision laparoscopic surgery
WHO - World Health Organization
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Rozdział 1.

Wprowadzenie

Stałemu rozwojowi cywilizacyjnem nieuchronnie towarzyszy coraz częstsze występowanie wcześniej nieznanych lub rzadko występujących negatywnych zjawisk zdrowotnych. Zmiana dziennej aktywności i jej form w kierunku siedzącego trybu życia i pracy połączonego z brakiem ruchu i nadmiarem łatwo dostępnego, wysoko-przetworzonego pożywienia wpływa na powstawanie chorób cywilizacyjnych, a w szczególności na rozwój otyłości [1]. Otyłość definiowana jest przez WHO jako patologiczne lub nadmierne gromadzenie tkanki tłuszczowej, które może prowadzić do niekorzystnych skutków zdrowotnych [2]. Powszechnie przyjętą i najczęściej stosowaną miarą zawartości tkanki tłuszczowej jest wskaźnik masy ciała BMI obliczany ze wzoru:

\[
\text{BMI} = \frac{\text{masa}}{(\text{wzrost})^2}
\]

Przy użyciu wskaźnika BMI masę ciała dorosłej osoby można opisać jako [3]:

- Niedowaga < 19 kg/m²
- Normalna masa 19 - 24,9 kg/m²
- Nadwaga 25 - 29,9 kg/m²
- Otyłość I stopnia 30 - 34,9 kg/m²
- Otyłość II stopnia 35 - 39,9 kg/m²
- Otyłość patologiczna > 40 kg/m²
- Otyłość patologiczna olbrzymia ≥ 50 kg/m²

Zgodnie z najnowszymi danymi liczba otyłych osób na świecie w ciągu ostatnich trzydziestu lat podwoiła się, osiągając rozmiary pandemii obejmującej około 500 milionów osób, co stanowi 11% dorosłej populacji [2].
Według danych Głównego Urzędu Statystycznego z 2009 roku, w Polsce otyłość rozpoznano u 17% mężczyzn i u 15% kobiet [4]. Ponadto, w ciągu 13 lat objętych analizą, dynamika wzrostu liczby osób otyłych wśród mężczyzn była znacznie wyższa i spowodowała niemalże podwojenie ich odsetka [4].

Według ekspertów WHO 65% ludzi mieszka w krajach, w których nadwaga i otyłość zabijają więcej ludzi niż głód [2]. Co najważniejsze, otyłość należy do chorób, którym można zapobiegać. Niestety światowe działania w tym kierunku nie są skuteczne.

Zarówno nieskuteczność w zapobieganiu otyłości, jak i odsetek osób otyłych wymuszają poszukiwanie skuteczniejszych metod leczenia otyłości. Otwierając jakąkolwiek codzienną gazetę, magazyn czy stronę internetową, można znaleźć reklamy licznych diet i kuracji odchudzających. Skuteczność proponowanych metod, ich rzeczywista wartość i bezpieczeństwo są co najmniej kontrowersyjne. Większość osób otyłych przynajmniej raz w życiu podejmowała próbę odchudzania przez zmniejszenie ilości spożywanego pokarmu. Najczęściej prób te kończyły się niepowodzeniem lub powrotem do wyjściowej masy ciała w ciągu kilkunastu miesięcy od zakończenia diety (tzw. efekt jo-jo) [5,6].

Przemysł farmaceutyczny od lat próbuje stworzyć bezpieczny lek na otyłość. Dotychczas w farmakologicznym leczeniu otyłości najczęściej stosowano leki nasilające uczucie sytości przy jednoczesnym zwiększeniu wydatku energetycznego (Sibutramina, Lorkaseryna), leki zmniejszające łaknienie (Rimonabant, Fentermina) oraz leki zmniejszające selektywnie wchłanianie tłuszczów (Tetrahydrolipostatyna). Skuteczność większości metod w porównaniu z placebo potwierdzano w badaniach z losowym doborom chorych, ale uzyskiwany średni spadek masy ciała wynosił po rocznym leczeniu około 5 kg [7,8]. Obecnie, zarówno w Europie jak i w Stanach Zjednoczonych, nie ma zarejestrowanych leków w leczeniu otyłości, głównie ze względu na ich niekorzystne ośrodkowe działanie, a tym samym liczne niepożądane efekty przy względnie niewielkiej skuteczności.
U chorych z patologiczną otyłością (BMI > 40 kg/m²) nadmiar masy ciała to zwykle kilkadziesiąt dodatkowych kilogramów, a tym samym leki powodujące zmniejszenie masy ciała o 5 kg w ciągu roku nie stanowią satysfakcjonującego i skutecznego rozwiązania. W tej sytuacji w ciągu ostatnich dekad rozwinięły się chirurgiczne metody leczenia otyłości pod nazwą chirurgii bariatrycznej, nazywane także chirurgią metaboliczną ze względu na szerszy wpływ na organizm pacjenta niż wyłącznie zmniejszenie masy ciała.

Chirurgia bariatryczna swoje początki miała w latach pięćdziesiątych ubiegłego wieku w Stanach Zjednoczonych, gdzie odsetek chorych z patologiczną otyłością jest najwyższy. Pierwsze techniki operacyjne zaproponowane przez Kremena i Lineara obarczone były wysokim odsetkiem powikłań pooperacyjnych, ze szczególnie dokuczliwymi objawami zespołu krótkiego jelita, oraz chorobami wynikającymi z zespołów niedoborowych [9,10]. Ich modyfikacje zaproponowane przez Payne’a i De Winda zyskały popularność również w Polsce i na następné 20 lat wyznaczyły standardy w chirurgicznym leczeniu otyłości [11-13]. Od roku 1966 stosowane jest również ominięcie żołądkowo-jelitowe Masona [14].

Obecnie dostępne są liczne techniki operacyjnego leczenia otyłości patologicznej, które zasadniczo dzieli się na podstawie mechanizmu działania na [10,15]:

1. Techniki restrykcyjne
   - założenie regulowanej opaski żołądkowej (AGB)
   - rekałową resekcję żołądka (SG)
   - założenie nierregulowanej opaski żołądkowej (NAGB) - rzadko stosowane
2. Techniki wyłączające
   - bypass czczo-krętniczy
3. Techniki o mieszanym mechanizmie restrykcyjno-wyłączającym
   - wyłączenie żółciowo-trzustkowe z przełączeniem dwunastnicy (BPD-DS.)
- ominięcie żołądkowo-jelitowe (RYGB) z późniejszymi modyfikacjami jak *mini-gastric bypass*

Zgodnie z zaleceniami Amerykańskiego Towarzystwa Chirurgów Endoskopowych i Przewodu Pokarmowego (Society of American Gastrointestinal and Endoscopic Surgeons - SAGES) i Europejskiego Towarzystwa Chirurgii Endoskopowej (European Association for Endoscopic Surgery - EAES) powstałyymi na podstawie zaleceń Narodowego Instytutu Zdrowia Stanów Zjednoczonych (National Institute of Health - NIH) wskazaniem do chirurgicznego leczenia otyłości jest BMI > 40 kg/m² lub BMI > 35 kg/m², któremu towarzyszy co najmniej jedna z następujących chorób: nadciśnienie tętnicze, cukrzyca, astma, choroba niedokrwienna serca, bezdech senny, choroba zwyrodnieniowa stawów, choroby tarczycy i depresja [16-18]. Potencjalni kandydaci do operacji powinni spełniać także dodatkowe kryteria, takie jak wysoka motywacja z kilkoma nieudanymi próbami odchudzania za pomocą modyfikacji stylu życia i diety, zrozumienie na czym polega leczenie i brak zaburzeń psychicznych [16,19]. Polskie zalecenia, opublikowane w 2009 roku przez komisję ekspertów Sekcji Chirurgii Bariatrycznej i Metabolicznej Towarzystwa Chirurgów Polskich oparte na wytycznych EAES z niewielkimi uzupełnieniami uwzględniającymi zalecenia światowej Bariatryczno - Naukowej Grupy Badawczej BSCG (Bariatric Scientific Collaborative Group) [19,20].

Na obecnym etapie zbierania doświadczenia i wiedzy na temat mechanizmów powstawania otyłości oraz wyników leczenia przy użyciu poszczególnych technik operacyjnych, grono ekspertów EAES opracowało wskazówki, jakimi można się kierować podczas wyboru techniki operacyjnej [18]. Równocześnie żadna z instytucji zajmujących się badaniami nad otyłością (grupa BSCG) nie określiła oficjalnie optymalnej metody chirurgicznego leczenia w zależności od BMI i współwystępujących chorób [19].
Przy wyborze techniki operacyjnej można się kierować skutecznością metody pod względem tempa i zakresu zmniejszania nadmiaru masy ciała mierzonego jako procentowy ubytek nadmiêrnej masy ciała (ang. % excess weight loss, %EWL), odwracalności metody, możliwości dodatkowych manipulacji procesem odchudzania ju¿ po operacji, wpływem metody na choroby towarzyszące, trwa³oœç efektu, czy typem i częstoœç występowania mo¿liwych powik³aœñ. Dane z piœmiennyœci wskazuj¹, ãe skutecznoœæ technik operacyjnych pod wzglêdem %EWL jest najwyœsza po operacji BPD i zmniejsza siê w kolejnoœci: BPD > RYGB > SG > AGB [18,21]. Skutecznoœæ tych czterech metod pod wzglêdem %EWL kszta³tuje siê na poziomie:

- BPD 65-75% [18]
- RYGB 60-70% [18]
- SG 60-65% [21]
- AGB 45-55% [18]

Wiêkszoœæ dostêpnych zestawieñ porównuj¹cych wyniki róœnych metod chirurgicznego leczenia oty³oœci nie uwzglêdnia metody rêkawowej resekcji œol¹dk¹. Jest to wzglêdnie nowa technika operacyjna, bo opisana przez Hessa w 1988 roku jako jeden z etapów operacji BPD-DS i stosowana jako samodzielna metoda chirurgiczna od 2004 roku [22]. Popularnoœæ zyska³a dzieki prof. M. Gagnerowi, który w 2000 roku opisa³ technikê laparoskopowej BPD-DS [23]. Od tego czasu technika ta stawa³a siê coraz bardziej popularna zarówno w Europie, jak i w Stanach Zjednoczonych.

Opaska œol¹dkowa jest jedyn¹ metod¹ o odwracalnym charakterze oraz, pod postaci¹ regulowanej opaski œol¹dkowej, jako jedyna pozwala na ma³oinwazyjne korekty stopnia restrykcji przewodu pokarmowego. Umo¿liwia to zastosowanie w konstrukcji opaski balona z wszczepianym podskórnie silikonowym portem. Pacjenci ze wszczepion¹ regulowan¹ opask¹ musz¹ jednak byœ poddawani okresowym kontrolom co 1,5-3 miesiące, celem korekcji
stopnia zaciśnięcia opaski, pozwalającej na modyfikację tempa odchudzania i utrwalenie jego efektów.

W ocenie wyników leczenia bariatrycznego stosowane są różne skale w tym skala SF-36, Sickness Impact Profile, czy Quality of Well-Being Scale [24-26]. Najbardziej kompleksowe podejście do oceny wyników chirurgicznego leczenia otyłości daje skala BAROS (ang. bariatric analysis and reporting outcomes system) [27]. Została ona stworzona pod koniec XX wieku i uaktualniona w roku 2009 [27,28]. Końcowy wynik uwzględnia zarówno procentową utratę nadmiernej masy ciała, powikłania, jak i ustąpienie lub zmniejszenie nasilenia chorób towarzyszących, jakość życia w pięciu aspektach (samoocena, aktywność fizyczna, zawodowa, towarzyska i seksualna) oraz konieczność ewentualnych reoperacji [27,28]. Podstawową i najczęściej stosowaną metodą oceny wyników chirurgicznego leczenia otyłości pozostaje jednak ocena spadku masy ciała i procentowe zmniejszenie jej nadmiaru [29]. Zakłada ona, iż dobry efekt operacji bariatrycznych oznacza zmniejszenie nadmiaru masy ciała o co najmniej 50% [29].

Patologicznej otyłości towarzyszą nierozłącznie inne choroby, takie jak nadciśnienie tętnicze, cukrzyca, astma, choroba niedokrwieniowa serca, bezdech senny, choroba zwyrodnieniowa stawów, choroby tarczycy i depresja [27]. To właśnie choroby towarzyszące, a nie sama nadmierna masa ciała stanowią zagrożenie dla otyłych osób. Otyłość wraz z chorobami współistniejącymi wpływają na długość życia, która jest odwrotnie proporcjonalna do współczynnika BMI [30,31].

Efektem operacji bariatrycznych jest zatem nie tylko zmniejszenie masy ciała, ale również zmniejszenie lub zlikwidowanie dolegliwości ze strony chorób towarzyszących [27,32-35]. Szwedzkie Badanie nad Otyłością „SOS” (Swedish Obesity Study), największe dotychczasowe badanie populacyjne dotyczące leczenia otyłości wykazało, że pod wpływem operacji bariatrycznej można uzyskać zmniejszenie ogólnej długoterminowej umieralności o 29% (współczynnik ryzyka, ang. hazard ratio, HR = 0,71) [32].
Towarzyszyło temu zmniejszenie częstości występowania cukrzycy, epizodów sercowo-naczyniowych, udarów mózgu i nowotworów [32].

Jednym z najważniejszych odkryć ostatnich lat jest korzystny wpływ operacji bariatycznych na cukrzycę. Po zabiegach bariatycznych obserwowano jej ustępowanie z ilorazem szans aż 8,42 w ciągu 2 lat i 3,45 po 10 latach [32]. Zgodnie z danymi meta-analizy Buchwalda i wsp., do całkowitego ustąpienia objawów cukrzycy dochodziło średnio u około 78% chorych w ciągu 2 lat od operacji bariatycznej [36]. Najwyższa skuteczność pod tym względem cechowała BPD (95% odsetek całkowitych remisji cukrzycy), a najniższa LAGB (57%) [36]. Na tej podstawie, od kilku lat szeroko dyskutowana jest możliwość stosowania operacji bariatycznych u chorych z cukrzycą typu II i z indeksem BMI < 35 kg/m² jako podstawowej metody leczenia cukrzycy typu II [37-44].

Wraz ze wzrostem skuteczności metody wzrasta liczba potencjalnych powikłań śródoperacyjnych, okołooperacyjnych i odległych. Klasyfikację powikłań na chirurgiczne i niechirurgiczne, duże i małe oraz wczesne i późne, w odpowiednich konfiguracjach zawiera skala BAROS [27]. Powikłania chirurgiczne wynikają bezpośrednio z samej techniki operacyjnej i ich liczba oraz nasilenie są proporcjonalne do liczby odcinkowych resekcji i zespołów przewodu pokarmowego. Najmniej powikłań towarzyszy operacjom restrykcyjnym, a najwięcej technikom o złożonym mechanizmie działania. Spośród technik restrykcyjnych rękawowa resekcja żołądka obarczona jest największym odsetkiem powikłań, co wynika z resekcji bogato ukrwionej krzywizny większej żołądka i w efekcie powstawania krwawień i nieszczelności przewodu pokarmowego. Powikłania te występują również często po operacjach BPD-DS i RYGB. Do istotnych wczesnych powikłań należą również roponie wewnątrzotrzewnowe, rozejścia i zakażenia ran, uszkodzenia lub zawały śledziony, uszkodzenia innych organów, niedrożność czy zadzierzgnięcia. Wśród późnych powikłań problemem są wzrody
trawienną, kamicę żółciową, rozejścia linii zszywek, przetoki, a w przypadku regulowanej opaski - jej erozja do światła przewodu pokarmowego, zsunięcie się lub rozpięcie i konieczność wykonania reoperacji [27].

Metody chirurgicznego leczenia patologicznej otyłości obarczone są również ryzykiem zgonu na poziomie 0,25-1,5 % we wczesnym, 30-dniowym okresie okołoperacyjnym, w zależności od typu operacji, stanu ogólnego chorego i chorób towarzyszących [10].

W ostatniej dekadzie nastąpiła zmiana podejścia w zastosowaniu technik minimalnie inwazyjnych w tym laparoskopii u chorych otyłych. Obecnie wytyczne europejskie i amerykańskie zalecają, o ile to możliwe, wykonywanie operacji bariatrycznych metodą laparoskopową, celem zmniejszenia urazu okołoperacyjnego, a otyłość została wykreślona z listy przeciwwskazań do innych operacji laparoskopowych [16,18-20]. W technice laparoskopowej, ze względu na ich względną łatwość wykonania najczęściej wykonywane są operacje restrykcyjne [33,45-47]. Sposobem minimalnie inwazyjnym wykonywane są jednak również operacje o mechanizmie mieszanym [48,49]. Powstanie narzędzi do operacji laparoskopowych z pojedynczego dostępu tzw. SILS (ang. single incision laparoscopic surgery) pozwoliło uzyskać dalszą minimalizację urazu okołoperacyjnego w chirurgii bariatrycznej. Znalazło to odbicie w licznych badaniach oceniających możliwość wykonywania takich operacji oraz ich efektów [50-63]. Oddzielną drogą rozwoju chirurgii minimalnie inwazyjnej są operacje przez naturalne otwory ciała tzw. NOTES (ang. natural orifice transluminal endoscopic surgery). Pierwszą na świecie operację założenia AGB w technice NOTES wykonano w Polsce w ramach badania klinicznego [64]. Operacje bariatryczne SILS oraz NOTES dotychczas nie upowszechniły ze względu na skomplikowanie techniki operacyjnej i stosowane są jedynie w ramach badań klinicznych.
Rozdział 2.

Cel

Celem niniejszej rozprawy jest:

1. Ocena skuteczności leczenia patologicznej otyłości metodami SG i AGB, wykonywanymi w technice laparoskopowej, SILS i NOTES
2. Analiza wczesnych i późnych powikłań leczenia patologicznej otyłości metodami SG i AGB, wykonywanymi w technice laparoskopowej, SILS i NOTES

Cel pracy został zrealizowany w cyklu sześciu opublikowanych doniesień:


Łączny IF prac: 12,858; Indeks Hirscha: 4 na dzień 20.11.2013
Rozdział 3.

Preliminary outcomes 1 year after laparoscopic sleeve gastrectomy based on bariatric analysis and reporting outcome system (BAROS)


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Paweł Lech
Maciej Michalik
Abstract

Background
The aim of this study was to assess outcomes of LSG as a stand-alone bariatric operation, according to the Bariatric Analysis and Reporting Outcome System (BAROS).

Methods
Out of 112 patients included and operated on initially, 84 patients (F:M 63:21) were followed up for 14-56 months (mean 22 ± 6.75). Patients lost to follow up did not attend scheduled follow-up visits or they have withdrawn their consent. Mean age was 39 years (range 17-67; SD ± 12.09) with mean initial BMI 44.62 kg/m$^2$ (range 29.39-82.8; SD ± 8.17). Statistical significance was established at the p < 0.05 level.

Results
Mean operative time was 61 min (30 - 140 min) with mean hospital stay of 1.37 days (0-4; SD ± 0.77). Excellent global BAROS outcome was achieved in 13% of patients, very good in 30%, good in 34.5%, fair in 8 (9.5%) and failure in 11 (13%) patients 12 months after surgery. Females achieved significantly better outcomes than males with the mean 46.5% of EWL versus 35.3% of EWL at 12 months (p=0.02). The mean %EWL was 43.6% at 12 months and 46.6% at 24 months. Major surgical complication rate was 7.1%; minor surgical complication rate 8.3%. There was one conversion (1.2%) due to the massive bleeding. Comorbidities improved or resolved in numerous patients: arterial hypertension in 62%, diabetes mellitus in 68.3% respectively.

Conclusions
Presented LSG series shows that the LSG as a stand-alone procedure provides acceptable %EWL and good global BAROS outcomes. It significantly improves comorbidities as well.
Introduction

Sleeve gastrectomy is one of the restrictive operations used to treat morbid obesity [1]. This operation was first described by Hess in 1988 as a part of the biliopancreatic diversion with duodenal switch (BPD-DS) [2]. In 1999 Gagner performed first laparoscopic sleeve gastrectomy (LSG) also as a part of the BPD-DS [3]. Later he used LSG as a staged procedure for super morbid obesity to finally use it as a stand-alone procedure. Since first implementation in 2004 as a stand-alone bariatric operation LSG was proved to be sufficient and became one of the procedures on the incline.

To assess the results of bariatric treatment authors use multiple outcome factors such as percentage of excess weight loss, quality of life and complications including postoperative deaths. Some use standardized tools such as SF-36 scale [4], Sickness Impact Profile (SIP) [5], Quality of Well-Being Scale (QWB) [6] and finally Bariatric Analysis and Reporting Outcome System (BAROS) [7]. BAROS, developed by Oria and Moorehead, is still the most comprehensive questionnaire; it is also easy to use in daily practice.

BAROS assesses: percentage of excess weight loss (%EWL), improvement and/or resolution of comorbid conditions, five aspects of quality of life (self-esteem, physical activity, social activity, work and sexual activity), complications and reoperations. The final outcome is based on improvement, worsening or no change in all five listed domains giving the most comprehensive assessment of the treatment results influencing not only the weight changes but also its impact on patients’ general health and well being.

The aim of this study was to assess outcomes of laparoscopic sleeve gastrectomy used as a stand-alone procedure for morbid obesity in a single institution in Poland according to BAROS criteria.

Method

The study was designed as a single-institution, observational study. There was a retrospective data analysis based on the patients’ hospital records (baseline data including height, weight,
comorbidities, data on operation and complications) and prompted self-reported data collected over the telephone (changes in time in weight, complications, reoperations, changes in QoL, changes in comorbidities, eating behaviours, physical activity changes).

The patients were included since the introduction of the procedure in the authors' institution. Between 13\textsuperscript{th} March 2008 and 16\textsuperscript{th} December 2009; 112 patients signed informed consent and were initially qualified to participate in the study and underwent a LSG operation. All operations were performed by one team of 3 surgeons following one standard technique. Only the size of bougie was under the surgeons discretion and was slightly modified depending on the surgeon's preference.

25\% of patients were lost to follow up. These patients did not attend scheduled follow-up visits, nor was there current contact data available or they have withdrawn their consent to participate in the study on the later stage when the data was collected in six-months intervals.

The mortality data was checked against the national registry. Remaining 84 patients (F:M 63:21) were followed up for 14-56 months (mean 22 ± 6.75). Mean age was 39 years (range 17-67; SD ± 12.09) (38.7 years for females and 40.1 years for males (p=0.6)), with mean initial BMI 44.62 kg/m\textsuperscript{2} (range 29.39-82.8; SD ± 8.17). Mean BMI significantly differed between genders and was 43 kg/m\textsuperscript{2} in females (SD ± 7.08) and 49.5 kg/m\textsuperscript{2} in males (SD ± 7.35) (p=0.001). Statistical analysis included only patients remaining in the follow up group to enable outcomes comparison.

BAROS questionnaire was used for data collection along with the department's bariatric qualification chart twelve months after surgery to assess preliminary outcomes of laparoscopic sleeve gastrectomy. BAROS incorporates five strategic outcomes of bariatric surgery: percentage of excessive weight loss (% EWL), resolution or improvement in comorbid conditions, quality of life (the Moorehead-Ardelt Quality of Life Questionnaire = QoL), surgical and medical complications as well as reoperations all scored as
listed below [7]. % EWL is stratified in five categories. The weight gain is scored -1 point, 0-24 % EWL gives 0 points, 25-49 % EWL +1 point, 50-74 % EWL +2 points, >75% +3 points. Comorbidities resolution gives +2 points, its improvement gives +1 point, no change is scored 0 and worsening gives -1 point. Quality of life assessment based on Moorehead-Ardelt QoL Questionnaire evaluates five aspects of live: self-esteem, physical activity, social involvement, ability to work, interest in sex. Each aspect is evaluated as: much worse, worse, no change, improved, significantly improved receiving -0.5; -0.25; 0; +0.25 or +0.5 points respectively. Each major complication deducts one point and a minor complication deducts 0.2 points. Finally, any reoperation deducts one point from the score. Complications were stratified as minor and major according to Oria et al. [7].

Statistical analysis was performed using computer software ‘Statistica’ 8.0, StatSoft, Krakow, Poland. Statistical significance was established at the p < 0.05 level for t-student’s test and chi² test.

**Results**

**Background**

Mean operative time was 61 min (range 30 - 140 min) with mean hospital stay of 1.37 days (range 0-4; SD ± 0.8). Nine out of 84 patients (10.7%) were subjected to previous bariatric surgery. Two patients underwent vertical gastric banding, six patients had laparoscopic adjustable gastric banding procedure and one patient had laparoscopic sleeve gastrectomy. The linear regression model did not show any statistically significant positive or negative impact of having previous bariatric surgery on outcomes of LSG in presented series. Super morbid obesity with BMI>50 kg/m² was present in 21.4% (N=18) of patients before the operation and was reduced to 3.6% (N=3) after the operation. 66.7% of patients declared having been obese since childhood and 65.5% having at least one first degree relative suffering from obesity. 81% of patients declared having changed their diet with significant calories
and carbohydrates intake reduction following the surgery. 33% declared increase of physical activity (more than three times a week) and 56% of patients did not commence any physical activity postoperatively according to self-reported data.

**BAROS data**

Initial mean BMI of 44.6 kg/m² has reduced every six months to 36.8 kg/m², 35.2 kg/m², 35.9 kg/m², 35.3 kg/m² and 32.2 kg/m² consecutively at 6, 12, 18, 24 and 30 months after surgery (Tab. 1.).

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Mean</th>
<th>Minimum</th>
<th>Maximum</th>
<th>SD</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>44.6</td>
<td>29.4</td>
<td>82.8</td>
<td>8.17</td>
<td>84</td>
</tr>
<tr>
<td>6 months after surgery</td>
<td>36.8</td>
<td>23.1</td>
<td>75.3</td>
<td>7.69</td>
<td>80</td>
</tr>
<tr>
<td>12 months after surgery</td>
<td>35.2</td>
<td>22.7</td>
<td>82.8</td>
<td>8.17</td>
<td>82</td>
</tr>
<tr>
<td>18 months after surgery</td>
<td>36.0</td>
<td>23.7</td>
<td>90.3</td>
<td>10.6/4</td>
<td>55</td>
</tr>
<tr>
<td>24 months after surgery</td>
<td>35.3</td>
<td>23.7</td>
<td>53.1</td>
<td>7.62</td>
<td>26</td>
</tr>
<tr>
<td>30 months after surgery</td>
<td>32.2</td>
<td>25.6</td>
<td>40.3</td>
<td>5.04</td>
<td>10</td>
</tr>
</tbody>
</table>

**Table 1.** Body Mass Index before and after surgery

This corresponded with the mean 36.8% of Excess Weight Loss (%EWL) in first 6 months and 43.6% EWL at 12 months, 45.4% EWL at 18 months, 46.6% EWL at 24 months and 51.1% of EWL at 30 months following surgery. Fig. 1 shows changes of the percentage of Excess Weight Loss in time.
Figure 1. Changes of % of Excess Weight Loss in time following LSG

23.75%, 33%, 36.4%, 38.5% and 50% of patients lost more than 50 % of EWL at 6, 12, 18, 24 and 30 months after surgery respectively.

Eight most common comorbidities were assessed and they were present in 59.5% (N=50) of patients before surgery. Complete resolution of one comorbid condition was observed in 23 cases and improvement or significant improvement was observed in 21 cases. As the most common, arterial hypertension improved or resolved in 62% of cases, and diabetes mellitus improved or resolved in 68.3% of affected patients. Changes in all present comorbid conditions have been presented in Tab. 2.
Results of the Moorehead-Ardelt Quality of Life Questionnaire are shown in Table 3. The self-esteem and physical activity aspects of QoL have improved most significantly with interest in sex remaining in more than 50% of patients at the same level.

All surgical and medical complications were stratified as major and minor as well as early and late according to the Oria and Moorehead classification and were summarised in Tab. 4.

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Before surgery N</th>
<th>Improvement N (%)</th>
<th>Resolution N (%)</th>
<th>No change N (%)</th>
<th>Worsening N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial Hypertension</td>
<td>42</td>
<td>12 (28.6%)</td>
<td>14 (33.3%)</td>
<td>16 (38%)</td>
<td>0</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>22</td>
<td>6 (27.3%)</td>
<td>9 (41%)</td>
<td>7 (31.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>9</td>
<td>1 (11.1%)</td>
<td>0</td>
<td>8 (89.9%)</td>
<td>0</td>
</tr>
<tr>
<td>Asthma</td>
<td>4</td>
<td>1 (25%)</td>
<td>0</td>
<td>3 (75%)</td>
<td>0</td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>Sleep Apnoea</td>
<td>1</td>
<td>1 (100%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Thyroid disorders</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>6 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1 (100%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2. Improvement and resolution of comorbidities (N – responds to the number of affected patients – one patient could have more than one comorbidity).
<table>
<thead>
<tr>
<th></th>
<th>Much worse</th>
<th>Worse</th>
<th>Same</th>
<th>Better</th>
<th>Much better</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-esteem</td>
<td>1 (1.2%)</td>
<td>3 (3.6%)</td>
<td>4 (4.8%)</td>
<td>20 (23.8%)</td>
<td>56 (66.6%)</td>
</tr>
<tr>
<td>Physical activity</td>
<td>0</td>
<td>3 (3.6%)</td>
<td>9 (10.7%)</td>
<td>23 (27.4%)</td>
<td>49 (58.3%)</td>
</tr>
<tr>
<td>Social involvement</td>
<td>0</td>
<td>5 (5.9%)</td>
<td>17 (20.2%)</td>
<td>26 (31%)</td>
<td>36 (42.9%)</td>
</tr>
<tr>
<td>Ability to work</td>
<td>0</td>
<td>2 (2.4%)</td>
<td>25 (29.7%)</td>
<td>33 (39.3%)</td>
<td>24 (28.6%)</td>
</tr>
<tr>
<td>Interest in sex</td>
<td>3 (3.6%)</td>
<td>3 (3.6%)</td>
<td>44 (52.4%)</td>
<td>16 (19%)</td>
<td>18 (21.4%)</td>
</tr>
</tbody>
</table>

**Table 3.** Moorehead-Ardelt Quality of Life Questionnaire results
Surgical Complications

<table>
<thead>
<tr>
<th>Major 7.1% (N=6)</th>
<th>Minor 8.3% (N=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early 4.8% (N=4)</td>
<td>Late 2.4% (N=2)</td>
</tr>
<tr>
<td>Late 1.2% (N=1)</td>
<td>Late 7.1% (N=5)</td>
</tr>
</tbody>
</table>

- Infarction of the upper splenic pole 2.4% (N=2)
- GI leak with peritonitis 1.2% (N=1)
- Wound abscess 1.2% (N=1)
- Incisional hernia 2.4% (N=2)
- Small wound infection 1.2% (N=1)
- Persistent nausea or vomiting 4.8% (N=4)
- Stenosis of the stomach 1.2% (N=1)
- Electrolyte imbalance 1.2% (N=1)

Medical Complications

<table>
<thead>
<tr>
<th>Major 3.6% (N=3)</th>
<th>Minor 15.5% (N=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early 3.6% (N=3)</td>
<td>Late 0%</td>
</tr>
<tr>
<td>Early 4.8% (N=4)</td>
<td>Late 10.7% (N=9)</td>
</tr>
</tbody>
</table>

- Depression 2.4% (N=2)
- Breathing disturbances 1.2% (N=1)
- Atelectasis 1.2% (N=1)
- Vomiting 1.2% (N=1)
- Electrolyte imbalance 1.2% (N=1)
- Urinary tract infection 1.2% (N=1)
- Hair loss 4.8% (N=4)
- Anaemia 4.8% (N=4)
- Metabolic deficiency (protein, vitamins) 1.2% (N=1)

Table 4. Complications

There was one conversion (1.2%) to the open technique due to the massive bleeding that could not been stopped with the laparoscopic approach and there were no reoperations in the first 30 postoperative days. During the follow up period three patients underwent another bariatric operation due to unsatisfactory weight loss (1x resleeve, 2x Roux-en-Y gastric bypass).
Based on all the above factors, the global BAROS outcomes were calculated. Excellent outcome was achieved in 11 (13%) patients, very good in 25 (30%), good in 29 (34.5%), fair in 8 (9.5%) and failure in 11 (13%) patients.

Further analysis has shown that females achieved significantly better outcomes than males (Tab. 5.) with the mean 46.5% of EWL versus 35.3% of EWL at 12 months (p=0.02). There was no statistically significant difference in outcomes in correlation to education (p=0.17), smoking (p=0.06), obesity of the first degree relative (p=0.13), childhood obesity (0.47), having had previous bariatric surgery (p=0.59), declared increased physical activity (p=0.96), declared decreased calories intake and diet modification (p=0.6).

<table>
<thead>
<tr>
<th>Gender</th>
<th>Outcome</th>
<th>Female N=63 (100%)</th>
<th>Male N=21 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Excellent</td>
<td>11 (17.5%)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Very good</td>
<td>21 (33.3%)</td>
<td>4 (19%)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>19 (30.2%)</td>
<td>10 (47.6%)</td>
</tr>
<tr>
<td></td>
<td>Fair</td>
<td>5 (7.9%)</td>
<td>3 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>Failure</td>
<td>7 (11.1%)</td>
<td>4 (19.1%)</td>
</tr>
</tbody>
</table>

**Table 5.** Outcome based on gender.

The outline of the BAROS system excludes patients lost to follow up or the ones who died during the operation or shortly postoperatively. Among 112 patients initially eligible for inclusion to the study one female patient (0.9%) died due to the pulmonary artery embolism on the fifth postoperative day therefore was excluded from final analysis.
Discussion

Among many well-established bariatric operations, LSG as a stand-alone operation is relatively new. Nevertheless, the operative technique is well developed, established and standardized [1]. In the available literature, there are few large series studies assessing its outcomes, and authors use multiple outcome measures and assessment instruments, therefore the outcomes are difficult to compare [8-10]. Bariatric Assessment Reporting and Outcome System (BAROS) give broader assessment of the outcome than the use of percentage of the excess weight loss on its own [7]. Among limitations of BAROS is exclusion of patients with perioperative deaths and the ones lost to follow up.

In the presented series operative time of 61 min and hospital stay of 1.37 days were shorter than in the recent review by X. Shi et al. summarising outcomes of 940 cases (100.4 min and 4.4 days respectively) [8].

74% of patients (81% of females and 66.6% of males) have achieved scores from good to excellent using BAROS criteria. 13.1% of operations in total were classified as failures due to the poor global BAROS scores. Those patients had poor weight loss or weight re-gain during the first 12 months following surgery with poor QoL scores and some postoperative complications. Three (3.6%) of those patients consecutively underwent another bariatric operations.

In opposition to the single criterion outcome measures, BAROS shows global outcome apart from % EWL including also QoL, resolution of comorbidities, complications and need for reoperations [7]. Therefore, the global impact of bariatric surgery is assumed greater than only percentage of excess weight loss. In the presented series, the mean percentage of the EWL of 43.6% at 12 months and 46.6% at 24 months of follow up is lower than the expected mean 60% and 65% loss of EWL in 12 and 24 months in review by Shi et al. [8]. It is still much better than the results published by Regan et al. [11] and Milone et al. [12] with EWL reaching only 33-35%. Nevertheless, the explanation of this fact
could potentially lie in the poor adherence to the recommendations following surgery with only 32.9% of patients declaring increase of physical activity to at least 30 min three times a week and as many as 55.7% of patients not having any physical activity postoperatively. According to the systematic review by Livhits et al., increase in physical activity to at least 30 min a day, three times a week might be associated with decrease of BMI by as much as 4% of initial BMI [13]. Interestingly as many as 79.7% of patients declared change of their diet with significant calories and carbohydrates intake reduction following surgery, which did not correspond to %EWL and the global outcomes \( p=0.6 \). In the presented series, the LSG had greater influence on the body mass reduction in females with statistically significant higher percentage of excess weight loss at 12 months after surgery (46.5% EWL versus 35.3% EWL \( p=0.02 \)) and thanks to that fact they achieved better outcomes than males. Most probably this difference is based mainly on significantly lower initial BMI. Nevertheless, the data collected during the study did not allow the analysis that would show its background. If the above conclusion is true, one might attempt a further conclusion that the LSG as a stand-alone procedure is more effective in ‘slimmer’ patients with lower initial BMI but to prove it further large case controlled studies should be performed. The number of super morbid obesity patients was reduced from 21.4% \( \left( N=18 \right) \) to 3.6% \( \left( N=3 \right) \), although the weight loss was more limited in this group than in the group of patients with lower preoperative BMI.

The well-known positive outcome of metabolic surgery is resolution or improvement of comorbid medical conditions [14]. Eight most common comorbidities were assessed and they were present in 59.5% \( \left( N=50 \right) \) of patients preoperatively. Complete resolution of one comorbid condition was observed in 23 cases and improvement or significant improvement was observed in 21 cases. Improvement or resolution in 62% of cases of arterial hypertension
and 68.3% of diabetes mellitus cases is just the same as achieved by Basso et al. in their large series of 300 cases of LSG [9].

The quality of life assessment incorporated in BAROS scale assumes changes of QoL in time following bariatric surgery and compares current state with baseline from before the surgery. Major positive changes in QoL were reported in self-esteem and physical activity domains with some improvement in social involvement and ability to work and the moderate improvement in the interest in sex.

Major early surgical complications (listed by the BAROS questionnaire) in the presented series reached 4.8%, which is a good result when compared to 12.1% in the review by Shi et al. [8] and 9% in the single institution study by Basso et al. [9]. On the contrary, upper splenic pole infarction was the most frequent complication (2 patients), followed by one staples line leak and one wound abscess.

Interestingly 10.7% of patients developed late medical complications uncommon for restrictive bariatric procedures but typical for malabsorptive procedures with anemia, hair loss and metabolic deficiencies including proteins and vitamins deficiencies [15]. The study design did not allow identification of the causative factors.

Out of the 112 patients initially qualified into the study and operated on, one female patient (0.9%) died due to the pulmonary artery embolism on the fifth postoperative day despite antithrombotic prophylaxis. This patient was not included in the outcomes analysis, as those patients are excluded accordingly to the BAROS scale design. Mortality was slightly higher than the mortality in other LSG studies 0.5% [16] and 0.3% [8]; nevertheless, surgery-related mortality decreases with the center’s bariatric experience.

Conclusions

The presented series of laparoscopic sleeve gastrectomies shows that it provides acceptable percentage of weight loss and
good global BAROS outcomes. It significantly improves comorbidities. However, its metabolic impact still needs further studies to explain deficiencies typical for malabsorptive procedures.

References

Splenic infarction as a complication of laparoscopic sleeve gastrectomy


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Anna Trybull
Paweł Lech
Maciej Pawlak
Konrad Szydłowski
Grzegorz Wallner
Abstract

Objective

The article describes splenic infarction, not reported so far, potentially serious complication of LSG, analyze its causes, and suggest a considerate treatment and follow-up protocol.

Introduction

Laparoscopic sleeve gastrectomy (LSG) as a stand-alone or a first step in BPD-DS procedure is frequently an operation of choice for the XXI century’s epidemic of morbid obesity. Up to date, LSG as a relatively new method has few complications reported and analyzed.

Methods

During the observation period between March and November 2008, 24 LSG patients (20 female and 4 male) were enrolled with mean BMI of 44 kg/m². All LSG operations have been recorded. Computerized statistical software ‘Statistica 7’ StatSoft, Krakow, Poland was used for analysis. Statistical significance was calculated with nonparametric tests (p <0.05).

Results

In 4 patients (17%) splenic infarction was diagnosed intraoperatively. Consecutive Angio-CT scan confirmed infarction of the upper splenic pole with 12% to 33% of the splenic pulp affected. Two out of four patients had one minor perioperative complication. There were no significant differences between patients. Video analysis excluded possible technical errors.

Conclusions

Described analysis suggests short gastric vessels and upper terminal splenic artery branch dissection as a possible causative factors of splenic infarction in course of LSG. We suggest a considerate protocol with abdominal cavity inspection at the beginning and end of procedure, Angio-CT scans, prophylactic LMWH, initial broad spectrum iv antibiotics, appropriate follow-up with neither splenectomy nor related immunization.
Introduction

Morbid obesity is often called the first global epidemic of the twenty first century [1]. As in all epidemics, obesity raises wide concerns and represents a great challenge for current medical practice. Conservative therapy of obesity is based on pharmacological and behavioral strategies which as well as dietary regimens are believed to have limited effectiveness. After many years of limited success, surgery is now considered to be one of the main methods of effective and durable treatment of obese patients [2]. One of the surgical procedures that has been proved to be effective in bariatric surgery is sleeve gastrectomy (SG). This was developed in the 1990s and was first described by Hess and Marceau [3,4]. In 1999 Ganger performed the first laparoscopic sleeve gastrectomy (LSG) and a year later, he suggested this operation to be the first stage in treatment of patients with a Body Mass Index (BMI) higher than 60 kg/m$^2$ [5,6]. LSG was adapted in 2003 as an initial surgical intervention of choice for patients with Super Morbid Obesity (BMI greater than 50). LSG induced rapid body mass loss and distinctly improved the technical capabilities of a final operation, such as Gastric By-Pass or Duodenal Switch procedures. Recently, numerous data have supported the treatment of obesity with LSG as a stand-alone and final procedure, because of its good results and permanent effects. Nowadays, such a view is supported by numerous health care professionals [7-10].

Methods and characteristics of the group

The LSG operation was introduced in the Department of General and Vascular Surgery of Ceynowa Hospital, Wejherowo, Poland in January 2006, after several years of experience with other bariatric and general surgical laparoscopic procedures.

During the observation period between March 2006 when the first splenic infarct was recorded intraoperatively and November 2008, a total of twentyfour LSG operations due to morbid obesity, were performed after obtaining informed consent. Twenty women
and four men were enrolled with a mean BMI of 44 kg/m². In 2 patients LSG has been performed as the second stage treatment, after failure of Laparoscopic Gastric Banding procedures. All patients received subcutaneous Enoxaparin sodium injection (40 mg) 12 hours prior to operation and intravenous antibiotic prophylaxis with 1.2 g Amoxicillin-Clavulanate directly before the procedure.

All LSG were recorded on a DVD disc for later review. When intraoperative disturbance of the splenic blood supply was noted (Fig. 1), an angio-CT was performed the day following surgery (Fig. 2). Each patient with radiologically confirmed splenic infarction was empirically given intravenous antibiotic treatment with amoxicillin-clavulanate 1.2 g three times a day for the length of the hospital stay. These patients were also given clinic review appointments, 7 days, 28 days and 3 months after surgery.
Figure 1. Splenic infarction recognised intraoperatively (arrow points to the infarcted splenic pulp).

Figure 2. CT-angiography scan of splenic infarction (arrow points to the infarcted splenic pulp).

Surgery technique

The procedures were performed with five trocars (three 11 mm and two 5 mm trocars) placed in the epigastric region. After dissection of the omental sac, the greater curvature was freed by section of the gastrocolic ligament very closely to stomach surface, starting 6 cm from the antrum up to the angle of His using a 5 mm harmonic scalpel (Harmonic ACE® Curved Shear Ethicon Endo-Surgery, Inc.). The short gastric vessels were clipped when necessary. Longitudinal gastric resection of the fundus and greater curvature was performed using the linear stapler system (EchelonTM60 ENDOPATH® Stapler Ethicon Endo-Surgery, Inc.) Occasional bleeding from the staple line was controlled using single hand-tied sutures. During every procedure the condition of the spleen was assessed twice: firstly when examining the peritoneal cavity at the beginning of the procedure, and secondly after removal of the excised part of the stomach before abdominal closure.

Results

In the 24 patients treated by the LSG method since March 2008, 4 patients (16.6%), all female (no comorbidities), were diagnosed with an infarct of the upper splenic pole. All splenic infarcts were diagnosed intraoperatively and then confirmed radiologically using angio-CT. This identified infarction of the upper splenic pole involving 12% to 33% of the total splenic pulp. Analysis of the course of treatment has shown no significant differences between patients with splenic infarct and the group with no complications. Video analysis of all performed procedures excluded the possibility of technical failure. However, this analysis identified that short gastric vessels and dissection of the upper terminal splenic artery branch whilst mobilising the stomach’s greater curvature represented likely causative factors of splenic segmental
infarction. No major differences could be identified when comparing the group characteristics of splenic infarct patients with those who did not develop complications (Tab. 1).
Patients
No complications group
Splenic infarct group

<table>
<thead>
<tr>
<th>Patients</th>
<th>Number</th>
<th>Mean age [years]</th>
<th>Mean operating time [min]</th>
<th>Mean hospitalization time [days]</th>
<th>Mean BMI [kg/m²]</th>
<th>Prior abdominal surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20</td>
<td>34.80 (20 - 50)</td>
<td>75.52 (45 - 95)</td>
<td>3.94 (2-6)</td>
<td>42.68 (30.99 – 53.63)</td>
<td>10 (50%)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>34.25 (25 - 46)</td>
<td>47.50 (45 - 50)</td>
<td>3</td>
<td>42.40 (36.71 – 53.63)</td>
<td>2 (50%)</td>
</tr>
</tbody>
</table>

Table 1. Comparison of patients’ groups

One of the patients with iatrogenic post-LSG splenic infarction complained of pain in the left hypochondrium, which radiated to the left loin, during the first 24 h following the procedure. There were no other complications following LSG in the group of 24 patients. Both on the day of the discharge, and during the routine follow-up appointments until the present time, none of the patients presented symptoms related to splenic infarction, either surgical or infective. To date no deaths have been recorded.

Discussion

Laparoscopic sleeve gastrectomy provides not only a restrictive mechanism by reducing the intake of excessive food, but also causes a decrease in ghrelin serum concentration and causes a statistically significant reduction in hunger sensation when compared with other bariatric procedures [4, 11-13].
Laparoscopic sleeve gastrectomy like other similar procedures includes some risk. To date, the following complications of LSG have been described in the available literature [6, 8, 10, 14-18]:

- Staple line leakage
- Stricture of the created tube
- Dilatation of the created tube
- Haemorrhage from the short gastric vessels or staple line
- Trocar site bleeding
- Splanchnic vessel thrombosis
- Pulmonary embolism
- Delayed stomach emptying
- Intraperitoneal abscess
- Iatrogenic splenic injury
- Postoperative wound infection
- Postoperative hernia.

The perioperative mortality after LSG is reported at levels of up to 0.6% [14, 15].

When the first splenic infarct during LSG was diagnosed, we conducted a comprehensive literature search using the following search engines, databases and websites: PubMed, the Cochrane Library, EBSCO, ProQuest/Embase, ScienceDirect, Wiley InterScience, and Medpilot. The key words used were: surgery, laparoscopy, bariatriy, obesity, iatrogenic, complication, sleeve resection, sleeve gastrectomy, splenic infarct, laparoscopic sleeve resection, and laparoscopic sleeve gastrectomy, as well as combinations of the above words and MeSH terms. The search did not identify any previous descriptions of splenic infarct as a complication of sleeve gastrectomy. Splenic infarction in bariatric patients has potentially serious consequences. In the absence of case reports in the medical literature, we deemed it necessary to analyse and present the frequency of splenic infarction in our own material.
As mentioned above, to date there have been no reports of post-LSG splenic infarcts. In general, splenic infarct is a rare pathology, described usually as a complication of left upper quadrant abdominal surgery or minimally invasive procedures e.g. colonoscopy, and has been shown to be associated with a heterogeneous group of medical conditions (collated in Tab. 2) [19-26].

| Surgical                  | Total gastrectomy  |
|                          | Antrectomy          |
|                          | Vagotomy            |
|                          | Hemicolecctomy      |
|                          | Salphingectomy      |
|                          | Pancreatic resections|
|                          | Liver transplantation|
|                          | Oesophagectomy      |

| Haematological            | Leukemia            |
|                          | Myelofibrosis       |
|                          | Lymphoma            |
|                          | Sickle cell anaemia  |
|                          | Sickle cell trait   |
|                          | Hemoglobin SC disease|
|                          | Polycythemia vera   |

| Infectious                | Mononucleosis       |
|                          | AIDS                |
|                          | Malaria             |
|                          | Disseminated varicella|
|                          | Sepsis              |
|                          | Pyelonephritis      |

| Traumatic                 | Blunt and penetrating abdominal trauma |
|                          | Chest trauma (especially of the left side) |

| Cardiac                   | Endocarditis        |
**Table 2. Causes of splenic infarction**

The LSG is impeded by the close proximity of the upper part of the stomach body, its fundus and the spleen. The procedure is further complicated by the diverse course of vessels running within the stomach's ligaments, which are dissected during the surgery. The left and right gastric arteries supply the lesser curvature of the stomach. In contrast, the greater curvature of the stomach derives its arterial blood supply from three to six short gastric arteries running through the gastrophrenic ligament and the upper part of the gastroplenic ligament up to the splenic hilum, also providing blood supply to the upper pole of the spleen. The remaining part of the greater curvature is supplied by anastomosed gastroepiploic arteries known as Hyrtl’s arterial arc and their branches, running in

<table>
<thead>
<tr>
<th>Valvular diseases</th>
<th>Superior mesenteric artery or celiac axis thromboembolism</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Portal vein or splenic vein thrombosis</td>
</tr>
<tr>
<td></td>
<td>Cirrhosis with portal hypertension</td>
</tr>
<tr>
<td></td>
<td>Atherosclerosis</td>
</tr>
<tr>
<td></td>
<td>Aortic aneurysms</td>
</tr>
<tr>
<td>Connective tissue diseases</td>
<td>SLE</td>
</tr>
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<td></td>
<td>Polyartheritis nodosa</td>
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<tr>
<td>Drugs</td>
<td>Cocaine</td>
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<tr>
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<tr>
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<td>Erythropoietin</td>
</tr>
<tr>
<td></td>
<td>Clofazimine</td>
</tr>
<tr>
<td>Others</td>
<td>Sarcoidosis</td>
</tr>
<tr>
<td></td>
<td>Amyloidosis</td>
</tr>
<tr>
<td></td>
<td>Wegener’s granulomatosis</td>
</tr>
<tr>
<td></td>
<td>Pancreatitis or pancreatic cancer</td>
</tr>
<tr>
<td></td>
<td>Gaucher disease</td>
</tr>
</tbody>
</table>
the gastrosplenic and gastrocolic ligaments. The gastroepiploic arteries usually occur about 1-2 cm from the stomach wall. Their course is tortuous and shows high individual variability. In general, there is considerable anastomotic communication between the stomach arteries and the blood supply systems of other organs such as the spleen, oesophagus, adrenals and diaphragm (Figure 3) [27].

Physiologically, splenic segmental arteries are terminal arteries without any collateral circulation. Therefore, closure of a segmental artery usually leads to infarction of the vascularised splenic segment or splenic pole. The possible anatomical variants of upper splenic pole arterial blood supply are shown in Figure 4 [28, 29].

The majority of patients with partial splenic infarcts has an asymptomatic or mildly symptomatic clinical course usually without significant complications and do not typically require surgical treatment. In these cases conservative management of the associated symptoms is usually adequate. Specifically, antibiotics, analgesia, intravenous fluids and anticoagulation may be required depending on the status of the patient. Occasionally there is a need for transfusion of blood products. Sometimes, a splenic infarct undergoes fibrosis of the malperfused segment or leads to complications such as the development of a haematoma, splenic rupture, abscess, or pseudocyst formation [30]. In such cases surgical intervention should be considered. There is an ongoing discussion concerning the advantages and disadvantages of partial and total splenectomy in these patients, but at present there is no consensus on the patient management guidelines [31, 32].
Figure 3. Arterial blood supply of stomach and spleen.
Figure 4. Variants of upper splenic pole arterial blood supply.

Widespread splenic infarctions are associated with potentially serious immunological and haematological implications. Affected patients require frequent and regular haematological tests in addition to necessary immunisations including meningococcus, pneumococcus and haemophilus influenzae vaccinations with prolonged prophylactic antibiotic treatment [31-33].

In the presented cases only one or two upper pole splenic segments were observed to be affected. Two patients encountered only minor complications such as nausea, vomiting and left epigastric pain during the first postoperative day and no subsequent late complications were observed. All affected patients received antibiotic prophylaxis during the perioperative period, though there were no other specific alterations to their medical treatment. The patients in this study who encountered splenic infarction during LSG did not develop sufficiently widespread damage to require splenectomy or further operative intervention. The only extra measure taken in this group was the use of angio-CT to investigate the extent of splenic infarction. All patients were assigned to regular
outpatient follow-up to monitor their clinical status and introduce appropriate treatment if required. We decided not to immunise our patients, as the infarcts they developed were relatively small, with the largest accounting for 33% of the total splenic pulp.

In Poland, there are only a few bariatric centres, so some of the patients are hospitalised longer for social reasons (to ensure full recovery before long travel back home). That explains the situation of longer hospitalization periods in some of the patients with no complications.

Conclusions

Based on the observations we conclude that splenic infarction is an under-reported and frequent complication of laparoscopic sleeve gastrectomy as well as many other laparoscopic procedures. We observed that splenic infarction occurred in 16.6% of these procedures performed at a longstanding laparoscopic surgical centre. We believe that the presence of splenic infarction in obese subjects is underdiagnosed due to the spleen’s location (usually behind the stomach, covered with intraabdominal fat) and lack of guidelines on detailed inspection of the abdominal cavity after the procedure with little emphasis currently being placed on the status of the spleen.

Retrospective analysis of video recordings of the relevant LSG ruled out technical errors as the cause of splenic infarction. However, this analysis identified that short gastric vessels and dissection of the upper terminal splenic artery branch whilst mobilising the stomach’s greater curvature represented likely causative factors.

The collective experience at the centre led us to create a rule of detailed abdominal cavity inspection with special emphasis on the spleen at the beginning and at the end of every procedure as well as a local protocol for patients with intraoperatively recognised splenic upper pole infarction, which comprises:
• angio-CT scan the day following the procedure to assess the extent of splenic pulp damage and at 3 months if symptomatic,
• low molecular weight heparin in thrombo-prophylactic doses,
• if asymptomatic – regular discharge,
• review and follow-up on the 7th and 28th day and the 3rd month after surgery,
• no splenectomy and no related immunization in cases of infarct < 33% of total splenic pulp.

Further evaluation of the above protocol on a larger group of patients is currently underway. We hope that other centres will share their experience in this matter to enable coprocedure on improving the outcomes and safety of laparoscopic sleeve gastrectomy as one of the few effective treatments for morbid and super morbid obesity.

Acknowledgments

The authors would like to thank and acknowledge the work and contribution to the article of Alexander Kidd MD, PhD.

References


Rozdział 5.

A 5-Year experience with Laparoscopic Adjustable Gastric Banding - focus on outcomes, complications, and their management


Maciej Michalik
Paweł Lech
Maciej Bobowicz
Michał Orłowski
Andrzej Lehmann
Abstract

Background

Laparoscopic adjustable gastric banding (LAGB) remains the most popular surgical modality for obesity management in Europe. The aim of this publication is to present a 5-year experience in obesity treatment with LAGB operation with the assessment of outcomes, frequency of complications, and their management. Management of the band-related complications is crucial for continuous obesity treatments, despite the fact of initial failure, allowing further excess weight loss in patients with morbid obesity.

Methods

One hundred sixty patients underwent the LAGB procedure with standard pars flaccida technique during the years 2005–2009. A retrospective analysis of the data was performed; chi-squared test and Student’s t test at the level of significance of \( p < 0.05 \) were used. Information on reoperations was gathered from hospital case notes.

Results

In the presented group, the mean body mass index (BMI) was 48.13 kg/m² (33.46–83.04 kg/m²; standard deviation [SD] ±8.45). Of the patients, 36.2% had super morbid obesity with BMI >50 kg/m². The mean observation period reached 549 days (31–2,026 days; SD ±390.1), with the mean number of control visits of 4.2 (1–12). The mean percentage of excess weight loss during the observation period was 34% (from −9.9% to 85.1%; SD ±20.6), with the mean body mass reduction of 24.4 kg. Complications appeared in 30 patients (20.1%). Twenty-four patients (16.1%) required reoperation. There were no mortalities recorded.

Conclusions

The mean operative time of 59 min was relatively short. Morbidity and mortality rates were comparable to many published series. Failure or complications of LAGB did not stop the obesity treatment. Most of the band-related complications occurred late and could be provided for laparoscopically.
Introduction

Obesity is an increasing health problem concerning over 20% of adults in Western Europe and over 30% in the USA. In Poland obesity affects over 300,000 people [1]. Abnormal increase in body weight is connected with a considerable increase in the risk of diabetes type II, arterial hypertension, myocardial ischemia, stroke, dyslipidaemia, apnea and cancer [2]. In 1997 the World Health Organization (WHO) recognized obesity as the first global pandemia of the XXI century and a surgical treatment is currently the only successful therapy. Despite some differences in the amount of performed procedures, depending on the region of the world, laparoscopic adjustable gastric banding (LAGB), as a pure restrictive method, still remains the most popular surgical modality [3].

There is an increasing number of publications based on large groups of patients presenting the distant (even 10-years) results of the patients after LAGB [4,5]. In comparison with other methods, patients after LAGB have similar results, taking into consideration the percentage of the excess body weight loss (%EWL) and improvement in the quality of life [3,6].

The aim of this publication is to present 5-year experience in obesity treatment with LAGB operation with the assessment of outcomes, frequency of complications and their management. Management of the band-related complications is crucial for continuous obesity treatments despite the fact of initial failure allowing further excess weight loss in patients with morbid obesity.

Materials and methods

In years 2005-2009, 160 patients underwent LAGB procedure. The indications for the surgery were Body Mass Index (BMI) > 40 kg/m² or BMI > 35 kg/m² with comorbidities. Initial mean BMI for the whole group was 48.13 kg/m² (33.46-83.04 kg/m²; SD±8.45). The exclusion criteria were: omission of all follow-up visits (N=7; 4.4%) or removal of port or band before the first post-operative visit due to various complications (N=4; 2.5%).
149 patients (93.1%) attended at least one follow-up visit and were included in the final analysis.

Operations were performed by five surgeons, using Swedish Adjustable Gastric Band (SAGB; BD2XV with Velocity Injection Port and Applier, Ethicon Endo-Surgery), applying the “pars flaccida” technique [7]. The band was not secured by fixation to the walls of stomach and the drainage was not commonly used. Oral fluids and patients’ mobilization were applied on the day of surgery. On the discharge patients received recommendations concerning the diet.

The first follow-up visit took place six weeks after the surgery, when the band was first filled with 0.9% NaCl solution under the X-ray control with the use of barium contrast. Thereafter, follow-up visits were scheduled every 3-6 months.

A retrospective analysis of the data was performed with the use of a computer software Statistica 8.0 StatSoft, Krakow, Poland, with the use of chi² and t-student’s test at the level of significance of p<0.05.

Results
Follow-up assessment
149 patients (93.1%) attended at least one control visit. The mean number of control visits was 4.2 (1-12). The mean time from operation to the first follow-up visit was 77.9 days (26-394 days; SD±50.1). Table 1 presents participation in follow-up visits.

<table>
<thead>
<tr>
<th>Follow-up months</th>
<th>Seen</th>
<th>Eligible patients</th>
<th>Follow-up rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>142</td>
<td>152</td>
<td>93.4%</td>
</tr>
<tr>
<td>6 months</td>
<td>125</td>
<td>152</td>
<td>82.2%</td>
</tr>
<tr>
<td>12 months</td>
<td>95</td>
<td>145</td>
<td>65.6%</td>
</tr>
<tr>
<td>24 months</td>
<td>43</td>
<td>119</td>
<td>36.1%</td>
</tr>
<tr>
<td>36 months</td>
<td>13</td>
<td>74</td>
<td>17.6%</td>
</tr>
<tr>
<td>48 months</td>
<td>6</td>
<td>40</td>
<td>15%</td>
</tr>
<tr>
<td>50 months</td>
<td>1</td>
<td>4</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table 1. Participation in follow-up visits
General outcomes

The mean operative time was 59 min (20-130 min, SD±25) with 2.4 days of hospitalization (2-15 days; SD±1.4). Tab. 2. presents patients’ characteristics. 36.2% of patients were diagnosed as having super morbid obesity with BMI>50 kg/m². The comorbidities were present in 88.6% of patients.

The mean %EWL during the observation period was 34% (from -9.9 to 85.1%; SD±20.6) with the mean body mass reduction of 24.4 kg. Mean BMI decreased from 48.1 kg/m² (range 33-83) to 39.1 kg/m² (range 25.3-64.1) in the observation period. Fig. 1. presents %EWL during the observation.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Range</th>
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</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>39.6</td>
<td>22-74</td>
</tr>
<tr>
<td>Initial weight (kg)</td>
<td>137.5</td>
<td>90-240</td>
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<tr>
<td>Initial BMI (kg/m²)</td>
<td>48.13</td>
<td>33.5-83.1</td>
</tr>
<tr>
<td>Duration of hospitalization (days)</td>
<td>2.4</td>
<td>2-15</td>
</tr>
<tr>
<td>Number of patients with comorbidities</td>
<td>132</td>
<td>88.6%</td>
</tr>
<tr>
<td>Females</td>
<td>n=112</td>
<td>75.2%</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>129.1</td>
<td>90-210</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>47.36</td>
<td>33.5-70.1</td>
</tr>
<tr>
<td>Males</td>
<td>n=37</td>
<td>24.8%</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>162.9</td>
<td>110-240</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>50.4</td>
<td>37.2-83</td>
</tr>
</tbody>
</table>

Table 2. Patient’s characteristics
Figure 1. %EWL following SAGB

Conversions

Three conversions to open operation were performed (2.0%) because of technical difficulties. The mean BMI of these three patients was 57.8 kg/m² (54.4-60.4 kg/m²; SD±3.1). The mean body mass was 188.7 kg (180-200 kg; SD±10.3). The mean time of the operations with conversion was 110 min (65-175 min; SD±57.7).

Complications

Complications requiring more than a 2-day hospitalization, re-hospitalization or reoperation appeared in 30 patients (20.1%). Early complications (up to 30 days after surgery) occurred in 8 patients, late complications occurred in 22 patients. Among all the patients 24 (16.1%) needed reoperation. 6 patients (4.0%) were treated non-invasively in the ICU due to the early post-operative breathing insufficiency. Only one patient, due to the port-site
infection, required port replacement followed by the SAGB removal due to the consecutive slippage. At the same time laparoscopic sleeve gastrectomy (LSG) operation was performed. There were no mortalities following SAGB procedures recorded. Tables 3 and 4 present the complications’ characteristic and undertaken measures.

<table>
<thead>
<tr>
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<th>Medical</th>
<th></th>
<th>Surgical</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Early</td>
<td>Late</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative respiratory insufficiency</td>
<td>6 (4%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Port-site infection</td>
<td>0</td>
<td>6 (4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trocar-site hernia</td>
<td>0</td>
<td>1 (0.7%)</td>
<td></td>
<td></td>
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<tr>
<td>SAGB-related</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slippage</td>
<td>2 (1.3%)</td>
<td>7 (4.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Port damage</td>
<td>0</td>
<td>3 (2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misplacement of the band</td>
<td>0</td>
<td>2 (1.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Port’s drain disconnection</td>
<td>0</td>
<td>2 (1.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migration of the band into the GI tract’s lumen</td>
<td>0</td>
<td>1 (0.7%)</td>
<td></td>
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Table 3. Complications

<table>
<thead>
<tr>
<th>Measure</th>
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<tr>
<td>Band or port reinsertion</td>
<td>10</td>
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<tr>
<td>Band removal</td>
<td>8</td>
</tr>
<tr>
<td>Sleeve gastrectomy after SAGB</td>
<td>8</td>
</tr>
<tr>
<td>Conservative management</td>
<td>6</td>
</tr>
<tr>
<td>Port removal</td>
<td>3</td>
</tr>
<tr>
<td>Port repair</td>
<td>2</td>
</tr>
<tr>
<td>Hernia repair</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4. Measures undertaken following specific complications

Re-operations

LSG as a secondary procedure was performed in total in 8 patients (5.4%). In five patients (3.4%) LSG was performed due to the lack of the effect of the LAGB (mean %EWL = 7.36% [range: -20.01-36.78%, SD±19.26]). Mean time to re-operation was 948.8 days (613-1202 days, SD±216.53). Two patients (1.3%) had LSG done because of band migration, and one due to its infection. In the examined series nine cases (6%) of band migration were noted. Two patients experienced early band slippage (less than 30 days after surgery), in seven patients it occurred later during the observation period.

On average the port infection occurred after 114 days since the last band fluid adjustment (5-165 days, SD±73.4). In two cases the band was not filled after the surgery (60 and 565 days after the operation). Three patients had their infected port removed and connection with a new port delayed. In one case an infected port was removed and LSG performed. Two patients (1.3%) had a new port implanted under the right rib arch and it was laparoscopically
connected with the band. In five cases (3.4%) a revision of a port was performed due to the drain disconnection or port damage.

One patient, who did not attend the follow-up after LAGB implantation, experienced band migration into the alimentary tract 1511 days after LAGB. Patient was hospitalized for 13 days due to the gastro-cutaneous fistula which healed with conservative management.

In the very first two patients, the band was placed not around the stomach but in front of it, embracing some fat tissue. The band was removed and implanted in a proper position.

Discussion

Since 1986 when Ukrainian surgeon Lubomyr Kuzmak invented a silicone band with an inflatable balloon, which allowed regulation of the alimentary tract’s lumen [8] and since Cadiere along with Bechalew performed laparoscopic implantation of adjustable gastric band in 1993 [9-11], the method has gained a lot of popularity. Anticipated benefits of LAGB are: simple technique, short operative time, no alimentary tract integrity interruption, and reversibility of this method. The initial reports on LAGB as well as distant results, even a 10-year old, are very promising [12-16].

Mean operative time of 59 min is relatively short and comparable to specialized centers [7]. Most authors take [17] a success achieving a decrease in %EWL > 50%. Therefore a good outcome was obtained by 24.7%, 31.5% and 38.5% patients, 12, 24 and 36 months following surgery respectively. The failure is usually described as a reduction in %EWL below 25%, every complication leading to a permanent band removal (5.4% of patients in the study) as well as reoperation. Morbidity rate was 20.1% and the nature of the complications enforced reoperation in 16.1% of patients. These results are better than in some published series [18-21]. The percentage of the band’s slippage in the study (6%) is slightly higher than in the meta-analysis by Singhal et al. [22].
In the presented series, reoperation was performed laparoscopically in five cases of slippage, and in four by open surgery. In two cases of slippage LSG was performed. In four cases the band and subcutaneous port were definitely removed. Three patients had their migrated band replaced with a new one, retaining a previous port. There were no pouch dilatations noted, similarly as in the study by Holeczy et al. [18]. In one patient (0.7%) on the 469 day after the surgery an incisional hernia appeared.

Unsatisfactory regular control visits attendance is one of the limitations of this study. In the presented study, 12 months after surgery, 65.5% of patients attended follow-up visits; and after 24 months only 36.1% of patients, with the mean number of visits equal four. These results are worse than in other developed countries [20]. The reason for this phenomenon is probably the fact that the majority of obese patients from Poland are treated in four high-volume centers among them in the authors’ institution. A large distance from the hospital could potentially influence the weaker determination of systematic control. The need for good cooperation between a doctor and a patient with periodic body mass control, eating habits and regulating the size of the band is emphasized by Mittermair et al. [4]. Both with Suter and Tolon [16,23], they draw attention to the fact that qualification to LAGB procedure should be considered on individual basis and it should be recommended for the patients promising a long-term cooperation, obeying strict eating rules and with reference to lifestyle. Probably stricter qualification rules applied during the first pre-operative visit could lead to much better cooperation and follow-up obedience in the presented study.

At present most of bariatric procedures are performed laparoscopically, and such experimental minimal invasive techniques as NOTES and SILS are on incline [24-26]. The analysis of LAGB procedure complications, failures occurrence and their causes allows more precise, personalized choice of proper treatment modality. Most LAGB complications can be handled laparoscopically or using local or regional anesthesia with short hospital stay. The occurrence
of a complication doesn’t mean the end of the obesity treatment as the band can be easily removed and other bariatric operation can be applied providing continuous body mass reduction.

Conclusions

1. LAGB is an effective mode of obesity treatment in well-selected group of patients.
2. Most of the band-related complications occur late (>30 days after surgery) and usually can be provided for laparoscopically.
3. Failure or complications of LAGB do not have to stop the obesity treatment.

References


19. Forsell P, Hellers G. The Swedish Adjustable Gastric Banding (SAGB) for morbid obesity: 9-year experience and 4-year


Rozdział 6.
Band misplacement: a rare complication of laparoscopic adjustable gastric banding

*Videosurgery Miniinv* 2012;7:40-4. DOI:10.5114/wiitm.2011.25930

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Abstract

Background

Laparoscopic adjustable gastric banding (LAGB) is considered to be a very effective minimally invasive procedure for treating morbidly obese patients. Nevertheless, there are numerous complications that a good surgeon should be aware of. Most of them have been widely presented in the literature.

Aim

In this study we would like to focus on the rare but important complication, which is ante-gastric positioning of the band.

Material and methods

Between January 2005 and May 2008, 122 patients (88 female and 34 male) with mean body mass index (BMI) of 48.5 kg/m² (range 35-80 kg/m²) underwent LAGB procedure. The average time of hospitalization was 2.47 days. The first radiological control with band calibration was performed 6 weeks after the operation. Consecutive follow-up depended on the percent excess weight loss (EWL%).

Results

Of the 122 patients, 4 (3.3%) presented herein had a band misplaced in the ante-gastric position. There were three out of five surgeons who faced complications of this type. The most and the least experienced team members avoided misplacing the band. Two physicians encountered it at the beginning of their learning curve, and for one it was not related to the process of education. Among other postoperative complications there were two incidents of band slippage, 2 patients had their port localization corrected and in one case drain disconnection occurred. There were no mortalities.

Conclusions

Ante-gastric positioning of the band was the most common cause of obesity surgery failure in our group of patients. It was very difficult to recognize during the typical postoperative checkups; hence there arose a question whether it has been disregarded in other studies.
Introduction

Laparoscopic adjustable gastric banding (LAGB) is a valued bariatric procedure [1-4]. The efficacy of this procedure has been widely presented [5-9]. There is an increasing number of LAGB operations performed worldwide each year [1, 2, 9] and therefore one must analyse all related complications and causes of failure so that they can be easily prevented. Typical problems are already well known and have been frequently described [7-13]. In this article, the authors would like to present a rare cause of bariatric surgery failure, which is ante-gastric positioning of the adjustable gastric band.

Material and methods

Between January 2005 and May 2008, 122 consecutive patients had Swedish Adjustable Gastric Bands implanted because of morbid obesity. All procedures were performed in the Department of General and Vascular Surgery, Ceynowa Hospital, Wejherowo, Poland. All interventions were performed laparoscopically by entering through the pars flaccida of the hepato-gastric ligament. The five-trocar standard technique [6,9] was used in each procedure. There were two conversions to open surgery in the whole group.

Technique

Pneumoperitoneum was achieved via the closed technique with Veress needle insertion and abdomen inflation up to 15 mmHg of CO2. The peritoneal cavity was inspected and all subsequent ports were placed under visual control. The left liver lobe was retracted upward and the lesser curvature of the stomach with the pars flaccida was identified and incised. The right crus of the diaphragm was exposed. The peritoneum was incised at the point intended for placement of the band. The laparoscopic manipulator Goldfinger®, Ethicon Endo-Surgery, was introduced through the dissected opening and directed through the retrogastric fat tissue.
towards the angle of His. In the next steps the fundus of the stomach was released from the diaphragm and the angle of His with the left crus of the diaphragm and earlier implemented Goldfinger® were exposed. The band was tested for proper functioning by immersing it in NaCl and filling it with air. The band was inserted into the abdomen through the 15-mm trocar. By attaching the band to the Goldfinger®, it was pulled around the back of the stomach through the opening on the lesser curvature. The band-end tags were then locked and the access port was connected and fixed.

**Patient selection and perioperative period**

In the presented series 72% (88) of patients were female and 28% (34) were male. The body mass index (BMI) was in the range of 35-80 kg/m² (mean 48.53 kg/m²), and the average time of hospitalization was 2.47 days (2-30 days) (Table 1).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>88 (72%)</td>
<td>34 (28%)</td>
<td>122</td>
</tr>
<tr>
<td>Mean age [years]</td>
<td>38.02</td>
<td>38.88</td>
<td>38.20</td>
</tr>
<tr>
<td>Mean height [cm]</td>
<td>165.49</td>
<td>178.63</td>
<td>168.29</td>
</tr>
<tr>
<td>Mean BMI [kg/m²]</td>
<td>47.28</td>
<td>53.16</td>
<td>48.53</td>
</tr>
<tr>
<td>Mean time of hospitalization [days]</td>
<td>2.43</td>
<td>2.63</td>
<td>2.47</td>
</tr>
<tr>
<td>Mean points in ASA</td>
<td>1.91</td>
<td>2.56</td>
<td>2.06</td>
</tr>
</tbody>
</table>

**Table 1.** Demographic data of patients who underwent LAGB

Indications for this procedure were BMI > 40 kg/m² or 35 kg/m² with concomitant diseases associated with obesity. Prior to surgery each patient had two consultations, during which the level of the patient’s motivation was established. All included patients had previously tried a few non-surgical modes of treatment for morbid obesity. The following examinations were performed before admission:
abdominal ultrasound scan,
gastroscopy,
surgical, endocrinological, anaesthesiological and psychiatric consultations.

During the preoperative period, both antibiotic prophylaxis (premedication with 2 g of cefazolin \textit{i.v.}) and antithrombotic prevention (standard dosage regimen of low molecular-weight heparin LMWH) were given in all cases. The first radiological control with potential band fill up was performed 6 weeks after surgery. Subsequent control visits were carried out in correlation with the level of excessive weight loss and the appearance of lack of satiety.

**Results**

In four of our patients the mispositioned band was found to be in the ante-gastric position, encircling the adipose tissue (Figure 1). There were 3 male patients (aged 37, 49 and 50 years with BMI 39, 48 and 54 kg/m$^2$ respectively) and 1 female (aged 31 years with BMI 45 kg/m$^2$). Each patient was hospitalized for 2 days.

**Figure 1A, B.** Chest radiographs with the barium swallow showing the band misplacement in the ante-gastric region.
Taking into consideration the surgeons in the bariatric team, three out of five had encountered band misplacement. Only two surgeons had avoided this complication. In the case of the third surgeon, who incorrectly implanted the band twice, it happened at the beginning of his learning curve, during the first and the third procedure (Figure 2). Also for the second surgeon the discussed procedure failure occurred at the beginning of the learning process, during the fifth operation (Figure 3). The fourth surgeon encountered band misplacement relatively late, during his 22nd procedure (Figure 4). Among the team, the lead surgeon (Number 1) had the greatest experience and the highest number of LAGB operations performed and none of his procedures were followed by this type of complication (Figure 5). The fifth surgeon executed the fewest operations and also did not misplace the band (Figure 6).
Figure 2. The learning curve for surgeon number 3

\[ y = -2.9567x + 100.03 \]

Figure 3. The learning curve for surgeon number 2

\[ y = -4.9265x + 119.38 \]
Figure 4. The learning curve for surgeon number 4

\[ y = -2.188x + 94.08 \]

Figure 5. The learning curve for surgeon number 1

\[ y = -1.1064x + 99.012 \]
Postoperative control and band calibration were performed by two surgeons. Each of 4 patients with the band in the ante-gastric region were subjected to the first checkup 6 weeks after surgery and had their band adjusted based on the assessment of excess weight loss. Percent excess weight loss (EWL%) 6 weeks after surgery was similar for each patient and hold in span of the mean for the whole group, which was 20.36% (6-36%).

Furthermore, the barium swallow study indicated impression dependent on the band calibration that did not differ from the radiological image of other participants. It was probably due to band impression on the ventricle cardiac area.

In 3 patients there was no weight change between the first and the second control visit. In one case during the second control the band was adjusted to maximum volume and finally because of insufficient results on the third visit the misplacement was identified. Two corrections of the band implantation were done by open surgery, and laparoscopically in two other patients.

**Figure 6.** The learning curve for surgeon number 5

![Graph showing the learning curve for surgeon number 5.](image)

\[ y = -3.0952x + 63.929 \]
Among postoperative complications associated with the band itself, band slippage was observed in 2 cases (1.7%). One of the bands slipped near the pyloric region without symptoms and an open procedure was performed to correct its localization. In the second case there was early slippage with gastric frontal wall necrosis, stomach perforation and extensive peritonitis. In this case emergency surgery was performed to remove the band and sleeve resection was done as the alternative bariatric procedure. Two other patients in the presented series had their port localization corrected under local anaesthesia. Disconnection of the port was reported in one case. Reparation was performed laparoscopically. Type and number of other complications were similar to data from other papers [7, 13-16].

Discussion

Typical complications of LAGB implantation have already been frequently evaluated and presented. Among them, one can list erosion, fluid leakage, band slippage and migration. Additionally, there are complications associated with port and tube connection, for example, leakage, tubing rupture, and disconnection. Last but not least, we can encounter oesophageal dilatation, pouch dilatation and stomach stenosis [7, 10-13, 16-18].

Apart from those, there are rare complications, such as injury of the small [10] or large intestine [11] caused by disconnected tube or obstructive jaundice as the result of incorrect band placement.

The issue of band implantation ante-gastrically has been scarcely analysed in the literature. A Medline search using the phrases ‘band misplacement’ and ‘ante-gastric band implantation’ returned only two articles.

The first broached the subject of radiological imaging to diagnose complications after LAGB procedures. Among 218 patients band misplacement was identified in 2 patients (0.9%) during the routine radiological follow-up in the first month after the operation
The second article was a case report of a patient with the band implanted around the hepato-duodenal ligament [12]. Only when biliary peritonitis with jaundice was detected 7 months after surgery was the computed tomography and magnetic resonance imaging done and misplacement identified. In the described cases laparotomy was performed to remove the band.

In our material there were four patients in a group of 122 (3.3%) with incorrect ante-gastric band implantation and it was one of the most common adverse events in this series. In comparison, there were only 2 cases (1.7%) of band slippage.

Two out of five surgeons in our institution placed the band incorrectly once and it was associated with the learning curve. In one case, the failure occurred late and most likely due to a random event. However, two surgeons avoided it, one with the greatest experience who performed the majority of LAGB operations and another with only a few procedures performed.

One can draw interesting conclusions from the timing of the diagnosis of incorrect band localization. During the first control, which usually takes place between the 4th and 6th week after surgery, abnormalities are very difficult to recognize. This is due to similar short-term weight loss results found in all patients. Additionally, radiological images of the barium swallow study were inconclusive.

Surprisingly, patients with band misplacement lost weight in the early stage, probably due to postoperative stress, liquid diet and compression made by swollen tissue and band impression on the ventricle’s cardiac region. Furthermore, this could explain the phenomenon of proper barium swallow study, during the first check-up, among patients with band misplacement. Final diagnosis can be made when lack of weight loss occurs and contrast medium is applied directly to the band.

The question that arises is whether it is a very rare adverse event or it is disregarded for different reasons. In some publications, patients with unsatisfactory results after LAGB are recognized [14].
Those patients usually have their bands removed and they are subjected to other procedures. If it was not possible to recognize misplacement during LAGB, hypothetically the band may have been placed incorrectly.

It has been proven that among surgeons performing less than 10 procedures of one kind per year, the number of complications and mortality rate are higher [19]. The number of complications triples in centres with less than 100 bariatric operations performed annually [6]. Therefore, these data suggest that band misplacement should be more frequent in the small series being evaluated.

Currently, based on available data, it is difficult to assess the actual number of ante-gastric LAGB implantations. Therefore we submit that the band misplacement is a more common cause of bariatric surgery failure than cited in previous medical publications.

References


Rozdział 7.

Bariatric single incision laparoscopic surgery – review of initial experience

*Videosurgery Miniinv 2011; 6:48-52;*

*DOI:10.5114/wiitm.2011.20994.*

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Abstract

The aim of this review was to assess the results of published experience with bariatric SILS surgery, with a particular focus on treatment feasibility and safety. EMBASE and MEDLINE database search was performed identifying thirteen articles totalling 87 patients in Laparoscopic Adjustable Gastric Banding (LAGB) group, 10 patients in Laparoscopic Sleeve Gastrectomy (LSG) group, and 1 patient in Roux-en-Y SILS group. In most series the learning curve was steep and operating times halved with time, reaching 53 minutes for LAGB and 90 minutes for LSG. In single case reports using strict selection criteria patients were discharged up to 24 hours following surgery. Treatment safety was satisfactory. Only two studies reported some minor complications with rates of up to 9.8%, including port malposition, port site infection, and seroma or haematoma formation. There were no complications in other studies. LAGB, LSG and Roux-en-Y operations were feasible although technically demanding and difficult.
**Introduction**

The primary goal of surgery is to provide the best possible care according to evidence based medicine. Development of new instruments enables innovative operations that result in smaller perioperative trauma and stress response enabling better and faster healing and recovery. Examples of such approaches are Natural Orifice Transluminal Endoscopic Surgery (NOTES) or Single Incision Laparoscopic Surgery (SILS), also known as Laparo-Endoscopic Single Site surgery (LESS). Both concepts are associated with minimal trauma during the exploration of the abdominal cavity and leave at most a small scar in the umbilicus. Both concepts are still experimental and long-term outcomes are awaited. Potentially, SILS has fewer limitations when compared with NOTES and the range of current indications for its use is relatively broad. During the last two years, SILS has been investigated in the surgical treatment of cholelithiasis [1,2], abdominal hernias [3], appendicitis [4,5], benign tumours of the colon [6] and in the obesity. In this paper authors shortly review the current status of bariatric single incision laparoscopic surgery.

**Methods**

**Results**

Thirteen articles were identified and reviewed. One, by Teixeira et al. [7] was excluded from the analysis as the presented data on 10 patients was further included by authors in larger published case series [8]. Seven articles were case reports or series of cases of laparoscopic adjustable gastric banding (LAGB) using one of the SILS techniques (a total of 87 patients) [8-14]. Four articles described ten cases of Laparoscopic Sleeve Gastrectomies (LSG) using SILS technique [15-18]. There was one article describing single incision transumbilical laparoscopic Roux-en-Y gastric bypass [19].

Most of the studies used strict selection criteria with preoperative abdominal ultrasound examination, BMI in range of 35-45 kg/m², female gender and young age. Ultrasound scans were used to assess liver size (mainly the left lobe) as well as the amount of abdominal visceral fat. Female to male ratio was respectively 67:20 and 6:4 in LAGB and LSG groups. Age ranged between 21 and 62 years, Body Mass Index (BMI) ranged between 32 and 68 kg/m². LSG group comprised patients representing slightly higher BMI than the LAGB patients. Group characteristics for SILS LAGB and LSG are shown in Tables 1 and 2 respectively.

<table>
<thead>
<tr>
<th>Reference</th>
<th>No of patients (gender ratio)</th>
<th>Mean age</th>
<th>Mean BMI kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim et al. [1]</td>
<td>51 (35F:16M)</td>
<td>33</td>
<td>40</td>
</tr>
<tr>
<td>Teixeira et al. [2]</td>
<td>22 (20F:2M)</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>Saber et al.</td>
<td>8 (7F:1M)</td>
<td>49</td>
<td>39</td>
</tr>
<tr>
<td>Tacchino et al.</td>
<td>3F</td>
<td>30</td>
<td>41</td>
</tr>
<tr>
<td>Nguyen et al. [3]</td>
<td>1F</td>
<td>38</td>
<td>39</td>
</tr>
<tr>
<td>Oltman et al. [4]</td>
<td>1M</td>
<td>30</td>
<td>48</td>
</tr>
<tr>
<td>De la Torre et al. [5]</td>
<td>1F</td>
<td>40</td>
<td>41</td>
</tr>
</tbody>
</table>

*Table 1. Characteristics of the patients in LAGB group*
<table>
<thead>
<tr>
<th>Reference</th>
<th>No of patients (gender ratio)</th>
<th>Mean age</th>
<th>Mean BMI kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saber et al. [6]</td>
<td>7 (4F:3M)</td>
<td>46</td>
<td>53.5</td>
</tr>
<tr>
<td>Nguyen et al. [7]</td>
<td>1F</td>
<td>53</td>
<td>41</td>
</tr>
<tr>
<td>Reavis et al. [8]</td>
<td>1M</td>
<td>54</td>
<td>38</td>
</tr>
<tr>
<td>Amezquita</td>
<td>1F</td>
<td>39</td>
<td>36</td>
</tr>
</tbody>
</table>

*Table 2. Characteristics of the patients in LSG group*
**Access**

Particular investigators used different locations of the access ports and different skin incisions (Tables 3 and 4).

<table>
<thead>
<tr>
<th>Reference</th>
<th>Abdominal access</th>
<th>Number and type of the port(s)</th>
<th>Mean operating time (min.)</th>
<th>Mean hospital stay (days)</th>
<th>Complications</th>
<th>Length of follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim et al. [9]</td>
<td>3.0 cm periumbilical incision, Nathanson liver retractor inserted through the incision</td>
<td>4 ports (12, 3x5 mm)</td>
<td>166</td>
<td>2.6</td>
<td>Overall 9.8%</td>
<td>At least 3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Port malposition 3.9%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Port site infection 1.9%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Seroma formation 3.9%</td>
<td></td>
</tr>
<tr>
<td>Teixeira et al. [8]</td>
<td>3 cm periumbilical incision, liver retractor inserted through the incision</td>
<td>3x5 mm</td>
<td>80</td>
<td>&lt;23 hours</td>
<td>none</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saber et al. [13]</td>
<td>2.5 cm intraumbilical incision, liver retractor inserted through additional 5 mm subxiphoid incision</td>
<td>3 ports (12, 2x5 mm)</td>
<td>105</td>
<td>22 hours</td>
<td>none</td>
<td>2.6</td>
</tr>
<tr>
<td>Tacchino et al. [14]</td>
<td>1.2 cm intraumbilical incision, transfix stitch for liver retraction</td>
<td>1 (ASC TriPort, Olympus)</td>
<td>101</td>
<td>1</td>
<td>1 subcutaneous periumbilical haematoma</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Table 3. Abdominal access and patients’ outcomes in LAGB group

<table>
<thead>
<tr>
<th></th>
<th>Incision Type</th>
<th>Ports</th>
<th>Patients</th>
<th>Complications</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nguyen et al.</td>
<td>4 cm transverse incision in midline between xiphoid process and umbilicus</td>
<td>4x5 mm</td>
<td>55</td>
<td>1</td>
<td>none</td>
</tr>
<tr>
<td>Oltman et al.</td>
<td>8.5 cm left subcostal oblique incision</td>
<td>4 ports (12, 3x5 mm)</td>
<td>140</td>
<td>1</td>
<td>none</td>
</tr>
<tr>
<td>De la Torre et al.</td>
<td>3.5 cm vertical incision in umbilicus</td>
<td>3 ports (15, 2x5 mm)</td>
<td>58</td>
<td>1</td>
<td>none</td>
</tr>
</tbody>
</table>

The most frequent site of incision was periumbilical area as it leaves a barely visible scar and provides best cosmetic effect [8-10,15,16]. Other frequently used location was midpoint in midline between xiphoid process and umbilicus [11,17]. Access in the midpoint of midline with vertical incision adds to the safety of the procedure, although misses the cosmetic benefit from SILS. Oltman et al. used left subcostal incision for port placement [12]. The incision length varied between 1.2 cm and 8.5 cm [8-18]. Subcostal incision, especially 8.5 cm long, certainly does not add to the cosmetic effect and many surgeons would consider it a minilaparotomy due to not fulfilling all criteria of SILS surgery.

Two different approaches of accessing peritoneal cavity were used in particular series. Some authors utilised a TriPort Access System (ACS, Olympus) [14,18] whereas others used multiple standard low profile ports.
Table 4. Abdominal access and patients’ outcomes in LSG group

**Outcomes**

The operating times varied. As expected, first performed SILS cases using both LAGB and LSG necessitated relatively long operating times of 196 [9] and 177 minutes [15], respectively. In most series the learning curve was steep and operating times halved with time, reaching 53 minutes for LAGB [11] and 90 minutes for LSG [15,16]. Hospitalisation period was usually short. In single case reports using strict selection criteria patients were discharged up to 24 hours following surgery [8,10-14].
Postoperative pain score reduction compared with multiport laparoscopy is believed to be one of the advantages of LESS. As most of the studies were ‘feasibility studies’ they did not formally assess postoperative pain, nevertheless one study reported decreased opioid analgesics use in the postoperative period [7].

**Technical difficulties**

Three studies suggested that placement of additional ports may be required in cases of significant hepatomegaly and air leak from the port sites [8], to enable creation of the retrogastric tunnel [13] or for facilitation of bleeding management [15]. Additionally, in some patients additional skin incisions (without ports) may be necessary for liver retractor insertion [13]. Some authors used other knacks for liver support, such as suspending stitches or tapes passing through the skin and abdominal wall [10,14] or inserting liver retractor directly through the periumbilical incision [8,9]. Amezquita et al. used a transfix stitch for traction of the greater curvature of the stomach [18]. In most of the LAGB operations adjustable port of the band was placed in the near proximity of the umbilicus [13].

**Complications**

All but two studies reported no complications. One study reported complications rates as high as 9.8% (5 out of 51 patients) [9]. These complications were classified as minor though, and included port malposition, port site infection and seroma formation. These results are comparable with multiport LAGB reports [20-22]. In the study by Tacchino et al. in 1 in 3 patients subcutaneous periumbilical haematoma appeared, that later resolved spontaneously [14].

**Follow-up**

In all studies the follow up periods have been short and data on efficacy is lacking. BMI reduction was reported only in 3 studies with slightly longer than average follow-ups. BMI was reduced from
54 to 46 kg/m² during 3.4 months of follow up in LSG group [15] from 39 to 35.5 kg/m² in 2.6 months in the LAGB group [13] and from 36 to 22 kg/m² in 4 months [18].

**Roux-en-Y**

The only report on a single incision transumbilical laparoscopic Roux-en-Y gastric bypass [19] by Huang et al. also proved its feasibility with reasonable operating time of 170 min. with no postoperative complications. Authors used omega shaped periumbilical incision with three low profile ports (1x15mm, 2x5mm) and a liver suspension tape. 53-years-old female patient with preoperative BMI of 36 kg/m² was discharged on the 2nd postoperative day with standard postoperative care.

**Discussion**

Technical development has allowed improvement in surgical instruments and progress in modern surgery, which has become rapid in recent years. New generations of equipment continuously emerge, which increases the feasibility of novel methods. Currently, several operative techniques almost do not leave a scar and produce a minimal trauma; of those NOTES and SILS are among the most promising procedures. Currently multiple concepts of single access surgery use several acronyms for the same simple concept [23]. The idea is to make just one incision in umbilicus, the ‘natural scar’ of the human body. Currently these new instruments and concepts start to be utilized to address the 21st century’s epidemic of obesity. There are however several challenges for LESS/SILS/SPA operations in surgical treatment of obesity [24]. First, they are still experimental methods with unknown long-term efficacy and the risk of complications, therefore ethics committee approval and patients consent should be mandated. Second, these techniques may prove relatively difficult as stated by Huang et al. in their article [9]. All single access operations require good laparoscopic operative skills and do not provide good triangulation and fulcrum compared to standard laparoscopy. All instruments are in line, and good traction
and range of movement require special articulated instruments; hence appropriate surgical skills are of paramount importance. Third, most of bariatric operations are considered complex and demanding technically.

In conclusion, initial experience from numerous centres in SILS bariatric surgery is encouraging. The results are comparable to reported laparoscopic series. LAGB and LSG performed through single access surgery are feasible and safe in short term follow-up, with acceptable complication rates. Larger studies focusing on patient safety, improving pain scores and long term results are warranted for a thorough assessment of these techniques.

References
Rozdział 8.
The first report on hybrid NOTES adjustable gastric banding in human

DOI:10.1007/s11695-010-0130-2.

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Maciej Bobowicz
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Anna Trybull
Abstract

Background

Despite their current limitations, metabolic surgery and natural orifice transluminal endoscopic surgery (NOTES), set new horizons. In this article, the first three cases of adjustable gastric banding (AGB) through transvaginal access in obese women are described.

Methods

In General and Vascular Surgery Department, Ceynowa Hospital, Poland, three cases of AGB through the transvaginal access in hybrid, laparoscopically assisted NOTES technique were performed. All patients were female with BMI range 35-37. Dual channel endoscope and regular laparoscopic instruments were used.

Results

The mean operating time was 110 minutes. Indometacyn was given intravenously PRN for postoperative pain. None of the patients required more than 3 grams of indometacyn and for longer than 24 hours postoperatively. None required opioids either. There was one major complication of iatrogenic damage to the ureter, that required subsequent hospitalization and laparoscopic repair. Hospitalization time was 2 days. During two months follow up the mean weight loss was 15 kg. There were no malpositions of the band. There was no early mortality in the study group.

Conclusion

Feasibility of the proposed hybrid laparoscopically assisted NOTES adjustable gastric banding was proved. It is a technically demanding procedure, requiring appropriate endoscopic and laparoscopic skills. To avoid ureteric damage one should acquire safe colpotomy skills before commencing transvaginal NOTES operations.
Introduction

Since Kallo described the idea of natural orifice transluminal endoscopic surgery (NOTES) in 2004, it yields new proponents [1]. One of the main benefits is minimalisation of operative trauma. Despite technical difficulties, NOTES starts to be perceived by surgeons and patients as a logical next step in evolution of minimally invasive surgery and probably as a beginning of a post-laparoscopic era. There have been several hundred NOTES operations performed worldwide till June 2009, and this number increases rapidly. Our knowledge and experience in NOTES surgery grows even faster.

The very first article regarding bariatric NOTES operation in human was published in October 2008 [2]. Ramos et al. from Sao Paulo, Brasil, presented experience with transvaginal sleeve gastrectomy [2]. He was followed by S. Horgan (San Diego, USA) [3], J. Marescaux (Strasbourg, France) [4] and A. Lacy (Barcelona, Spain) [5].

In this article, the first published experience with transvaginal placement of an adjustable gastric band in three female patients is described.

Material and methods

In General and Vascular Surgery Department, Ceynowa Hospital, Wejherowo, Poland, three operations of placement of an adjustable gastric band through the transvaginal access were performed in April 2009. There were strict patients selection criteria. Age ranged between 29 and 52 years. All patients were relatively ‘slim’ regarding bariatric surgery with mean BMI 36 kg/m² (range of 35-37 kg/m²). Two patients had a minor comorbidity of arterial hypertension. None had previous abdominal operations. One underwent thyroidectomy for nontoxic goitre. Patients’ characteristics are summarized in Table 1.
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**Table 1.** Patients’ characteristics

**Technique**

Operations were performed with patients in gynaecological position. On the induction to general anaesthesia, all patients received 1.2 gram Amoxicillin with Clavulonic Acid i.v., as per local protocol for preoperative antibiotic prophylaxis. Pneumoperitoneum of 12-14 mm Hg was achieved with Veress needle, inserted in the left hypochondriac area. The Veress needle insertion spot was later used to place 15 mm trocar and at the end of procedure as a location for the gastric band’s port. An additional 5 mm trocar was inserted in the umbilicus. Through the umbilical trocar laparoscopic camera was inserted for better control of colpotomy. The incision was made in the posterior vaginal fornix, and the flexible, dual channel endoscope GIF-Q 165, Olympus, was inserted directly through the incision, without trocars’ use. At this stage patient was moved to reverse Trendelenburg’s position. This manoeuvre’s additional benefit was perfect sealing of air leaks by viscera dislocated to the pelvis minor. 10 mm laparoscopic liver retractor was introduced through the 15 mm abdominal trocar and was used to visualise pars flaccida. The standard pars flaccida technique of adjustable gastric banding was used (Figure 1 A-C).
Figure 1. Operative technique (A. Dissection of pars flaccida of gastrohepatic ligament; B. Endoscope passing behind the stomach, through pars flaccida to angle of Hiss to catch the band with endoscopic forceps; C. Closing the band with endoscopic forceps and laparoscopic grasper)

Dissection of pars flaccida (Figure 1A) was performed using endoscopic HookKnife KD-620LR (Olympus) and endoscopic grasping forceps FG-47L-L (Olympus) introduced through the endoscope’s working channels. When left diaphragmatic crus was identified, preparation of the space behind the stomach’s cardia towards the angle of Hiss was performed. At this stage, Swedish Adjustable Gastric Band ™, was inserted through the 15 mm abdominal port into the abdominal cavity. In two cases, endoscope has been passed behind the stomach, through pars flaccida to angle of Hiss to enable catching the band with endoscopic grasping forceps FG-47L-L (Olympus) and positioning it in the right place (Figure 1B). In one case this manoeuvre was not possible, therefore the 5 mm laparoscopic manipulator Goldfinger®, Ethicon Endo-Surgery, was introduced through the 15 mm abdominal port and was used as in standard laparoscopic procedure. This stage of operation required laparoscopic camera to provide better visualisation and control of instruments at least in the first performed cases. The band was
closed with its ‘quick close’ system by using endoscope’s grasping forceps and one laparoscopic grasper (Figure 1C). The band was not secured with stitches. The procedure was followed by band’s placement control, abdominal cavity inspection performed with the endoscope, CO\(_2\) desuflation and trocars retraction. The defect of posterior vaginal fornix was fixed with interrupted sutures under visual control. The SAGB subcutaneous port was implanted in the left upper quadrant through the extended 15 mm trocar skin incision.

**Results**

Mean operating time was 110 minutes. Indometacyn was given intravenously PRN for postoperative pain. None of the patients required more than 3 grams of indometacyn and for longer than 24 hours postoperatively. None required opioids either. All patients underwent gynaecological evaluation the day after procedure. All patients were discharged home on the second postoperative day with standard recommendations as for laparoscopic SAGB implantation.

During two months follow up the mean weight loss was 15 kg (14-16 kg). There were no malpositions of the band. On average, 3 ml of fluid was injected into each SAGB port for the best restrictive effect. There were no dysphagic symptoms.

One of the patients reported urinary incontinence on the discharge day. Gynaecology opinion was sought and on gynaecology advice patient was discharged home with ambulatory follow up. Right ureteric damage with uretero-vaginal fistula was diagnosed on the 10\(^{th}\) postoperative day. Right ureter was damaged about 4 cm from its vesical ostium. Operation’s video documentation was analysed to identify the ureteric damage that occurred during transvaginal insertion of endoscope. Uretero-vaginal fistula was provisionally decompressed through the right nephrostomy. After fistula healed, patient was readmitted and the distal end of ureter was laparoscopically implanted into the bladder by the urology team.
Apart from this one, postoperative period till now was not complicated.

**Discussion**

Natural orifice transluminal endoscopic surgery seems to be a logical next step in the minimally invasive surgery evolution. In most of the cases it eliminates skin incision which results in minimalisation of the body trauma and stress response. It does reduce the risk of infective wound complications as well as postoperative hernias. Finally the use of analgesics is reduced. NOTES shortens the postoperative recovery time and enables earlier return to occupational activity. Decarli et al. proved that the greatest beneficiaries of the advantage of NOTES are obese patients [6]. This group of patients has the highest risk of immunological deficiencies with comorbid diabetes, therefore with defected wound healing predisposing to wound infections and postoperative hernias. Decarli et al. noted decreased number of complications with reduced analgesics’ use in his transvaginal NOTES cholecystectomies group when compared to the laparoscopic group [6].

In this paper authors prove feasibility of the adjustable gastric band implantation procedure through the transvaginal access in NOTES technique. There has to be an appropriate patients selection to make sure the procedure is safe. Operation can be done with standard flexible, dual-channel endoscope introduced through the vaginal fornix incision and long (bariatric) laparoscopic instruments. In this three cases transvaginal access was used along two abdominal access points, one in the left epigastric region and one in the periumbilical area. Left epigastric region was chosen deliberately for the 15 mm incision and trocar. This incision was utilized for the 15 mm port for the liver retractor use and as the SAGB port implantation site later in the procedure. 5 mm port in the periumbilical area was used to provide the most safety for the patient with initial experience with the new operative technique through adding an extra source of intraoperative imaging. With
greater experience this additional port could well be excluded. The band was not secured with stitches as our experience shows that there are very few slippages when the appropriate technique is used. Initially, the average operating time of 110 minutes was above the average for laparoscopic SAGB implantation, nevertheless comparable with the first laparoscopic SAGB cases performed by the team, and shortened significantly with consecutive operations. The procedure itself was straightforward, although the insertion of flexible endoscope had the greatest burden of complications. Hence, operating surgeon should acquire appropriate colpotomy and safe abdominal cavity entry skills [7].

The pain control was very good with no patients requiring more than 3 grams of indometacyn, for longer than 24 hours postoperatively. None required opioids as in other published studies [8]. There were no wound complications noted. The average weight loss of 15 kg was satisfactory for 2 months follow up period. Lack of the skin incision does not mean lack of complications. Experience with NOTES operations in our department proves that despite broad experience with laparoscopic surgery and operative endoscopy each new technique brings new challenges and possible complications. Described cases were preceded by five transvaginal cholecystectomies and still the transvaginal access was associated with major complication of right ureteric damage that occurred in 1 in 8 patients operated through this access. Most probably when the learning curve comes to the plateau for the team, the complication rate would decidedly decrease as happened in all previous laparoscopic procedures with improved outcomes compared to open surgery.

To our knowledge there were only few obesity operations performed through the transvaginal access in NOTES technique. All published papers describe transvaginal sleeve resection or gastric by-pass operations and prove feasibility and safety of this operation [2-5, 9]. This is the first published report of three cases of transvaginal adjustable gastric banding in NOTES technique proving its feasibility,
safety and benefits comparing with laparoscopic procedure. Based on published reports and own experience, authors believe that NOTES could play a crucial role in the future of bariatric surgery.

Finally, it is important to note that the search for the least invasive bariatric operation led surgeons not only towards the NOTES but also towards the laparoendoscopic single site surgery (LESS). Publications on those very promising techniques started to appear in 2008 [10-12]. Published LESS techniques are relatively straightforward and the cosmetic effect is very good. Nevertheless, both NOTES and LESS bariatric operations are at their development stage regarding the operative technique itself as well as required instruments. Proper evaluation and comparison of the end results of NOTES and LESS bariatric operations requires further studies on larger groups of patients.

Conclusions

Transvaginal adjustable gastric banding is technically feasible with several benefits when compared to laparoscopic banding. To avoid most common access complications the operating team should acquire appropriate colpotomy and safe abdominal cavity entry skills.

References


11. de la Torre RA, Satgunam S, Morales MP, Dwyer CL, Scott JS.: Transumbilical single-port laparoscopic adjustable gastric banding
Rozdział 9.

Najważniejsze spostrzeżenia z poszczególnych doniesień

I. W pierwszej pracy: „Preliminary outcomes 1 year after laparoscopic sleeve gastrectomy based on bariatric analysis and reporting outcome system (BAROS)”, opublikowanej w piśmie *Obesity Surgery* w 2011 roku, przeprowadziliśmy prospektywną analizę wyników leczenia patologicznej otyłości zgodnie z protokołem BAROS, zaproponowanym w 1998 roku przez Orię i Moorehead [27,33]. Wykazaliśmy, że:

1. Operacje LSG zapewniają akceptowalny poziom %EWL z dobrymi wynikami w skali BAROS;
2. Leczenie to powoduje znaczną poprawę lub ustępowanie chorób towarzyszących;
3. Konieczne są dalsze badania, celem wyjaśnienia wpływu techniki operacyjnej na wystąpienie zaburzeń typowych dla metod wyłączających.

II. Drugi artykuł, zatytułowany: „Splenic infarction as a complication of laparoscopic sleeve gastrectomy” i opublikowany w kwartalniku *Videosurgery and Other Minimvasive Techniques* w 2011 roku, dotyczy typowego powikłania operacyjnego leczenia otyłości przy zastosowaniu techniki LSG, jakim jest zawał jednego z biegunów śledziony [65]. Głównym wnioskiem z przeprowadzonej analizy, i z przeglądu piśmiennictwa na temat postępowania w przypadku splenektomii z jatrogennych przyczyn, jest zaproponowany protokół [66-68]:

- kontrolne angio-TK trzy miesiące po operacji;
- profilaktyczna dawka heparyn drobnocząsteczkowych;
- wypisanie ze szpitala bezobjawowych chorych w trybie zwykłym;
- wizyty kontrolne po 7 i 28 dniach, oraz po 3 miesiącach po operacji;
brak konieczności splenektomii i szczepień ochronnych, o ile zawał śledziony nie przekracza 33% objętości śledziony.

III. W kolejnej publikacji pod tytułem „A 5-year experience with laparoscopic adjustable gastric banding - focus on outcomes, complications, and their management”, opublikowanej w 2011 roku w Obesity Surgery, przeprowadziliśmy ocenę skuteczności drugiej popularnej techniki operacji restrykcyjnych, jaką jest założenie regulowanej opaski żołądkowej w technice laparoskopowej [45]. W pracy tej wykazaliśmy, że:

1. LAGB jest skuteczną metodą leczenia otyłości w odpowiednio dobranej grupie pacjentów;
2. Większość powikłań związanych z samą opaską żołądkową występuje po 30 dniach od operacji i może być zaopatrzona laparoskopowo;
3. Powikłania związane z LAGB nie przekreślają możliwości dalszego leczenia otyłości.

IV. W pracy “Band misplacement: a rare complication of laparoscopic adjustable gastric banding”, opublikowanej w Videosurgery and Other Miniinvasive Techniques w 2012 roku, przedstawiliśmy własne doświadczenia dotyczące dość rzadkiego, aczkolwiek poważnego powikłania operacji LAGB, jakim jest założenie regulowanej opaski na tłuszcz trzewny, zamiast na okolicę podwpustową żołądka w materiale własnym [69].

Wnioski:

1. Zdarzenie to było udziałem trzech spośród pięciu chirurgów wykonujących LAGB;
2. Większość zdarzeń wystąpiła na początku krzywej uczenia.

V. Chęć dalszej minimalizacji urazu okołooperacyjnego u chorych z patologiczną otyłością doprowadziła do badań nad możliwością zastosowania technik laparoskopowych z pojedynczym dostępem oraz technik operacji przez naturalne otwory ciała. Pierwsze opisy takich zabiegów zaczęły się pojawiać w 2008 roku, a w roku 2010
możliwe było przygotowanie pracy poglądowej zgodnej z zasadami „systematic review”. Praca ta została opublikowana w piśmie *Videosurgery and Other Miniinvasive Techniques*, w 2011 roku, pod tytułem: „Bariatric single incision laparoscopic surgery – review of initial experience” [50].

Wnioski:

1. Operacje LAGB i LSG z pojedynczego dostępu są możliwe i związane są z akceptowalną liczbą powikłań;
2. Uzyskane wyniki są porównywalne do wyników operacji LAGB i LSG w technice wieloportowej;
3. Ze względu na niewielką liczebność badanych grup, wyciągnięcie wiążących wniosków nie jest jeszcze możliwe, niemniej uzyskane wyniki wydają się być zachęcające.

VI. Dalsze minimalizowanie wielkości widocznych blizn doprowadziło do prac nad technikami operacji przez naturalne otwory ciała (NOTES). Pierwszy raport oceniający możliwość założenia regulowanej opaski żołądkowej w technice NOTES z dostępu przezpochwowego przedstawiliśmy w 2011 r. w artykule: „The first report on hybrid NOTES adjustable gastric banding in human”, opublikowanym w *Obesity Surgery* [64].

Wnioski:

1. Wykonanie założenia regulowanej opaski żołądkowej w hybrydowej technice NOTES jest technicznie możliwe;
2. Ryzyko jatrogennego uszkodzenia moczowódów wymaga odpowiednich umiejętności wejścia do jamy otrzewnej z dostępu przezpochwowego.
Rozdział 10.
Podsumowanie

Przedstawiony cykl doniesień wykazał skuteczność oraz bezpieczeństwo leczenia patologicznej otyłości przy zastosowaniu regulowanej opaski żołądkowej oraz rękawowej resekcji żołądka w technice laparoskopowej i z dostępu SILS oraz możliwość wykonania operacji AGB w technice NOTES. Wyniki zastosowania rękawowej resekcji żołądka w leczeniu otyłości zostały przedstawione w dwóch pierwszych pracach. Pierwsza z nich, to opis metodologii, techniki operacyjnej LSG oraz skal oceny wraz z wynikami leczenia. Druga stanowi szczegółową analizę przyczyn oraz mechanizmów powstania jednego z częstych powikłań operacji LSG oraz propozycję algorytmu diagnostyczno-leczniczego w przypadku zawału górnego biegunu śledziony. W dwóch kolejnych donieseniach o podobnej strukturze, przedstawiono wyniki leczenia otyłości przez zastosowanie LAGB, oraz poddano analizie problem szczególnego powikłania jakim jest założenie opaski żołądkowej na tłuszcz trzewny, z opisem postępowania w takich przypadkach. Znając wyniki zastosowania laparoskopowych technik SG i AGB w chirurgicznym leczeniu otyłości, w piątym doniesieniu przeprowadzono systematyczny przegląd piśmiennictwa, mający na celu ocenę wyników dalszej minimalizacji urazu okołooperacyjnego przez zastosowanie techniki dostępu SILS. Na podstawie wniosków płynących z powyższych prac, uczestniczyłem w zespole, który wykonał 3 operacje założenia AGB w hybrydowej technice NOTES wspomaganej laparoskopowo. Wyniki przedstawiono w szóstej publikacji.

Wnioski
1. Zastosowane wybrane techniki minimalnie inwazyjne (regulowanej opaski żołądkowej oraz rękawowej resekcji żołądka w technice laparoskopowej, SILS oraz operacje LAGB w technice NOTES) są skuteczne w chirurgicznym leczeniu patologicznej otyłości.
2. Analiza występujących powikłań pooperacyjnych wykazała bezpieczeństwo opisywanych technik chirurgicznych. Analiza ta wraz z opisem postępowania w takich przypadkach, może być pomocna dla osób rozpoczynających wykonywanie powyższych operacji.

3. Ze względu na ciągły postęp w dziedzinie technik minimalnie inwazyjnych, konieczne są dalsze badania nad nowymi, skuteczniejszymi metodami leczenia otyłości.
Rozdział 11.
Streszczenie w wersji angielskiej
Summary

Introduction

Continuous civilizational progress has had a negative impact on human health, resulting in the increasing incidence of several diseases. The changes in daily activities towards a more sedentary work and life-style, in addition to the lack of physical activity and superabundance of highly-processed food, increase the occurrence of civilizational diseases, and in particular obesity [1]. The World Health Organization defines obesity as a pathological or excessive accumulation of fat tissue, which may lead to adverse health events [2].

The body mass index (BMI) is a broadly accepted and used index, defining the fat tissue content of the body. It is calculated as follows:

\[
\text{BMI} = \frac{\text{body mass}}{(\text{height})^2}
\]

Based on the BMI, adults can be categorized as [3]:

- Underweight < 19 kg/m²
- Normal body mass 19-24.9 kg/m²
- Overweight 25-29.9 kg/m²
- 1st degree obesity 30-34.9 kg/m²
- 2nd degree obesity 35-39.9 kg/m²
- Pathological obesity >40 kg/m²
- Super-morbid obesity ≥50 kg/m²

According to the current data, the number of obese adults worldwide has doubled in the last 30 years, reaching the size of a pandemic including 500 million people, which constitutes 11% of all adults [2].
According to the Polish Central Statistical Office, in 2009, 17% of men and 15% of women in Poland suffered from obesity [4]. Moreover, during the thirteen years included in the analysis, the dynamics of the increase in obesity were significantly higher in males than in females and resulted in almost doubling the number of obese males [4].

According to the WHO experts, 65% of people live in countries where obesity is a more likely cause of death than starvation [2]. More importantly, obesity is one of the few preventable chronic diseases. Unfortunately, current methods of obesity prevention are generally ineffective.

Both the percentage of the obese in the general population and the ineffectiveness in fighting obesity prompted the search for the best treatment methods. Daily newspapers, magazines or web pages are full of advertisements for several diets and slimming therapies. The effectiveness, real value and safety of these methods are at least questionable. The vast majority of obese subjects have tried to reduce their body mass by decreasing their food intake at least once in their lifetime. Usually, these attempts fail, or their body mass returns to its initial value within a few months’ time of the diet’s completion (‘yo-yo’ effect) [5,6].

For many years, pharmaceutical companies have been making efforts to develop safe medications for obesity. Drugs used in the pharmacological treatment of obesity increase the feeling of satiety with a simultaneous increase in the energetic expenditure (Sibutramine, Lorcaserin), cause appetite suppression (anorexigenics: Rimonabant, Phentermine) or selectively inhibit fat absorption (Tetrahydrolipostatin). The efficacy and safety of the majority of these drugs have been confirmed in randomized trials. However, the achieved mean body mass reduction with these means fluctuated around 5 kg after one year of therapy [7,8]. Additionally, these compounds have a negative impact on the central nervous system and result in frequent side effects. In consequence, there is
currently no agent registered for the treatment of obesity in Europe and in the United States.

The morbidly obese patients (BMI > 40 kg/m$^2$) have several dozen kilograms of excessive body mass and thus the drugs reducing it by 5kg a year cannot be considered satisfactory.

Owing to the limited efficacy of the above-mentioned methods, surgical treatment techniques of obesity called bariatric surgery have been developed over the past few decades. This branch of surgery is also frequently referred to as ‘metabolic surgery’ because of the broader impact on the patient’s organism rather than just reducing the body mass.

Bariatric surgery was developed in the 1950s in the United States, where the proportion of pathologically obese citizens is highest. The first techniques proposed by Kremen and Linear [9,10] carried a high risk of postoperative complications, with particularly burdensome symptoms of short bowel and deficiency syndromes. Modifications of these methods described by other authors became popular also in Poland and remained the mainstay of the surgical management of morbid obesity for the next 20 years [11-13]. Since 1966, the gastro-jejunal bypass described by Mason et al. [14] has also been frequently used.

There are several techniques used for the surgical treatment of morbid obesity and their classification is based on the mechanism of action [10,15]:

1. Restrictive techniques
   • adjustable gastric banding (AGB)
   • sleeve gastrectomy (SG)
   • non-adjustable gastric banding (NAGB) - rarely used nowadays
2. Malabsorptive techniques
   • jejun-ileal bypass
3. Techniques with complex restrictive-malabsorptive mechanism
• biliopancreatic diversion - duodenal switch (BPD-DS.)
• Roux-en-Y gastric bypass (RYGB) with further modifications, such as mini-gastric bypass.

According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the European Association for Endoscopic Surgery (EAES), guidelines based on the National Institute of Health (NIH) recommendations, surgical treatment of obesity is advisable in patients with aBMI > 40 kg/m² or BMI > 35 kg/m², with at least one of the following comorbid conditions: arterial hypertension, diabetes mellitus, asthma, ischemic heart disease, obstructive sleep apnea, osteoarthritis, thyroid disorders and depression [16-18]. Candidates for surgery should also fulfill additional criteria, such as high motivation with at least a few attempts to reduce weight by diet and lifestyle modifications, understanding of the procedure and no psychological disorders [16,19]. Polish recommendations were published in 2009 by the expert panel of the Section of Metabolic and Bariatric Surgery of the Polish Surgical Society [20]. They were based on the EAES guidelines with some minor changes based on the Bariatric Scientific Collaborative Group guidelines [19].

The EAES experts published recommendations based on the current knowledge of the mechanisms leading to obesity, on the experience with bariatric surgery, and on the results of particular techniques that should guide patient-tailored choice of the most appropriate technique [18]. At the same time, the leading institutions investigating obesity were not able to specify the optimal choice of the type of surgery based on the BMI and comorbidities [19].

The efficacy of the particular method, the degree of the excessive weight loss (%EWL), reversibility, possibility to perform additional corrections, the influence on the comorbidities, the sustainability of the effect and the incidence of possible complications can guide the choice of the operative technique.
Published data show that the efficacy of bariatric operations expressed as means of %EWL is the highest after BPD and decreases in the following fashion: BPD > RYGB > SG > AGB [18,21]. These four methods have the following efficacy:

- BPD 65-75% [18]
- RYGB 60-70%[18]
- SG 60-65% [21]
- AGB 45-55% [18]

Most of the available reviews addressing particular bariatric techniques do not consider the results of sleeve gastrectomies. This is a relatively new technique, described by Hess et al. [22] in 1988 as one of the two stages of BPD-DS procedure, and has been used as a stand-alone procedure since 2004. It has gained popularity both in Europe and the United States since 2000, when the team of M. Gagner described a laparoscopic approach of BPD-DS [23].

The gastric banding is the only fully reversible bariatric procedure and the adjustable gastric band allows mini-invasive corrections of the degree of the gastrointestinal tract restriction. This adjustment is possible thanks to the balloon that is an integral part of the band and can be filled up through the silicone port implanted in the subcutaneous tissue. Patients with implanted adjustable band have to undergo regular follow-up visits every 6-12 weeks for the adjustment of the gastric restriction allowing modifications of the extent and the speed of weight loss.

Several scoring systems, such as SF-36, the Sickness Impact Profile, or the Quality of Well-Being Scale, were used to assess outcomes of bariatric surgery [24-26]. The most complex approach to the assessment of outcomes is the bariatric analysis and reporting outcomes system (BAROS) [27]. The BAROS scale was created in the 1990s and updated in 2009 [27,28]. The final outcome of surgery is based on the %EWL, complications, postoperative resolution or improvement of comorbid conditions, quality of life in five domains (self-esteem, physical, occupational,
social and sexual activity) and reoperations [27,28]. The most basic and most frequently used outcome assessment is based on the excessive weight reduction (%EWL) [29]. The loss of at least 50% of excess weight is considered a good outcome [29].

There are several comorbid conditions related to pathological obesity, including arterial hypertension, diabetes mellitus, asthma, ischemic heart disease, obstructive sleep apnea, osteoarthritis, thyroid disorders and depression [27]. Moreover, the comorbid conditions and not just the excessive weight present the highest burden and health-risk for obese patients. The survival time correlates inversely to the BMI, as a result of obesity and its comorbidities [30,31]. Therefore, the main outcome of bariatric surgery is not simply the body mass reduction but also a resolution or at least improvement of comorbid conditions [27,32-35]. The Swedish Obesity Study, the largest population study so far, showed that bariatric surgery leads to the reduction of long-term mortality by 29% (hazard ratio, HR = 0.71) and is accompanied by the lower occurrence of diabetes, cardiac events, strokes and neoplasms [32].

One of the major discoveries of the past years was the positive impact of bariatric surgery on diabetes type 2. Diabetes resolved with adjusted odds ratio (OR) of 8.42 at 2 years and OR of 3.45 at 10 years [32]. According to the meta-analysis by Buchwald et al. [36], a complete remission of diabetes was achieved in 78% of patients at 2 years. The highest proportion of complete diabetes remissions was in BPD patients (95%) and the lowest in LAGB patients (57%). These facts initiated the discussion on the use of bariatric operations as a primary treatment in diabetic patients with BMI < 35 kg/m² [37-44].

The number of possible intraoperative, perioperative and late complications correlates with the difficulty of the method. Classification of bariatric complications is a part of the BAROS scale and divides complications into surgical and medical, major and minor, as well as early and late [27]. Surgical complications are a direct derivative of the complexity of the particular technique. The
risk of complications and their severity are proportional to the number of resections and anastomoses of the gastrointestinal tract. Restrictive techniques have the smallest number of complications in contrast to the techniques with complex mechanisms of action. Among the restrictive techniques, sleeve gastrectomy is associated with the highest number of complications. The main reason for this is the resection of the very well vascularized greater gastric curvature. It leads to hemorrhages and anastomotic dehiscence. These complications are also frequently seen following BPD-DS, and RYGB operations are also frequently followed by these complications. The serious surgical complications include intraabdominal abscess, wound dehiscence and infection, splenic damage or infarct, damage to other internal organs, bowel obstruction or intussusception. Late complications are usually peptic ulcers, cholelithiasis, dehiscence of the gastrointestinal wound at the anastomosis, fistulas and in the case of AGB – its erosion into the gastric lumen, slippage of the band or its uncoupling from the port, which requires reoperation [27]. Bariatric surgery is associated with early (30-day) mortality at the level of 0.25-1.5%, depending on the type of procedure, patient’s general condition and comorbidities [10].

Within the last decade, the use of mini-invasive techniques and laparoscopy in obese patients has considerably changed. At present, European and American guidelines recommend the use of laparoscopy in the surgical management of obesity in order to reduce the perioperative tissue trauma [16,18-20]. At the same time obesity was deleted from the contraindications’ lists for general laparoscopic surgery. Laparoscopy is mainly utilized in the relatively easy restrictive techniques [33,45-47], but is also used in operations with complex mechanism of action [48,49].

The development of the instrumentation for single incision laparoscopic surgery (SILS) allows further minimization of the perioperative trauma in bariatric surgery, and several studies demonstrated the feasibility and satisfactory outcomes of such
operations [50-63]. Mini-invasive surgery may also be performed through the natural orifice transluminal endoscopic surgery (NOTES). The first clinical study assessing the feasibility of AGB operation with NOTES technique was performed in Poland [64]. Nevertheless, bariatric SILS and NOTES operations are not yet routinely used due to their complexity and remain investigational procedures.
Objectives of the thesis

The aim of this dissertation is:

1. To assess the efficacy of the surgical treatment for morbid obesity with use of SG and AGB techniques performed with standard laparoscopy, SILS and NOTES;
2. To analyze early and late complications of the surgical treatment for morbid obesity with use of SG and AGB techniques performed with standard laparoscopy, SILS and NOTES.

These objectives have been addressed in a series of six published scientific papers constituting the thesis:


Major findings

I. The first article: ‘Preliminary outcomes 1 year after laparoscopic sleeve gastrectomy based on bariatric analysis and reporting outcome system (BAROS)’, published in *Obesity Surgery* in 2011, is a prospective analysis of outcomes of the surgical treatment for morbid obesity according to the BAROS scoring system developed by Oria and Moorehead in 1998 [27,33]. This study showed that:
1. LSG procedures provide acceptable level of the %EWL with good general outcomes according to the BAROS scale;
2. This treatment allows a significant improvement or full resolution of comorbid conditions;
3. Further studies are required to investigate the occurrence of complications typical for malabsorptive procedures.

II. The second article: ‘Splenic infarction as a complication of laparoscopic sleeve gastrectomy’, published in the quarterly *Videosurgery and Other Mini-invasive Techniques* in 2011, describes a typical complication of the LSG technique, the splenic pole infarction [65]. The main conclusions from the analysis of own material and the literature review of interventions in cases of iatrogenic splenectomies were summarized in the form of recommendations [66-68]:

- Angio-CT three months after the operation;
- Prophylactic administration of low molecular weight heparins;
- Discharge of asymptomatic patients;
- Follow-up visits 7 and 28 days and 3 months after surgery;
- No need for splenectomy and vaccinations for the infarction not exceeding 33% of splenic volume.

III. The article: ‘A 5-year experience with laparoscopic adjustable gastric banding - focus on outcomes, complications, and their management’, published in 2011 in *Obesity Surgery*, analyzes the
efficacy of AGB, another popular laparoscopic restrictive procedure [45]. This article demonstrates that:

1. LAGB is an effective therapeutic option in obesity treatment in well-selected patients;
2. The majority of band-related complications occur later than 30 days from operation and may be managed laparoscopically;
3. The complications of LAGB do not prevent further surgical management of obesity.

IV. The article: ‘Band misplacement: a rare complication of laparoscopic adjustable gastric banding’, published in *Videosurgery and Other Mini-invasive Techniques* in 2012, presents a relatively rare but serious complication of LAGB: the placement of the band in the ante-gastric position [69] showed that:

1. Three out of five surgeons performing LAGB caused such a complication;
2. The majority of these occurrences happened at the beginning of their learning curve.

V. The desire to further minimize perioperative trauma in morbidly obese patients led to the feasibility studies on the utilization of single incision laparoscopic surgery and natural orifice transluminal endoscopic surgery in the surgical treatment of obesity. The first reports of such procedures appeared in 2008, and in 2010 it was possible to summarize the experience with SILS bariatric procedures in the form of a systematic review entitled ‘Bariatric single incision laparoscopic surgery – review of initial experience’, published in *Videosurgery and Other Miniinvasive Techniques* in 2011 [50]. Major conclusions of this articles are:
1. LAGB and LSG procedures using the SILS technique are feasible and are associated with an acceptable level of complications;
2. Outcomes are comparable to the results of LAGB and LSG in the multiport laparoscopy;
3. Due to small number of patients, no firm conclusions can be drawn, although the initial outcomes are very encouraging.

VI. The need to minimize visible scars led to studies on the NOTES access also in bariatric surgery. The first article reporting the results of the feasibility study on NOTES AGB implantation through the vagina entitled: ‘The first report on hybrid NOTES adjustable gastric banding in human’, was published in 2011 in the *Obesity Surgery* journal [64]. The main findings of this article include:

1. Implantation of an AGB using the hybrid NOTES technique is feasible;
2. The risk of iatrogenic ureter injury necessitates adequate experience in accessing the peritoneal cavity through the vagina.
Summary

This series of articles showed the efficacy and safety of AGB and sleeve gastrectomy in the multiport and SILS laparoscopic technique, as well as AGB in the NOTES technique when used for the surgical treatment of morbid obesity. The outcomes of sleeve gastrectomies are presented in the two initial papers. The first describes the methodology and the LSG technique itself, together with bariatric scoring systems and outcomes of the surgery, and the second presents the results of the analysis of causes and mechanisms of one of the most frequent complications of the LSG procedure, the splenic pole infarction. It also includes the proposal of the diagnostic-therapeutic protocol in such cases. The subsequent two articles present the outcomes of the LAGB procedure and analyze the management of the rare complication of the ante-gastric positioning of the band. The fifth article: a systematic review evaluating the results of further minimization of the perioperative trauma by the use of the SILS technique is based on the results of the treatment of morbid obesity with laparoscopic SG and AGB. Finally, based on the conclusions from the above-mentioned articles, the results of the first three innovative operations of AGB implantation in the hybrid laparoscopic - NOTES technique were presented in the sixth article.

Conclusions:

1. Selected mini-invasive techniques used for the surgical treatment of morbid obesity (adjustable gastric banding and sleeve gastrectomy performed laparoscopically by SILS surgery and the AGB procedure in the NOTES technique) effectively reduce excessive body mass.

2. The analysis of postoperative complications of these techniques confirmed their safety. This analysis, together with the description of the management of treatment
complications, might be helpful for surgeons initiating such procedures.

3. Due to the continuous progress in mini-invasive surgery, further studies on the novel, more effective surgical techniques for the treatment of morbid obesity are warranted.
Rozdział 12. CV

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Curriculum Vitae

Doświadczenie zawodowe

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• 22/09/2008 – 11/07/2010 - rezydentura z chirurgii ogólnej w Oddziale Chirurgii Ogólnej i Naczyniowej Szpitala im. F. Ceynowy w Wejherowie
• Od 01/07/2009 do chwili obecnej – lekarz części zabiegowej Szpitalnego Oddziału Ratunkowego, Powiatowego Centrum Zdrowia w Kartuzach
• 01/08/2006 – 30/08/2008 dwuletni staż na stanowisku Junior House Officer, a następnie Senior House Officer w New Cross Hospital, Royal Wolverhampton NHS Hospitals Trust, Wolverhampton, Wielka Brytania

Kwalifikacje Zawodowe

• Pełne Prawo Wykonywania Zawodu Nr 2350320, wydane przez OIL w Gdańsku z dnia 14/02/2008
• Uzyskanie Pełnego Prawa Wykonywania Zawodu w Brytyjskim General Medical Council Nr GMC 6152399 z dnia 01/08/2007
Niepełne Prawo Wykonywania Zawodu w Brytyjskim General Medical Council 01/08/2006-31/07/2007
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Członkostwo Towarzystw Naukowych

- The European Association for Endoscopic Surgery (No. 4639) od 2010
- Towarzystwo Chirurgów Polskich od 2010
- Sekcja Wideochirurgii Towarzystwa Chirurgów Polskich od 2010
- Polskie Towarzystwo Onkologiczne od 2011

Tłumaczenia Angielski-Polski/Polski-Angielski

- Videosurgery and Other Miniinvasive Techniques Journal, Warszawa, od Sierpnia 2010
- ITEM Publishing, Warszawa, od Listopada 2011
- Oncologia, Medycyna Praktyczna, od 2012

Zainteresowania zawodowe

- chirurgia onkologiczna
- chirurgia minimalnie inwazyjna
- robotyka
- chirurgia kolorektalna
- chirurgia piersi
- onkoplastyka
- badania kliniczne
- biologia molekularna
- biologia nowotworów
Rozdział 13.
Działalność naukowa

I. Oryginalne opublikowane naukowe prace twórcze


II. Pozostałe publikacje: (prace kazuistyczne, prace poglądowe, prace popularno–naukowe)


III. Tłumaczenia książkowe


IV. Opublikowane streszczenia zjazdowe


11. Bobowicz M, Michalik M, Frask A, Trybull A. Transumbilical single incision laparoscopic cholecystectomy with use of a TriPort Access System as a new access device – initial experience. 18th


15. Tytuł oryginału: Bariatric and antireflux surgery in severe, steroid dependent asthmatic with coexisting obesity, chronic obstructive pulmonary disease and pulmonary fibrosis [Dokument elektroniczny]


18. Michalik M, Bobowicz M. Right hemicolecction for caecal adenocarcinoma through LESS. 24th Congress of the International
Society University Colorectal Surgeons, Seoul, South Korea March 19-23, 2010

**Rozdział 14.**
**Podziękowania**

Chciałbym gorąco podziękować wszystkim osobom, bez których realizacja celu powyższej rozprawy nie byłaby możliwa. W szczególności:

Dziękuję promotorowi prof. Januszowi Jaśkiewiczowi za pomoc merytoryczną, liczne wskazówki i nadzór nad postępem prac oraz wsparcie.

Dziękuję promotorowi pomocniczemu dr Wojciechowi Makarewiczowi za pomoc merytoryczną oraz organizacyjną w trakcie realizacji projektu.

Dziękuję dr hab. Maciejowi Michalikowi za możliwość współpracy nad całym projektem, wyrażenie zgody do użycia materiału w powyższej rozprawie oraz szkolenie w zakresie chirurgii minimalnie inwazyjnej, a w szczególności szkolenie z chirurgicznego leczenia otyłości.

Dziękuję panu Andrzejowi Umiastowskiemu za możliwość wykorzystania zdjęcia obrazu umieszczonego na okładce zatytułowanego "Molo" (2009 r).

Szczególne podziękowania składam mojej żonie Joannie, za cierpliwość, wsparcie i czas poświęcony na to, aby przedstawione badanie i poszczególne publikacje uzyskały swoją końcową formę. Dziękuję za całą pracę edytorską i korekty językowe. Dziękuję za czas, który dzięki Tobie mogłem poświęcić badaniom.

Dziękuję całej rodzinie za wsparcie i pomoc w badaniach – dzięki Waszej wiedzy i pomocy na co dzień to wszystko było możliwe.

Dziękuję też Wszystkim pominiętym powyżej, bez których realizacja powyższego badania nie byłaby możliwa.
Rozdział 15.

Piśmiennictwo

30. Mizuno T, Shu IW, Makimura H, Mobbs C. Obesity over the life course. Sci Aging Knowledge Environ 2004;re4


