

Long-term outcomes of sleeve gastrectomy in a patient group with mainly high BMI: a single-center study

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Diese Dissertation ist auf den Internetseiten der Universitätsbibliothek online verfügbar.

Diese Arbeit widme ich meinen Eltern, die mir diesen Weg überhaupt erst ermöglicht haben. Durch ihre bedingungslose Unterstützung, ihr Vertrauen und die Sicherheit, die sie mir stets gegeben haben, konnte ich meinen Weg gehen. Ohne sie wäre diese Dissertation nicht möglich gewesen.

Danke für alles.

Publikationsverzeichnis

Anna Magdalena Thiel

Publikation, die die Dissertation darstellt

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Long-term outcomes of sleeve gastrectomy in a patient group with mainly high BMI: a single-center study

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Abstract

Since long-term results after laparoscopic sleeve gastrectomy (LSG) are rather scarce, this study aims to add LSG results with a minimum of 5 years of follow-up. Prospectively collected data from primary LSG in a tertiary bariatric center from 08/2007 to 12/2018 with follow-up ≥ 5 years were analyzed retrospectively. Primary endpoints included total body weight loss (%TBWL) and excess weight loss (%EWL), insufficient weight loss (IWL), weight regain (WR), remission of associated diseases, development of new-onset gastroesophageal reflux disease (GERD), and nutritional deficiencies. Furthermore, the study focused on incidence, time point, and causes of conversion and revision operations. A total of 207 LSG (132 female, mean age $43 (\pm 10.7)$ years) entered this study. 33.3% (52 of 156 without conversion) were lost to follow-up for ≥ 5 -year data. Perioperative mortality was 0.5% ($n=1$). %TBWL was 27.1% (± 12.4) and %EWL 52.5% (± 24.3). IWL or WR was found in 48.8%, new-onset GERD occurred in 27.5% of cases, leading to conversion in 26.6% and revisions in 2%. Nutritional deficiencies were observed in 23.7%, while resolution of associated diseases was sufficient. This patient group with a mean BMI $> 50 \text{ kg/m}^2$ at baseline showed fair results regarding weight loss issues and remission of associated diseases at ≥ 5 years postoperatively. Yet, a rate of 48.8% of either IWL and/or WR and 27.5% of new-onset GERD required conversion and revision operations in 28.6%. To better learn about long-term results of LSG, further studies preferably with larger multicenter samples and comparisons with alternative primary procedures, preferably in a prospectively randomized approach, possibly with focus on high BMI patients, are required.

Keywords Sleeve gastrectomy · Long-term results · Conversion operation · Reflux · Malnutrition

Introduction

Bariatric surgery is considered to be the most powerful treatment of severe obesity and its associated diseases [1, 2]. The additional life expectancy for patients with obesity after bariatric surgery has been estimated to be as high as 5 years

for patients without diabetes and 9 years for patients with diabetes [3].

Since 2014, laparoscopic sleeve gastrectomy (LSG) represents the most frequently performed bariatric surgery globally [4, 5].

LSG is considered a viable surgical option for a patient group with a high BMI, providing a safe and easily implementable choice that delivers good weight loss results [6–8].

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However, long-term data are contradictory with recent reporting of good long-term-result on one side [9–12] and frequent need for revisional surgery after LSG on the other side due to weight regain [13] and new-onset gastroesophageal reflux disease (GERD) [14–17]. Furthermore, real-world data appear to differ in terms of weight loss and remission of comorbidities from data from large randomized-controlled trials [6, 10–12, 18, 19].

To address complications from primary LSG, achieve further weight reduction, and manage the recurrence or persistence of associated diseases, there is a growing trend toward performing revision and conversion operations, which have been shown to bring additional improvements [20].

This analysis of primary LSG in mainly high BMI patients was designed to evaluate the outcome of LSG in a real-world setting.

Methods

Prospectively collected data from patients who underwent primary LSG at a single tertiary bariatric center in Germany between August 2007 and December 2018 were descriptively analyzed. Data collection was conducted through routine follow-ups and additionally completed by a questionnaire. It contained questions about: current weight, lowest weight after surgery, status of comorbidities (classified as unchanged, improved and worsened), reflux symptoms with and without PPI, and overall well-being rated on a school grading scale.

The data collection was conducted via a platform provided by the German Society of General and Visceral Surgery (Study, Documentation and Quality center, StuDoQ [21]). Between 2007 and 2011, only 207 bariatric operations were performed. Following a 5-year implementation phase of our bariatric surgery program, a total of 1.751 procedures have been performed between 2012 and 12/2018, with an average of about 250 operations per year. Among the annual 250 bariatric operations, only an average of 22 LSGs were performed, indicating that mainly other procedures (such as gastric bypass) comprised the main activity of the study center (see Table 1).

Statistical analysis

The data were analyzed using the SPSS statistical software (version 29, Germany). Numerical data were presented as mean and standard deviation and categorical values were expressed as counts and percentages. The hypothesis test was conducted by the paired samples *t* test and considered significant with a *p* value < 0.05.

Table 1 Distribution of LSGs performed over the years

Year	<i>n</i>
2007	2
2008	10
2009	21
2010	19
2011	26
2012	13
2013	8
2014	14
2015	18
2016	13
2017	28
2018	57

Patient assessment

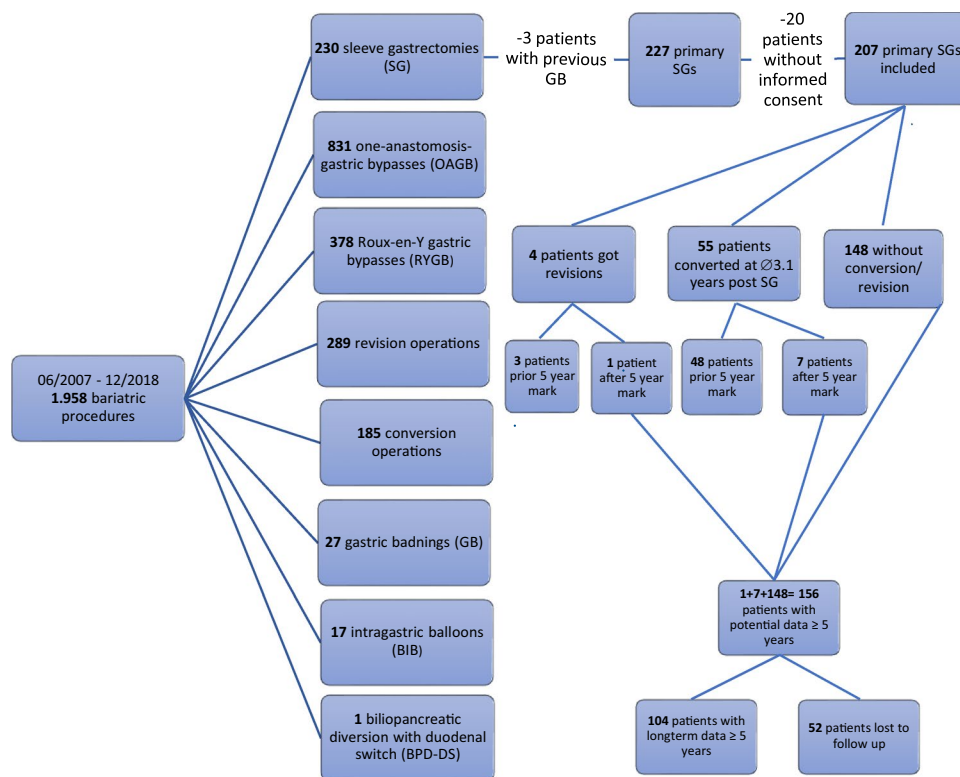
Patients with obesity were planned for surgery by adhering to the national guidelines for bariatric and metabolic surgery [22]. The preoperative set-up included a conservative multimodal treatment program incorporating counseling by nutritionists and psychologists, and additional enhanced physical therapy. The decision for surgical intervention was based on a comprehensive multidisciplinary evaluation, encompassing assessments by medical, surgical, psychiatric, and nutritional experts. Laboratory testing, abdominal ultrasound, and esophagogastroduodenoscopy were preoperative standard examinations for all patients. Patients with large hiatus hernia (≥ 4 cm), high grade reflux disease with esophagitis $\geq$ grade B according to the Los Angeles classification, and dependence on high dosages of proton pump inhibitors (PPI), were considered not suitable for LSG.

Simultaneous hiatal hernia repair was performed in five patients (2.4%) with preoperatively diagnosed hiatal hernias but who had contraindications for gastric bypass.

Out of 227 primary LSGs from 06/2007 to 12/2018, 20 (8.8%) patients did not give their consent for the processing of their data and were excluded. A flow chart is provided in Fig. 1. Follow-up was scheduled at 3, 6, 12, 18 months, and followed by annual intervals. At baseline, age, gender, weight, BMI, and comorbidities were registered. Out of 207 patients, 156 had the potential for long-term data on primary SG. Specifically, of the 207 patients, 148 had no conversion operations, 55 patients had a conversion, and 4 patients had a revision operation, 7 of which were converted and 1 who was revised after the 5-year mark. Thus, $148 + 7 + 1 = 156$ patients had the potential for long-term data. Of these, 104 (66.7%) had at least one follow-up at ≥ 5 years, while 52 (33.3%) patients were lost to follow-up.

Weight loss was expressed by %TBWL, %EWL, BMI loss, and nadir. Development of de novo GERD, remission

Fig. 1 Distribution of bariatric procedures between June 2007 and December 2018 and presentation of reoperations



of associated diseases, nutritional deficiencies, IWL and WR (according to Reinhold's criteria [23]), revision and conversion operations, and their outcomes were documented. The data regarding IWL/WR and reflux apply to the entire cohort of 207 patients, without specifying a specific time point of occurrence. After reoperation, patients were re-evaluated, and remission was documented if applicable.

In those patients experiencing GERD postoperatively, we initiated upper endoscopy and contrast studies, with manometry and pH-metry performed only in selected cases. Besides documenting the subjective experience of GERD, objective findings, which may include hiatal hernias and varying degrees of reflux esophagitis, were recorded.

Surgery

Of the 227 SGs, 78 procedures were performed during the implementation phase from 2007 to 2011 and included in the study. The remaining two-thirds of the total study population underwent surgery in the subsequent years, following the implementation phase, by the same surgical team. The performing surgeons used a standardized laparoscopic technique. After beginning dissection approximately 3–5 cm proximal of the pylorus, the greater curvature was mobilized up to the angle of His. A 36 Fr Bougie was placed along the lesser curvature to assist the vertical transection using a linear stapler, with particular focus on the complete

resection of the posterior fundus. Oversewing of the proximal 5–6 cm of the staple line and placing of a drain were usually performed.

Patients were permitted to drink sip-by-sip at the day of surgery and without restriction at the first postoperative day. A liquid diet was introduced at the second day.

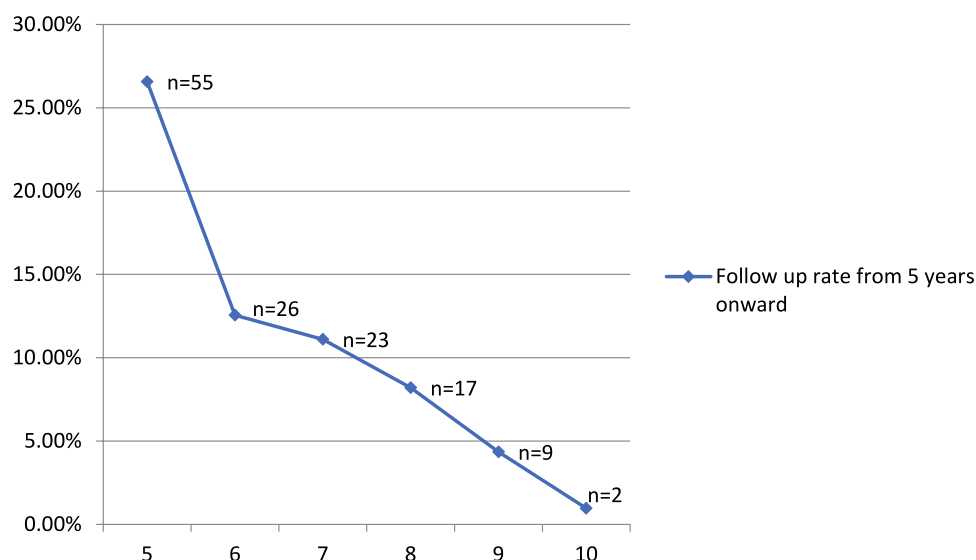
Results

A total of 207 patients were included. Gender distribution was 63.8% ($n = 132$) female and 36.2% ($n = 75$) male with a mean age of $43.3 (\pm 10.7)$ years. The mean preoperative weight was $157.7 (\pm 36.0)$ kg with BMI of $54.4 (\pm 10.1)$ kg/m² and a mean overweight of $85.2 (\pm 32.0)$ kg. There was one mortality case (0.5%) in the early postoperative phase (30 days) following an incarcerated umbilical herniation with small bowel ischemia (sleeve revision without remarkable findings).

Out of 207 patients, 156 had the potential for long-term data on primary SG. Of these, 104 (66.7%) had at least one follow-up at ≥ 5 years, while 52 (33.3%) patients were lost to follow-up either due to lack of compliance or non-communicated reoperations at other institutions. In addition, it is important to note that 57 patients underwent surgery as recently as 2018, indicating that future data updates are likely.

The follow-up rate is described in Fig. 2.

Fig. 2 Follow-up rates for data collected ≥ 5 years. Data beyond 10 years were censored due to low follow-up rates. The 132 mentions do not equate to 132 unique patients, as multiple mentions occurred. The 66.4% follow-up rate is based on a total of 104 individuals who presented for follow-up within the 5 to 14-year timeframe



The patients exhibited an average of 3.5 associated diseases. 95.6% ($n = 196$) had osteoarthritis, 72.7% ($n = 149$) arterial hypertension, 62.0% ($n = 127$) obstructive sleep apnea syndrome, 42.4% ($n = 87$) type 2 diabetes mellitus, and 12.2% ($n = 25$) had coronary artery disease or myocardial infarction (see Fig. 3). Data on associated diseases were unavailable for two patients, resulting in the analysis being based on a cohort of 205 patients.

The nadir-weight and BMI were measured from 1 year postoperative onwards but prior to any conversion or revision operation. The mean nadir for weight was 105.4 (± 29.3) kg and for BMI 36.4 (± 8.7) kg/m². The data represented highly significant improvements in comparison to baseline weight and BMI ($p < 0.001$). These data were available in 88.9% ($n = 184$).

Insufficient weight loss or weight regain was observed in 48.8%. New-onset GERD occurred in 27.5%. Here, the data encompass the entire study cohort.

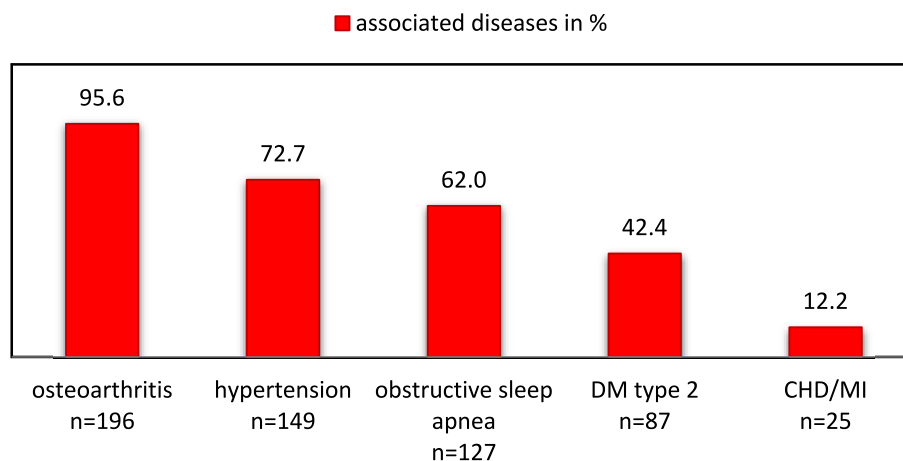
At a minimum of 5 years post-primary LSG, patients exhibited a mean BMI of 39.2 (± 8.8) kg/m², with a weight of 114.7 kg (± 30.9) ($p < 0.001$). %TBWL was 27.1 (± 12.4)%, %EWL was 52.5 (± 24.3)%, and there was a reduction of 14.5 (± 7.8) BMI points (see Fig. 4). The data are based on 104 patients, as described in Fig. 2.

Nutritional deficiencies were observed in 23.7% ($n = 49$). 75.5% ($n = 37$) presented with any kind of vitamin deficiency, 46.9% ($n = 23$) iron deficiency, 24.5% ($n = 12$) calcium deficiency, and 12.2% ($n = 6$) had hypoproteinemia (see Fig. 5).

Resolution of associated diseases

Remission of associated diseases was assessed only at the fifth year postoperatively to avoid bias in mean values due to multiple entries. Consequently, alternative follow-up rates for the associated diseases are demonstrated. Of the initial 127 patients with sleep apnea syndrome, only 35 returned

Fig. 3 Occurrence of associated diseases in percent (DM type 2 = diabetes mellitus type 2, CHD/MI = chronic heart disease or previous myocardial infarction)



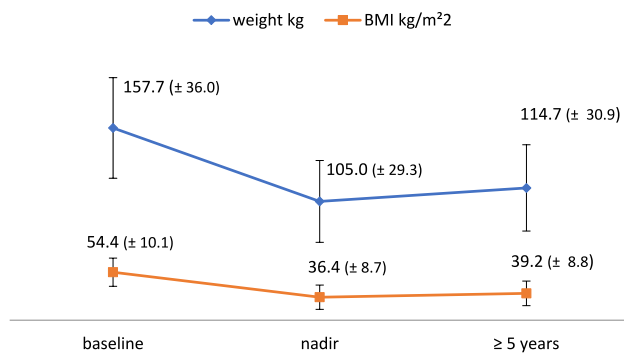


Fig. 4 Weight trend after primary LSG: from baseline to nadir to long-term outcome

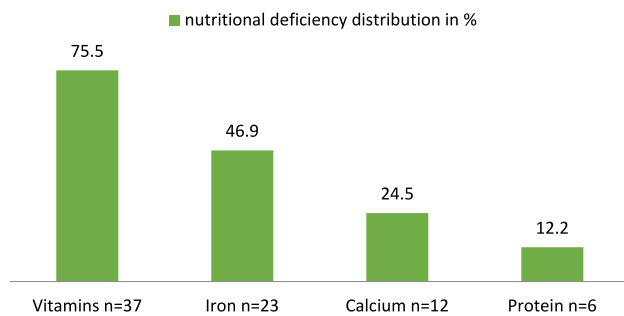


Fig. 5 Nutritional deficiencies after primary LSG were observed in 23.67%. The diagram depicts the distribution of deficiencies

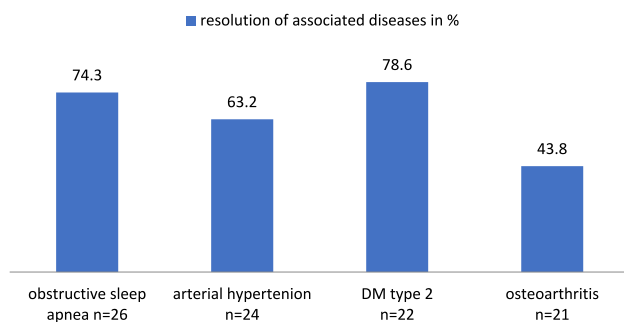


Fig. 6 Resolution of associated diseases visualized exclusively for the fifth year

for follow-up at the fifth year, resulting in a follow-up rate of 27.6%. Out of the 35 attending patients, 26 are in full remission. This pattern can also be applied to the remaining results for the associated diseases: 27.6% ($n=35/127$) for sleep apnea syndrome, 25.5% ($n=38/149$) for arterial hypertension, 32.2% ($n=28/87$) for type 2 diabetes mellitus, and 24.5% ($n=48/196$) for osteoarthritis.

Full remission rates were as follows: 74.3% ($n=26/35$), 63.2% ($n=24/38$), 78.6% ($n=22/28$), and 43.8% ($n=21/48$), respectively (see Fig. 6).

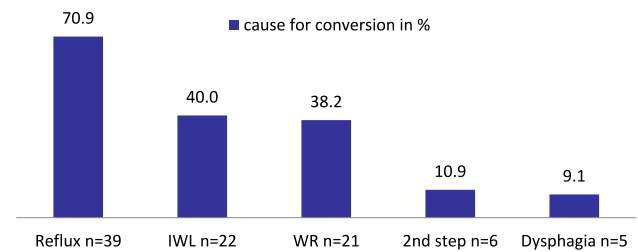


Fig. 7 Description of causes for a conversion operation in percent

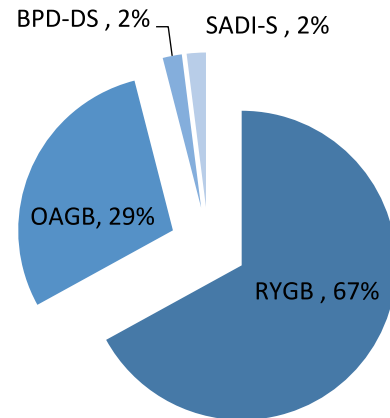


Fig. 8 Performed procedures in conversion operations

Conversion and revision operations

Conversion operations were performed in 55 patients (26.6%). The mean time after primary LSG was 36.9 (± 25.4) months. Causes for conversion included the deterioration of pre-existing and development of new-onset-reflux disease (70.9%, $n=39$), insufficient weight loss (40.0%, $n=22$), weight regain (38.2%, $n=21$), dysphagia (9.1%, $n=5$), as part of a planned second step (10.9%, $n=6$), or a combination of the above (see Fig. 7).

The most commonly performed procedure was Roux-Y-gastric bypass (RYGB) (67%, $n=37$) followed by one anastomosis gastric bypass (OAGB) (29%, $n=16$), Biliopancreatic diversion with duodenal switch (BPD-DS) (2%, $n=1$), and single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S) (2%, $n=1$) (see Fig. 8).

Results after conversion

Reflux symptoms significantly improved in 20.5% ($n=8$), and partially in 15.4% ($n=6$) (data missing in 64.1%, $n=25$). Dysphagia resolved in 40% ($n=2$), 60% ($n=3$) had no improvement. Before conversion, the mean weight and BMI in the group with IWL were 132.8 (± 27.5) kg and 44.1 (± 6.4) kg/m² and for the group with WR, it was 138.8 (± 23.0) kg and 48.0 (± 6.0) kg/m². One year after

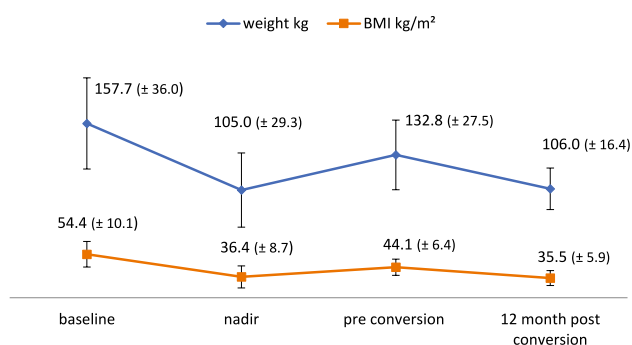


Fig. 9 Weight trend with results 12 months after conversion for the group with IWL following primary LSG

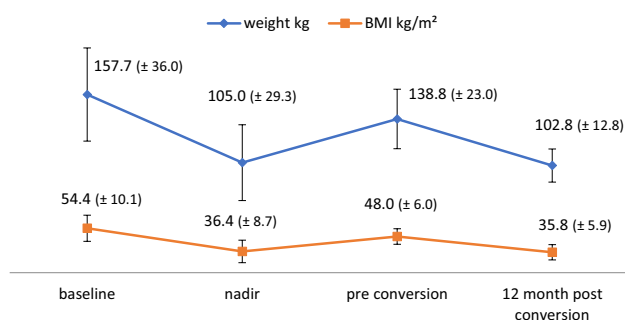


Fig. 10 Weight trend with results 12 month after conversion for the group with WR following primary LSG

conversion, the mean weight and BMI for the IWL group were 106.0 (± 16.4) kg and 35.5 (± 5.9) kg/m², respectively, and 102.8 (± 12.8) kg (see Fig. 9) and 35.8 (± 5.9) kg/m² for the WR group (see Fig. 10) ($p < 0.001$ in both groups). Data were available in 54.5% ($n = 12/22$) in the IWL and 40.9% ($n = 9/21$) in the WR group.

Results after revision

Four patients (2%) received a revision operation because of IWL ($n = 2$) and reflux ($n = 3$). The symptoms of all patients with reflux improved following a hiatal hernia repair. For the patients with re-sleeve ($n = 2$) operation or minimizer-ring implantation ($n = 1$), the 1-year follow-up data were unavailable.

Discussion

After initial enthusiasm regarding LSG, long-term results increasingly revealed undesirable observations such as new-onset GERD or IWL/WR. Kraljević et al. [24] reported 6-year outcomes following primary LSG (pLSG, $n = 262$) or LSG as a redo procedure after laparoscopic adjustable

gastric banding (rLSG, $n = 45$). They reported good weight loss results (%EBMIL = $61.6 \pm 25.2\%$ for pLSG and $50.1 \pm 22.2\%$ for rLSG). De novo reflux occurred in 32.4% and the full remission rates for comorbidities were good: hypertension (60.5%), T2DM (61%), GERD (45.8%), dyslipidemia (46%), sleep apnea (50.2%), and arthralgia (50.3%) (mean follow-up time of 7.5 ± 3.4 years postoperatively). Revisions were performed later than in our study (4.2 ± 2.6 years) and slightly less frequently (19.2%), but for similar reasons as we described: IWL (40.7%), reflux (20.3%), or a combination of both (39%).

In the recent published “SleeveBypass” study by Biter et al. [18], the 5-year outcomes of LSG and RYGB were compared in a phase III multicenter randomized-controlled trial. This study included a substantial randomized cohort of 312 patients undergoing LSG. The findings closely paralleled those of our study, particularly in terms of weight loss (22.5% TWL). Although we reported a superior rate of full remission of comorbidities, their study demonstrated a lower incidence of new-onset GERD (16.0%). They reported overall fewer revisional operations (12.5%) and among these were fewer surgical revisions due to new-onset GERD (28.2%). In earlier randomized trials such as the “SleevePass” study [11] and the “SM-BOSS” trial [12], LSG compared to RYGB demonstrated similarly favorable outcomes in terms of weight loss. Focusing on the outcomes of primary LSG in the “SleevePass” study, the %EWL was 49.0%, and the reoperation rate was 8.3%. In the SM-BOSS trial, the excess BMI loss was 61.1% with a reoperation rate of 15.8%.

Upon comparison with the existing literature, a significant observation in our results is the notably high rate of conversion operations (26.6%). In contrast to our findings, Lazdazi et al. [25] reported an expected conversion rate of 4.7% after 5 years and 12.2% after 10 years following SG. This assessment might potentially be associated with the elevated baseline BMI within our patient group. In our center, we observed that the majority of conversions occurred prior to the 5-year mark, with the reoperation rate decreasing significantly after this period (3.8%). Moreover, the elevated lost-to-follow-up rate suggests that a possibly relevant number of patients might have undergone subsequent surgical interventions without our awareness.

Furthermore, the comparisons suggest that the surgical expertise and proper technique appears to play a role in the surgical outcome after LSG. Hiatal hernia repairs, an appropriate distance to the incisura angularis and resection of the entire posterior fundus were elaborated to contribute to good results [26]. The underlying mechanism contributing to the high rate of reflux disease appears to be multifactorial. The lower esophageal sphincter pressure is influenced by altering the angle of His and by the dissection of ligaments and gastric sling fibers. The low sleeve volume acts as a

high-pressure reservoir which is linked to a decreased gastric compliance and reduced emptying [27, 28]. Given this contextual understanding and considering our surgical technique, the attained substantial weight reduction outcomes and rates of full remission of comorbidities seem credible when comparing with the long-term findings reported in other studies, as does the elevated incidence of reflux.

In our center, the patient group that received LSG exhibited an above-average level of obesity and associated comorbidities with a mean weight of 157.7 ($\pm$ 36.0) kg, a BMI of 54.4 ($\pm$ 10.1) kg/m², and an initial presence of 3.5 comorbidities per patient [29, 30]. In addition, a high prevalence of coronary artery disease or myocardial infarction, with a rate of 12.2%, compared to the broader database of bariatric patients (n = 4539) at this hospital, where the rate was 5.8%, was observed and furthermore underscores the aforementioned observation.

LSG as a single procedure, rather than as part of a first- and second-step approach in patients with high BMI, seems undoubtedly to result in a relatively high rate of IWL. Nevertheless, for patients with high BMI and severe comorbidities, LSG appears to be a viable option, leading to significant improvement in their health condition. However, since IWL and or WR as well as new-onset reflux disease presents a challenge, these patients benefit from conversion operations, resulting in a further reduction of BMI in kg/m² by 8.5 points in the IWL group and 12.2 points in the WR group which corresponds to our own 2-year data of LSG conversions to RYGB or OAGB [31].

Limitations

The primary limitation of this study is the high lost-to-follow-up rate, which indicates that the actual rates of unfavorable weight loss outcomes and reoperations may be even substantially higher than reported. Further limitations encompass that this study includes data from the initial experience with LSG and the bariatric surgery program. In addition, SG represents only 11.8% of the center's total surgical activity. The questionnaire that was used only collected qualitative data, with the exception of weight measurements. Limited outcome data from the period beyond 12 months after conversion and revision surgeries were available. In the early stages of the bariatric program, it was decided to collect qualitative rather than quantitative data on nutritional parameters. Due to the nature of the data collection, the specific timing of the occurrence of IWL/WR and reflux cannot be precisely assigned. The non-randomized allocation of patients represents another significant limitation. The WR observed in the long-term results appeared relatively low, contrasting with the substantial percentage (48.8%) of patients experiencing IWL or WR. This was certainly due

to the high rate of conversion operations (26.6%) at a mean of 3.1 ($\pm$ 2.1) years.

Conclusion

This primary LSG patient group, with a mean BMI of 54.4 kg/m², achieved fair results in terms of weight loss and resolution of associated diseases at $\geq$ 5 years, considering the high BMI and the significant percentage of associated diseases at baseline. Yet, a rate of 48.8% of patients experienced either insufficient weight loss and/or weight regain, and 27.5% developed new-onset gastroesophageal reflux, at an unspecified time after LSG, which caused the need for conversion and revision operations in 28.6%. Nutritional deficiencies following SG do not appear to be negligible and require further attention and evaluation. Further long-term studies are required, preferably with larger multicenter samples, comparisons with alternative primary procedures, and a prospectively randomized approach, focusing on higher follow-up rates and especially on data for patients with a high BMI.

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Author contribution Anna Thiel: data curation, first draft manuscript. Andreas Plamper: prospective data collection, manuscript revision. Julia Kroll: manuscript revision. Patrick H. Alizai: manuscript revision. Sophia M. Schmitz: conception, manuscript revision. Karl P. Rheinwald: conception, prospective data collection, manuscript revision. All authors read and approved the final manuscript.

Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The authors have no conflicts of interest or disclosures to report.

Ethical approval The study was executed according to the ethical standards of the institution. It is consistent with the 1964 Helsinki declaration and its revisions. A written informed consent was obtained from all patients.

Research involving human participants and/or animals This article does not contain any studies directly involving human participants, as it is a review of data already collected in a database.

Informed consent All participants provided informed consent prior to their data collection.

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	Alter bei OP	Gewicht präop/kg	Größe präop/m	BMI präop/ kg/m ²	Über- gewicht/kg	weiblich	Geschlecht männlich	Gesamt
Mittelwert	43,32	157,65	1,70	54,35	85,23			
Standardabweichung	10,74	35,95	0,10	10,13	32,00			
Minimum	18,00	95,00	1,52	35,12	30,20			
Perzentil 25	36,00	130,00	1,62	46,37	59,54			
Median	44,00	152,80	1,69	53,17	81,78			
Perzentil 75	52,00	179,00	1,78	61,25	105,39			
Maximum	67,00	276,00	1,97	87,11	196,79			
Anzahl						132	75	207
Anzahl als Zeilen (%)						63,8%	36,2%	100,0%

Häufigkeiten von Begleiterkrankungen

		Antworten	
		N	Prozent
Begleiterkrankungen	Ortho	196	95,6%
	Hypertonie	149	72,7%
	Dyslipopro	145	70,7%
	OSAS	127	62,0%
	DM	87	42,4%
	KHK/MI	25	12,2%
Gesamt		729	355,6%

IWL/ WR

		Häufigkeit	Prozent
Gültig	ja	101	48,8%
	nein	106	51,2%
Gesamt		207	100,0%

Reflux

		Fälle				Gesamt	
		ja	nein			N	Prozent
		N	Prozent	N	Prozent		
Reflux		57	27,5%	150	72,5%	207	100,0%

Malnutrition

	N	ja	Prozent
Malnutrition		49	23,7%

Häufigkeiten von Malnutrition

		Antworten	
		N	Prozent der Fälle
Malnutrition Kategorie ^a	Eiweiß/Albumin	6	12,2%
	Eisen	23	46,9%
	Calcium	12	24,5%
	Vitamine	37	75,5%
Gesamt		78	159,2%

NADIR und BMI ab 1. Jahr

Statistiken

NADIR

N	Gültig	184
	Fehlend	23
Mittelwert		105,4033
Median		99,2000
Std.-Abweichung		29,26833
Spannweite		162,40
Minimum		50,60
Maximum		213,00

Statistiken

BMI bei NADIR

N	Gültig	184
	Fehlend	23
Mittelwert		36,4374
Median		35,5554
Std.-Abweichung		8,66535
Spannweite		43,76
Minimum		21,26
Maximum		65,02

Statistik bei gepaarten Stichproben

		Mittelwert	N	Std.-Abweichung	Standardfehler des Mittelwertes
Paaren 1	Gewicht präop/kg	156,6180	200	35,59368	2,51685
	NADIR	103,5600	200	28,72342	2,03105

Test bei gepaarten Stichproben

	Gepaarte Differenzen						Signifikanz	
	Mittelwert	Std.- Abweichung	Standardfehler des Mittelwertes	95% Konfidenzintervall der Differenz		T	df	
				Unterer Wert	Oberer Wert			
Gewicht präop/kg - NADIR	53,05800	33,49398	2,36838	48,38765	57,72835	22,403	199	Einseitiges p 0,000 Zweiseitiges p 0,000

Effektgrößen bei Stichproben mit paarigen Werten

		Standardisierer ^a	Punktschätzung	95% Konfidenzintervall	
				Unterer Wert	Oberer Wert
Gewicht präop/kg - NADIR	Cohen's d	33,49398	1,584	1,375	1,791
	Hedges' Korrektur	33,62088	1,578	1,370	1,785

Fallzusammenfassung

	Gültig		Fälle		Gesamt	
	N	Prozent	N	Prozent	N	Prozent
Ab 5 Jahren	104	50,2%	103	49,8%	207	100,0%

D.h. 104 Patienten haben insgesamt Werte die im Jahr 5 oder darüber hinaus gemessen wurden.

	Gewicht präop/kg	aktuelles Gewicht 5J	aktuelles Gewicht 6J	aktuelles Gewicht 7J	aktuelles Gewicht 8J	aktuelles Gewicht 9J	aktuelles Gewicht 10J	aktuelles Gewicht 11 J	aktuelles Gewicht 12 J	aktuelles Gewicht 13J	aktuelles Gewicht 14 J
	Gewicht präop/kg (n=206)	aktuelles Gewicht 5J (n=55)	aktuelles Gewicht 6J (n=26)	aktuelles Gewicht 7J (n=23)	aktuelles Gewicht 8J (n=17)	aktuelles Gewicht 9J (n=9)	aktuelles Gewicht 10J (n=2)	aktuelles Gewicht 11 J (n=2)	aktuelles Gewicht 12 J (n=1)	aktuelles Gewicht 13J (n=3)	aktuelles Gewicht 14 J (n=2)
Anzahl	207	207	207	207	207	207	207	207	207	207	207
Fehlend	1	152	181	184	190	198	205	205	206	204	205
Gültige Anzahl	206	55	26	23	17	9	2	2	1	3	2
Mittelwert	158	109	119	106	123	111	144	108	220	132	148
Standardabweichung	35,95	25,5	31,2	25,8	36,3	45,4	51,5	38,9		78,3	35,9

Gepoolt (ab Jahr 5):

	aktuelles Gewicht 5J
Anzahl	207
Fehlend	
Gültige Anzahl	140
Mittelwert	114,66
Standardabweichung	30,87

	BMI präop/ kg/m2	aktuelle r BMI 5J	aktuelle r BMI 6J	aktuell er BMI 7J	aktuell er BMI 8J	aktuelle r BMI 9J	aktuelle r BMI 10J	aktuell er BMI 11J	aktuelle r BMI 12J	aktuelle r BMI 13J	aktuell er BMI 14J
	BMI präop/ kg/m2 (n=20 6)	aktuelle r BMI 5J (n=55)	aktuelle r BMI 6J (n=26)	aktuell er BMI 7J (n=23)	aktuell er BMI 8J (n=17)	aktuelle r BMI 9J (n=9)	aktuelle r BMI 10J (n=2)	aktuell er BMI 11J (n=2)	aktuelle r BMI 12J (n=1)	aktuelle r BMI 13J (n=3)	aktuell er BMI 14J (n=2)
Anzahl	207	207	207	207	207	207	207	207	207	207	207
Fehlend	1	152	181	184	190	198	205	205	206	204	205
Gültige Anzahl	206	55	26	23	17	9	2	2	1	3	2
Mittelwert	54,35	38,06	40,38	37,34	39,82	38,98	44,68	36,01	67,90	45,16	46,45
Standardabweichung	10,13	7,26	9,11	8,12	9,22	13,71	15,38	6,72		20,68	10,17

	aktueller BMI 5J
Anzahl	207
Fehlend	
Gültige Anzahl	140
Mittelwert	39,20
Standardabweichung	8,78

	TBWL % 5J	TBWL % 6J	TBWL % 7J	TBWL % 8J	TBWL % 9J	TBWL % 10J	TBWL % 11J	TBWL % 12J	TBWL % 13J	TBWL % 14J
	TBWL % 5J (n=55)	TBWL % 6J (n=26)	TBWL % 7J (n=23)	TBWL % 8J (n=17)	TBWL % 9J (n=9)	TBWL % 10J (n=2)	TBWL % 11J (n=2)	TBWL % 12J (n=1)	TBWL % 13J (n=3)	TBWL % 14J (n=2)
Anzahl	207	207	207	207	207	207	207	207	207	207
Fehlend	152	181	184	190	198	205	205	206	204	205
Gültige Anzahl	55	26	23	17	9	2	2	1	3	2
Mittelwert	28,07%	27,15%	28,75%	28,09%	26,86%	21,75%	20,77%	- 6,28%	15,95%	17,77%
Standardabweichung	12,97%	10,49%	12,19%	13,38%	14,74%	12,31%	11,92%		20,08%	2,45%

	TBWL % 5J
Anzahl	207
Fehlend	
Gültige Anzahl	140
Mittelwert	27,09%
Standardabweichung	12,43%

	EWL % 5J	EWL % 6 J	EWL & 7J	EWL % 8J	EWL % 9J	EWL % 10J	EWL % 11J	EWL % 12J	EWL % 13J	EWL % 14J
	EWL % 5J (n=55)	EWL % 6 J (n=26)	EWL & 7J (n=23)	EWL % 8J (n=17)	EWL % 9J (n=9)	EWL % 10J (n=2)	EWL % 11J (n=2)	EWL % 12J (n=1)	EWL % 13J (n=3)	EWL % 14J (n=2)
Anzahl	207	207	207	207	207	207	207	207	207	207
Fehlend	152	181	184	190	198	205	205	206	204	205
Gültige Anzahl	55	26	23	17	9	2	2	1	3	2
Mittelwert	54,16%	51,20%	56,29%	52,00%	57,28%	42,07%	47,02%	- 10,32%	38,67%	33,18%
Standardabweichung	25,21%	20,04%	22,57%	23,64%	36,66%	29,19%	28,75%		44,15%	9,66%

	EWL % 5J+
Anzahl	207
Fehlend	
Gültige Anzahl	140
Mittelwert	52,53%
Standardabweichung	24,27%

	BMI- Verlust 5J	BMI- Verlust 6 J	BMI- Verlust 7J	BMI- Verlust 8J	BMI- Verlust 9J	BMI- Verlust 10J	BMI- Verlust 11J	BMI- Verlust 12J	BMI- Verlust 13J	BMI- Verlust 14J
	BMI- Verlust 5J (n=55)	BMI- Verlust 6 J (n=26)	BMI- Verlust 7J (n=23)	BMI- Verlust 8J (n=17)	BMI- Verlust 9J (n=9)	BMI- Verlust 10J (n=2)	BMI- Verlust 11J (n=2)	BMI- Verlust 12J (n=1)	BMI- Verlust 13J (n=3)	BMI- Verlust 14J (n=2)
Anzahl	207	207	207	207	207	207	207	207	207	207
Fehlend	154	181	184	190	198	205	205	206	204	205
Gültige Anzahl	55,00	26,00	23,00	17,00	9,00	2,00	2,00	1,00	3,00	2,00
Mittelwert	15,34	14,87	15,38	15,83	13,88	11,57	9,31	- 4,01	7,22	9,88
Standardabweichung	8,39	6,77	7,82	9,24	8,50	4,57	5,06		10,84	0,52

	BMI Verlust 5J+
Anzahl	207
Fehlend	
Gültige Anzahl	140
Mittelwert	14,50
Standardabweichung	7,80

OSAS 5J		
	Anzahl	Anzahl als Spalten (%)
Vollremission	26	74,3%
gebessert	6	17,1%
Unverändert	3	8,6%

N=127 mit OSAS zu Baseline

Davon hatten n=26 eine Vollremission nach 5 Jahren.

Von 92 Patienten lagen keine Werte der Nachbeobachtung vor
27,6% (35/127)

aHT 5J		
	Anzahl	Anzahl als Spalten (%)
Vollremission	24	63,2%
gebessert	8	21,1%
unverändert	6	15,8%

25,5% (38/149)

DM 5J		
	Anzahl	Anzahl als Spalten (%)
Vollremission	22	78,6%
gebessert	3	10,7%
unverändert	3	10,7%

32,2% (28/87)

	Ortho 5 J	
	Anzahl	Anzahl als Spalten (%)
Vollremission	21	43,8%
gebessert	11	22,9%
unverändert	16	33,3%

24,5% (48/196)

Anzahl Redo nach primärem Sleeve

		Häufigkeit
Gültig	BPD-DS	1
	MGB	16
	Roux-Y	37
	SADI-S	1
	Gesamt	207

Anzahl	Anteil
1	2%
16	29%
37	67%
1	2%
Summe:	55 100%

Häufigkeiten von Gründen für Redo

		Antworten	
		N	Prozent der Fälle
Grund für Redo ^a	2Step	6	10,9%
	Reflux	39	70,9%
	IWL	22	40,0%
	WR	21	38,2%
	Dys	5	9,1%
Gesamt		93	169,1%

Analyse für alle mit Redo wegen IWL

Insg. 22

Von diesen 22 hatten 12 (54,5%) Follow-up-Werte ein Jahr nach der OP.
für die anderen 10 (45,5%) waren keine Nachsorgedaten verfügbar.

Gewicht vor und nach Redo bei IWL als Redo Grund

	Mittelwert	Std.- Abweichung
Gewicht präop/kg	132,792	27,5051
aktuelles Gewicht 1J	106,033	16,3701

		Signifikanztest			95% Konfidenzintervall der Differenz				Signifikanz	
		Mittelwert	Std.- Abweichung	Standardfehler des Mittelwertes	Unterer Wert	Oberer Wert	T	df	Einseitige s p	Zweiseitige s p
Paaren 1	Gewicht präop/kg - aktuelles Gewicht 1J	26,7583	20,2709	5,8517	13,8788	39,6379	4,573	11	0,000	0,001

	Mittelwert	Std.- Abweichung
BMI präop/ kg/m ² _1	44,08	6,37
aktueller BMI 1J_1	35,54	5,86

		Gepaarte Differenzen							Signifikanz	
		Mittelwert	Std.- Abweichung	Standardfehler des Mittelwertes	95% Konfidenzintervall der Differenz		T	df	Einseitige s p	Zweiseitige s p
					Unterer Wert	Oberer Wert				
Paare n 1	BMI präop/ kg/m2- aktuelle r BMI 1J	8,54	5,52	1,59	5,03	12,05	5,36	11,00	0,00	0,00

Gewicht vor und nach Redo bei WR als Redo Grund

		Mittelwert	Std.-Abweichung
	Gewicht präop/kg	138,822	23,0433
	aktuelles Gewicht 1J	102,822	12,7798

		Gepaarte Differenzen					Signifikanz			
		Mittelwert	Std.- Abweichung	Standardfehler des Mittelwertes	95% Konfidenzintervall der Differenz		T	df	Einseitiges p	Zweiseitiges p
					Unterer Wert	Oberer Wert				
Gewicht präop/kg - aktuelles Gewicht 1J		36,0000	16,1363	5,3788	23,5965	48,4035	6,693	8	0,000	0,000

		Mittelwert	Std.-Abweichung
Paaren 1	BMI präop/kg/m2	47,98	6,02
	aktueller BMI 1J	35,79	5,86

		Zeit zwischen 1. OP und Redo in Jahren	Zeit zwischen 1. OP und Redo in Monaten
N	Gültig	55	55
	Fehlend	0	0
Mittelwert		3,0784	36,9407
Median		2,5572	30,6858
Std.-Abweichung		2,11427	25,37127
Spannweite		9,38	112,59
Minimum		0,18	2,17
Maximum		9,56	114,76

KHK aus der Ursprungsdatei:

261 von 4539 macht 5,8%

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Erklärung § 5 Abs. 1 zur Datenaufbewahrung

Hiermit erkläre ich, dass die dieser Dissertation zu Grunde liegenden Originaldaten

- im Cellitinnen-Krankenhaus St. Franziskus in Köln
Klinik für Adipositas-, Metabolische und Plastische Chirurgie
Schönsteinstr. 63
50825 Köln-Ehrenfeld

hinterlegt sind.

Unterschrift Anna Magdalena Thiel

Erklärung gemäß § 5 Abs. (1) und (2), und § 11 Abs. (3) 12. der Promotionsordnung

Hiermit erkläre ich, Anna Magdalena Thiel, an Eides statt, dass ich den wesentlichen Anteil an der Publikation:

Anna Magdalena Thiel, Andreas Plamper, Julia Kroll, Patrick H. Alizai, Sophia M. Schmitz, Karl P. Rheinwalt: Long-term outcomes of sleeve gastrectomy in a patient group with mainly high BMI: a single-center study; Updates in Surgery, Springer; Received: 26 June 2024 / Accepted: 7 January 2025, 9 Seiten, geleistet habe.

Die Anteile an der Arbeit waren wie folgt:

	A. M. Thiel	PD K. P. Rheinwalt	PD P. H. Alizai	J. Kroll	Dr. med. A. Plamper	Chat GPT	PD S. M. Schmitz	Summe (%)
Studienüberwachung		50					50	100
Studiendesign/ Konzeption	60	20			20			100
Untersuchung der Probanden	55	25			20			100
Datenerhebung	60	20			20			100
Datenauswertung	100							100
Statistische Auswertung	100							100
Bereitstellung von Materialien		50			50			100
Interpretation der Datenauswertung	60	20					20	100
Verfassung des Manuskripts	100							100
Sprachliche Korrektur		50				10	40	100
Korrektur des Manuskripts		30	10	10	15		35	100

Aus diesem wesentlichen Anteil ergibt sich selbstverständlich die Stellung als Erstautorin.

Unterschrift der Doktorandin Anna Magdalena Thiel

Als Doktormutter bestätige ich die Angaben von Anna Magdalena Thiel

Unterschrift PD Dr. Sophia M. Schmitz (Doktormutter)

Ich schließe mich der Erklärung von PD Dr. Sophia M. Schmitz als Koautor an

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