Clinical outcomes in bariatric surgery

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Gastric Bypass Versus Sleeve Gastrectomy: Patient Selection and Short-Term Outcome of 47,101 Primary Operations from the Swedish, Norwegian, and Dutch National Quality Registries

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ABSTRACT

OBJECTIVE

The aim of this study was to compare the use and short-term outcome of Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) in Sweden, Norway, and the Netherlands.

BACKGROUND

Although bariatric surgery is performed in high volumes worldwide, no consensus exists regarding the choice of bariatric procedure for specific groups of patients.

METHODS

Data from 3 national registries for bariatric surgery were used. Patient selection, perioperative data (severe complications, mortality, and rate of readmissions within 30 days), and 1-year results (follow-up rate and weight loss) were studied.

RESULTS

A total of 47,101 primary operations were registered, 33,029 (70.1%) RYGB and 14,072 (29.9%) SG. Patients receiving RYGB met international guidelines for having bariatric surgery more often than those receiving SG (91.9% vs 83,0%, $P < 0.001$). The 2 procedures did not differ in the rate of severe complications (2.6% vs 2.4%, $P = 0.382$), nor 30-day mortality (0.04% vs 0.03%, $P = 0.821$). Readmission rates were higher after RYGB (4.3% vs 3.4%, $P < 0.001$).

One-year post surgery, less RYGB-patients were lost-to follow-up (12.1% vs 16.5%, $P < 0.001$) and RYGB resulted in a higher rate of patients with total weight loss of more than 20% (95.8% vs 84.6%, $P < 0.001$). While the weight-loss after RYGB was similar between hospitals, there was a great variation in weight loss after SG.

CONCLUSIONS

This study reflects the pragmatic use and short-term outcome of RYGB and SG in 3 countries in North-Western Europe. Both procedures were safe, with RYGB having higher weight loss and follow-up rates at the cost of a slightly higher 30-day readmission rate.

INTRODUCTION

To ensure and improve the quality of bariatric surgery, assessment of outcome is required.[1-5] The external validity of case series, observational studies, and randomized controlled trials may not reflect everyday practice and outcome.[6] The Rome Diabetes Surgery Summit achieved consensus for a need of standard national registries to collect "real-world" data.[6, 7] In recent years, several national bariatric registries have been established in Europe and early results have been published.[3, 6, 8, 9]

Although bariatric surgery has been performed in high volumes worldwide for several decades [10], no consensus exists in regard to the choice of procedure for specific groups of patients.[11, 12] Two procedures dominate at present, Roux-en-Y gastric bypass (RYGB) [13] and sleeve gastrectomy (SG).[14, 15]

Nationwide registries, suitable for international benchmarking, have been developed in Sweden, Norway, and the Netherlands.[3, 16] A main reason for using data from national registries is to reduce the risk of selection bias and intention-to-treat confounders from individual hospitals. However, selection biases may still impact findings such as choice of surgical procedure for the individual patient, which may to some extent rely on the surgeon's preference or institutional practice. Moreover, individual countries apply clinical protocols incorporating differences that may impact outcome after bariatric surgery. National differences between individual hospitals may thus be small, while differences in outcome between nations may be more easily found. A recent study showed an extended overview of the registered variables in both registries and also showed that the definitions used for perioperative measures in the registries were comparable thus facilitating evaluation of surgical and outcome indicators between registries.[17] The 30-day morbidity and mortality following primary bariatric surgery in Sweden, Norway, and the Netherlands documented comparable outcome in these countries.[17]

The aim of this study was to compare the use and short-term outcome of RYGB and SG in Sweden, Norway, and the Netherlands during 2015 to 2017.

METHODS

DATA REGISTRIES

Patients receiving a primary RYGB or a primary SG from January 2015 till December 2017 were included. Perioperative data included a 30 days follow-up period after primary surgery. Evaluations of 1-year follow-up outcome included patients operated from January

2015 till December 2016. Patients operated in Sweden, Norway, and the Netherlands were registered in the respective national registries. Patient data were retrieved during the preoperative consultations, during hospital stay, and from follow-up consultations by direct plotting the information into the online-based registries by responsible health care providers. Further details on the design of these registrations have been described previously.[3, 16-19] All procedures open or laparoscopic were included in the registries and analyzed in the present study.

SOREG

SOReg (Scandinavian Obesity Surgery Registry) was initiated in 2007 in Sweden,3 and is supported by the National Board of Health and Welfare, a government agency under the Ministry of Health and Social Affairs. In the last 5 years, more than 98% of all patients who underwent bariatric surgery in Sweden have been registered in SOReg-Sweden (SOReg-S). In 2014, Norway joined SOReg and received status as a nationwide register in June 2015. The coverage rate based on public hospitals was 64% in 2016 and 73% in 2017.

All variables in SOReg-Norway (SOReg-N) and SOReg-S apply the same definitions and the database platform is identical. An identical system for auditing of data to improve quality has been developed. Both the SOReg-N and SOReg-S registries performed external data verification, indicating high quality of data.[20]

DATO

The nationwide DATO (Dutch Audit for Treatment of Obesity) registry includes all Dutch bariatric patients. Information is collected through an online survey for all patients. The registry officially started on January 1, 2015, and covers over 99.9% of all patients who undergo bariatric surgery in the Netherlands. Nationwide coverage is enforced via the Association of Surgeons of the Netherlands, the umbrella organization of Dutch health insurers, and the Dutch National Health Care Institute.[16, 18] Recent third-party data verification showed an inclusion rate of 100% for all bariatric hospitals in the Netherlands.

The variables have an overlap of more than 90% between the SOReg and DATO registries.[17] For all the variables used in this study, the definitions of DATO correspond to those of SOReg.[17]

MAIN OUTCOME MEASURES AND DEFINITIONS

Six indicators were used to compare the use and outcome of RYGB and SG; patient eligibility for surgery, severe complications, mortality, readmissions, rate of follow-up

at 1 year, and 1-year weight loss. Analyses were performed on merged data as well as on national basis.

ELIGIBILITY CRITERIA FOR BARIATRIC SURGERY

The National Institutes of Health Consensus Development Conference Statement [21], recognized as IFSO-guidelines for bariatric surgery, were practiced in all 3 countries.[7, 22-26] To make a distinction between whether or not patients were operated in agreement with these guidelines, a process indicator was established. The patient had to be between 18 and 65 years at the time of surgery, with a body mass index (BMI) of ≥ 40.0 kg/m^2 or a BMI of 35.0–40.0 kg/m^2 in combination with at least 1 of the 6 major obesity-related diseases: type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, obstructive sleep apnea syndrome, gastroesophageal reflux disease, and musculoskeletal pain. These diseases were defined by continuous use of medication and with continuous positive airway pressure in sleep apnoea. [25, 27, 28] Currently, patients with BMI of ≥ 30.0 kg/m^2 and T2DM may be offered metabolic surgery on an individual basis, but this criterion was not incorporated in the guidelines during the entire study period.[28]

PERIOPERATIVE RESULTS

Postoperative complications were categorized according to the Clavien-Dindo Classification of Surgical Complications (CD) and represent complications within 30 days after primary surgery or during the same hospital stay.[29] CD-grade IIIb or higher was classified as a severe complication. CD-grade IIIb represents a complication for which a surgical, endoscopic, and/or radiological intervention was performed under general anesthesia. CD-grade IV is described as life-threatening complications requiring intensive care (IC) admission. CD-grade V reflects the 30-days mortality rate.[29] Readmissions within 30-days after surgery were studied.

ONE-YEAR RESULTS

Patients without a registered 1-year follow-up after primary surgery were considered as lost-to follow-up. Postoperative weight loss is presented by percentage total weight loss (%TWL), which was defined as: $\frac{preoperativeweight - postoperativeweight}{preoperativeweight} \times 100$.[5, 30]

STATISTICAL ANALYSIS

RYGB and SG were analyzed separately. Differences in regard to patient and treatment characteristics were described using frequency tables. Categorical variables were compared using the χ^2 test with Yates' correction. Statistical significance was set at $P < 0.05$. The use of case-mix adjusted outcomes are controversial and not applied.[31, 32]

Results for all 6 process and outcome indicators were presented using funnel plots with 95% control limits that vary in relation to total number of hospital procedures in the above specified study period.[17, 33]

The funnel plots provide information regarding specific process or outcome measures for individual hospitals in relation to the overall average and in relation to results of other anonymized hospitals. The Y-axis shows the percentage of primary bariatric procedures indicated on the X-axis that met the binomial result as the specific indicator indicates. The Y-axis shows the absolute percentage per hospital (dot) and the number of patients operated, as shown on the x-axis.

R version 3.4.3 (Copyright (C) The R Foundation for Statistical Computing Platform) was used for statistical analysis in combination with the 'Companion to Applied Regression'-package (car 2.1–6), and "A Grammar of Data Manipulation"-package (dplyr 0.7.4).

This study was approved by the regional ethical committee of Stockholm, Sweden (2013/535–31/5) for SOReg-S. The Regional Committee for medical and health research ethics in South East Norway approved the study (reference number: 2018/1631) for SOReg-N. For this study, no ethical approval or informed consent was required under Dutch law for DATO.[16]

RESULTS

From January 2015 till December 2017, a total of 47,101 primary bariatric procedures (>99% laparoscopic cases) were registered. Of these, 33,029 (70.1%) were RYGB and 14,072 (29.9%) were SG procedures. Patient characteristics per country and combined are given in **Table 1**.

RYGB was the most commonly applied procedure in Sweden (64.0%) and the Netherlands (77.0%), while in Norway, SG was more common (57.0%, $P < 0.001$). Patients who underwent RYGB had more preoperative comorbidities (73.5% vs 64.3%, $P < 0.001$) than patients receiving SG. Patients operated in the Netherlands had more comorbidities than both Sweden and Norway ($P < 0.001$). Moreover, in Norway and Sweden, gastroesophageal reflux disease was about twice as common in RYGB patients, while no difference between the 2 procedures was seen in the Netherlands (**Table 1**).

Table 1: Preoperative patient characteristics according to country and combined data.

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Number of procedures	21,055	77.0%	6,292	23.0%	1,365	43.0%	1,809	57.0%	10,609	64.0%	5,971	36.0%	33,029	70.1%	14,072	29.9%	<0.001
Patient characteristics																	
Age (mean, years, SD)	44.5	± 10.9	41.9	± 12.4	42.9	± 10.8	42.1	± 11.1	40.7	± 11.8	41.0	± 10.9	43.2	± 11.2	41.5	± 11.6	<0.001
BMI (mean, kg/m^2, SD)	43.5	± 5.0	45.6	± 6.6	43.3	± 5.2	41.9	± 5.4	41.7	± 5.6	39.5	± 5.4	42.9	± 5,2	42,5	± 5.9	<0.001
Female	17,064	81.0%	4,684	74.4%	1,045	76.6%	1,395	77.1%	2,188	77.8%	4,834	80.1%	26,171	79.2%	10,913	77.6%	<0.001
Comorbidities	17,139	81.4%	5,017	79.7%	890	65.2%	1,109	61.3%	6,256	59.0%	2,917	48.9%	24,285	73.5%	9,043	64.3%	<0.001
T2DM	4,521	21.5%	1,058	16.8%	199	14.6%	196	10.8%	1,456	13.7%	502	8.4%	6,176	18.7%	1,756	12.5%	<0.001
Hypertension	7,312	34.7%	2,016	32.0%	453	33.2%	475	26.3%	2,791	26.3%	1,208	20.2%	10,556	32.0%	3,699	26.3%	<0.001
Dyslipidaemia	4,260	20.2%	1,060	16.8%	228	16.7%	178	9.8%	1,046	9.9%	408	6.8%	5,534	16.8%	1,646	11.7%	<0.001
GERD	2,705	12.8%	784	12.5%	293	21.5%	175	9.7%	1,322	12.5%	341	5.7%	4,320	13.1%	1,300	9.2%	<0.001
OSAS	3,841	18.2%	1,205	19.2%	223	16.3%	226	12.5%	1,113	10.5%	412	6.9%	5,177	15.7%	1,843	13.1%	<0.001
Musculoskeletal pain	9,519	45.2%	2,843	45.2%	462	33.8%	545	30.1%	2,337	22.0%	877	14.7%	12,318	37.3%	4,265	30.3%	<0.001

Legend: **p*-values compared all three countries together.
Abbreviations: BMI, body mass index; T2DM, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnoea syndrome; N/A, not available.

ELIGIBILITY CRITERIA FOR BARIATRIC SURGERY

In total, 89.2% (n = 42,030) of patient met the eligibility criteria for bariatric surgery, 91.9% for the RYGB and 83.0% for SG patients, respectively (P < 0.001) (Fig. 1). Twenty-three of 59 (39.0%) hospitals [Sweden (SE): 19/28; Norway (NO): 4/13; Netherlands (NL): 0/18] operated significantly more RYGB patients (**Fig. 1B**), and 18 of 61 (29.5%) hospitals (SE: 13/28; NO: 5/16; NL: 0/17) operated significantly more SG patients (**Fig. 1A**), not meeting the eligibility criteria for bariatric surgery compared to the overall average.

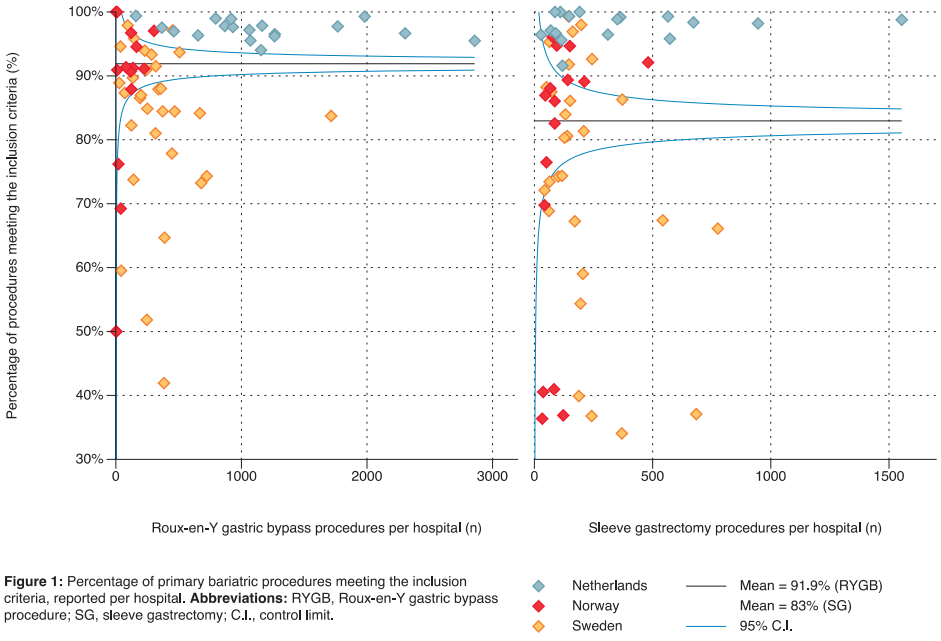

Figure 1: Percentage of primary bariatric procedures meeting the inclusion criteria, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

COMPLICATED POSTOPERATIVE COURSE

Severe complications (CD-Grade ≥IIIb) were registered in 2.6% (n = 846) patients after RYGB and 2.4% (n = 341) patients after SG (P = 0.382). Reinterventions due to severe complications were performed in 2.0% (n = 667) patients after RYGB and 2.1% (n = 290) patients after SG (P = 0.771). The overall number of patients registered with a CD-grade IV complication was 0.5% (n = 170) for RYGB and 0.3% (n = 47) after SG (P = 0.008) (**Table 2**). In the RYGB group, 4 of 59 (6.8%) hospitals (SE: 1/28; NO: 0/13; NL: 3/18) registered significantly lower rate of complications than the average. In contrast, a higher rate of severe complications was seen for SG in 9 of 61 (14.8%) hospitals (SE: 6/28; NO: 1/16; NL: 2/17) (**Fig. 2**). Thirty-day mortality was 0.04% (n = 13) after RYGB and 0.03% (n = 4) after SG (P = 0.821).

Table 2: Morbidity and mortality after primary sleeve gastrectomy and gastric bypass procedure.

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Number of procedures	21,055	77.0%	6,292	23.0%	1,365	43.0%	1,809	57.0%	10,609	64.0%	5,971	36.0%	33,029	70.1%	14,072	29.9%	< 0.001
Perioperative complications	420	2.0%	131	2.1%	66	4.8%	32	1.8%	284	2.7%	57	1.0%	770	2.3%	220	1.6%	< 0.001
Gastrointestinal perforation	135	0.6%	7	0.1%	24	1.8%	1	0.1%	121	1.1%	3	0.1%	280	0.8%	11	0.1%	
Bleeding	64	0.3%	44	0.7%	5	0.4%	0	0.0%	10	0.1%	12	0.2%	79	0.2%	56	0.4%	
Spleen injury	31	0.1%	21	0.3%	4	0.3%	8	0.4%	11	0.1%	17	0.3%	46	0.1%	46	0.3%	
Hepatic injury	44	0.2%	11	0.2%	0	0.0%	0	0.0%	16	0.2%	8	0.1%	60	0.2%	19	0.1%	
Major vascular injury	1	0.0%	1	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.0%	1	0.0%	
Postoperative complications	1,046	5.0%	347	5.5%	80	5.9%	94	5.2%	753	7.1%	309	5.2%	1,879	5.7%	750	5.3%	< 0.001
Bleeding	314	1.5%	129	2.1%	25	1.8%	25	1.4%	123	1.2%	66	1.1%	462	1.4%	220	1.6%	
Leakage	109	0.5%	46	0.7%	9	0.7%	16	0.9%	80	0.8%	30	0.5%	198	0.6%	92	0.7%	
Intra-abdominal infection	29	0.1%	15	0.2%	5	0.4%	11	0.6%	64	0.6%	22	0.4%	98	0.3%	48	0.3%	
Wound infection	28	0.1%	11	0.2%	4	0.3%	11	0.6%	54	0.5%	45	0.8%	86	0.3%	67	0.5%	
Intestinal obstruction	63	0.3%	10	0.2%	16	1.2%	0	0.0%	113	1.1%	7	0.1%	192	0.6%	17	0.1%	
Cardiac events	38	0.2%	12	0.2%	0	0.0%	5	0.3%	6	0.1%	3	0.1%	44	0.1%	20	0.1%	
Pulmonary events	71	0.3%	22	0.3%	5	0.4%	1	0.1%	33	0.3%	17	0.3%	109	0.3%	40	0.3%	
Thrombotic events	8	0.0%	4	0.1%	1	0.1%	2	0.1%	9	0.1%	2	0.0%	18	0.1%	8	0.1%	
Other	427	2.0%	115	1.8%	40	2.9%	46	2.5%	327	3.1%	164	2.7%	794	2.4%	325	2.3%	
Overall	506	2.4%	205	3.3%	29	2.1%	31	1.7%	315	3.0%	105	1.8%	850	2.6%	341	2.4%	< 0.001

Table 2: Morbidity and mortality after primary sleeve gastrectomy and gastric bypass procedure. (continued)

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Re-intervention *CD-grade IIIb*	346	1.6%	163	2.6%	27	2.0%	28	1.5%	294	2.8%	99	1.7%	667	2.0%	290	2.1%	
IC/ICU admission *CD-grade IV*	148	0.7%	38	0.6%	2	0.1%	3	0.2%	20	0.2%	6	0.1%	170	0.5%	47	0.3%	
Mortality *CD-grade V*	12	0.1%	4	0.1%	0	0.0%	0	0.0%	1	0.0%	0	0.0%	13	0.0%	4	0.0%	
Length of stay & readmission																	
Readmissions (<30 days)	572	2.7%	158	2.5%	87	4.6%	87	4.8%	752	7.1%	240	4.0%	1,411	4.3%	485	3.4%	< 0.001
Hospital stay (mean, days, SD)	1.6	± 2.9	1.6	± 2.7	1.7	± 3.4	2.0	± 2.2	1.5	± 4.6	1.6	± 2.3	1.6	± 3.5	1.7	± 2.5	< 0.001

Legend: **p*-values compared all three different countries together.

Abbreviations: N/A, not available; IC, intensive care; ICU, intensive care unit; CD, Clavien-Dindo Classification.

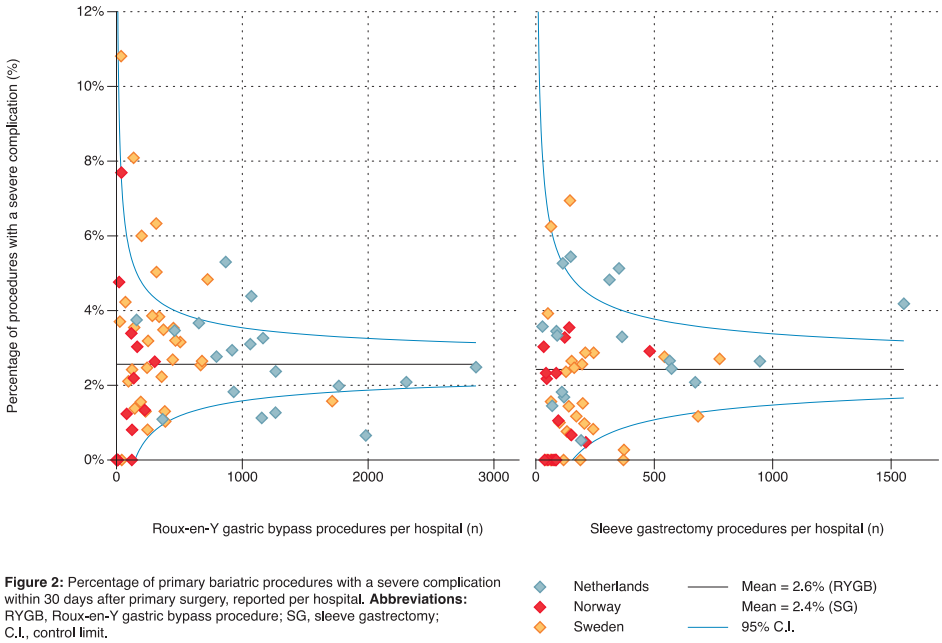

Figure 2: Percentage of primary bariatric procedures with a severe complication within 30 days after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

The 3 most common complications after RYGB and SG combined were bleeding (1.6%), leakage (0.7%), and wound infection (0.5%), with no statistical difference between the 2 procedures (**Table 2**).

LENGTH OF HOSPITAL STAY AND READMISSIONS

The length of stay was shorter after RYGB than SG, 1.6 days (SD ± 3.5) and 1.7 days (SD ± 2.5), respectively ($P < 0.001$) (**Table 2**). In the Netherlands, the length of hospital stay after RYGB and SG was comparable, while in Norway and Sweden, hospital stay was somewhat shorter after RYGB than SG in the same country ($P < 0.001$).

The readmission rate was 4.3% (n = 1411) after RYGB and 3.4% (n = 485) after SG ($P < 0.001$). Readmission rates were lowest in the Netherlands. Significantly more Swedish hospitals registered a readmission after RYGB (7.1%) than the overall average ($P < 0.001$) (**Table 2**).

LOST TO FOLLOW-UP AFTER 1 YEAR

On average, the 1-year lost to follow-up was lower after RYGB than SG, 12.1% (n = 2712) and 16.5% (n = 1433), respectively ($P < 0.001$). The largest difference between the 2 procedures was seen in Sweden, 11.9% for RYGB versus 20.1% for SG, respectively ($P < 0.001$). (**Fig. 3**).

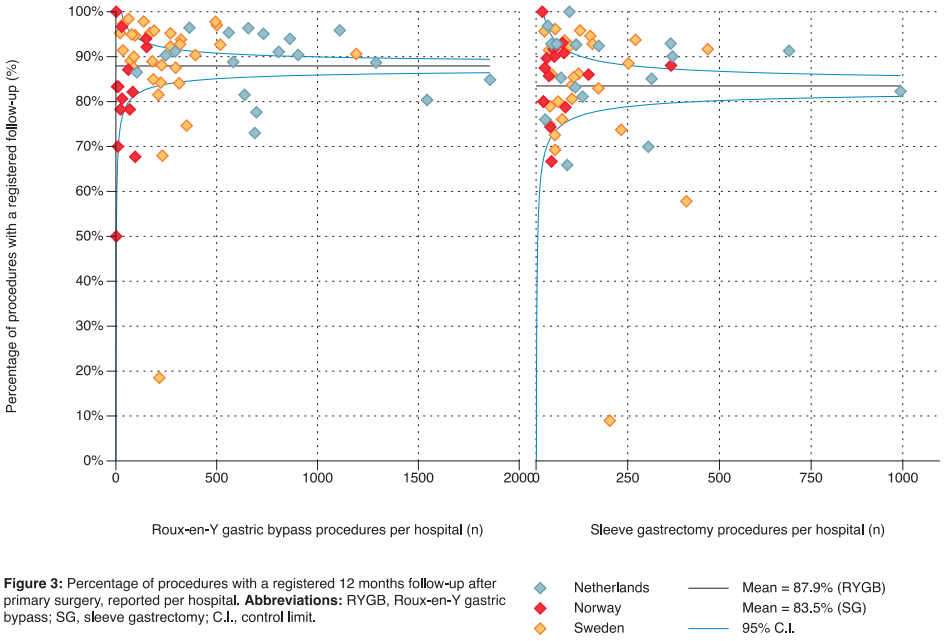

Figure 3: Percentage of procedures with a registered 12 months follow-up after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; C.I., control limit.

After RYGB, 12 of 59 (20.3%) (SE: 5/28; NO: 2/13; NL: 5/18) and after SG 8 of 61 (13.1%) (SE: 5/28, NO: 1/16; NL: 2/17) centres had significantly higher rates of lost to follow-up up than the overall average, respectively.

TOTAL WEIGHT LOSS (%TWL)

ATWL percent (%TWL) of more than 20% the first year after surgery was reached more often after RYGB than SG, 95.8% and 84.6% of the patients, respectively ($P < 0.001$) (Fig. 4). In total, after RYGB, 6 of 59 (10.2%) (SE: 4/28; NO: 1/13; NL: 1/18) hospitals and after SG 18 of 61 (29.5%) (SE: 16/28; NO: 0/16; NL: 2/17) hospitals scored significantly lower than the overall average.

There is a significant difference in 20%TWL after SG in Sweden (75.2%), Norway (93.4%), and the Netherlands (90.8%) ($P < 0.001$), while the difference is much smaller after RYGB (SE: 94.9%; NO: 95.0%; NL: 96.3%; $P < 0.001$). The considerable spread in outcomes between hospitals after SG compared with RYGB is easily noticeable in the funnel plot.

DISCUSSION

This study describes the pragmatic everyday outcome of RYGB and SG in 3 Northwest-European countries based on a standard platform of 6 quality indicators. RYGB was

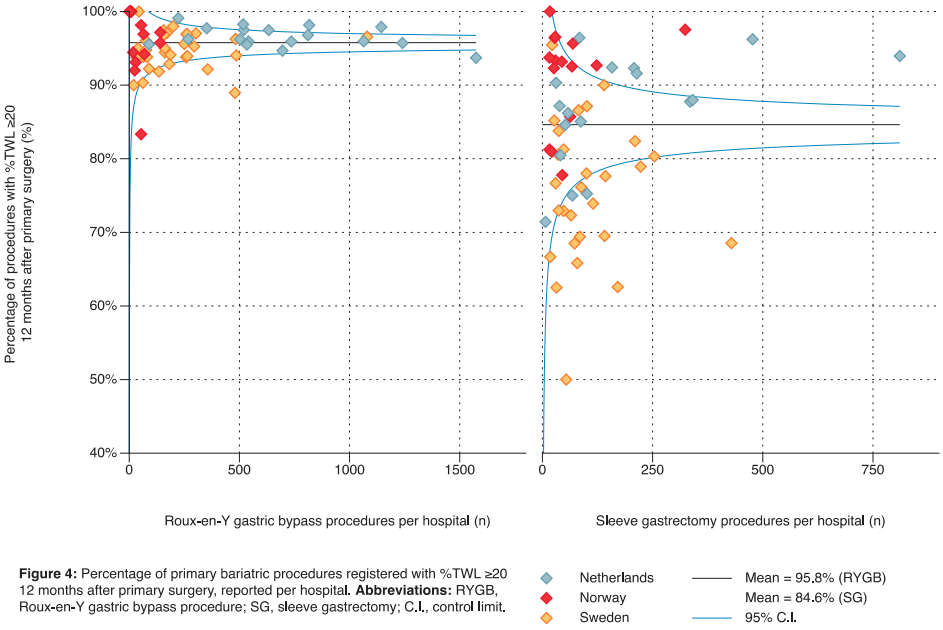

Figure 4: Percentage of primary bariatric procedures registered with %TWL ≥20 12 months after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

more often used in adherence to commonly accepted guidelines for eligibility to bariatric surgery. Postoperative severe complications (2.6% vs 2.4%) and mortality rates (0.04% vs 0.03%) did not differ between RYGB and SG, but readmission rates were higher after RYGB (4.3% vs 3.4%). In RYGB-patients, however, 1-year results were superior, with lower lost-to follow-up (12.1% vs 16.5%) and higher rate of %TWL ≥ 20% (95.8% vs 84.6%). These benchmarking findings may act as guidelines for expected early outcome of bariatric surgery in Northwest-Europe and elsewhere.

Most patients were operated in adherence to internationally used IFSO-guidelines for eligibility to bariatric surgery. Indications for bariatric surgery differ among European countries despite agreement on the international clinical guidelines.[34] At the moment, the BMI inclusion criteria in the Netherlands, Sweden, and Norway have been set at a BMI of 40.0 kg/m^2 or a BMI of 35.0 kg/m^2 for patients with obesity-related disease. Interestingly, we found that more RYGB patients were operated according to international guidelines for bariatric surgery than SG patients. This could be due the fact that there are some Swedish private clinics performing SG on patients with a BMI of 30 to 35 kg/m^2 or 35 to 40 kg/m^2 without any obesity-related comorbidity.

Comparing the 3 countries, the annual hospital case load was highest in the Netherlands. In all countries, mostly females were operated at a rate of about 75% or higher. Dutch patients were significantly older, had a higher BMI, and a higher number of

preoperative comorbidities. The mean age and BMI in the present study is lower than reported in most American series.[35] Overall, as well as in Sweden and the Netherlands, RYGB was the most common primary procedure, whereas in Norway, SG has reached 57% based on registered data. In the United States, SG surpassed RYGB in 2013 [36] and was estimated by ASMBS to constitute of 53% to 59% of all bariatric procedures during the present study period (2015 to 2017).[37] Interestingly, the findings indicate that there may be between-country differences in regarding to the use of SG in patients with gastroesophageal reflux disease (**Table 1**).

The present overall rates of severe postoperative complications were in line with results presented in the international literature. In a recent review on 107,874 patients [35], the leak rate was 1.1% in RYGB and 1.2% in SG. The associated factors for severe postoperative complications are laparoscopic versus open surgery, older age, surgical procedural experience, preoperative comorbidities, and BMI.[38-41] In Sweden, more postoperative complications were registered for RYGB surgery than SG (7.1% vs 5.2%). As significant outliers from all 3 countries were visible in all measured process and outcome indicators, this may provide insight to areas in need of improvements.

The present mortality of 0.03% to 0.04% compares favorably to others; Gribsholt et al [42] presenting 0.04% in 9,895 Danish RYGBs and the 0.20% to 0.22% presented in a large American cohort (n = 43,354) of RYGB and SG [43] and a recent meta-analysis on 69,494 patients [44]. These results underline the safety of RYGB an SG in these patients.

The overall hospital stay was short for both procedures (1.6 and 1.7 days, respectively), while Norway and Sweden had a significantly higher percentage of readmissions, especially after RYGB (4.6% and 7.1%, respectively). This could partly be explained by demographic differences between countries, where people often live closer to a (bariatric) hospital in the Netherlands. However, it could also be explained by centralization in the Netherlands, where hospitals perform a higher volume of bariatric procedures per year per clinic as demostrated in **Figs. 1 to 4**, and therefore have a higher number of procedures per surgeon per year. This could also explain the lower postoperative complication ratio described earlier.

Although it is generally not recommended to report weight loss with less than 2-year follow up, the present 1-year weight loss after RYGB is similar and more predictable between institutions, although there is a great variation in weight loss after SG. This can reflect the need for high technical quality in both procedures, as patients receiving large pouches and sleeves are known to have inferior weight loss. According to our data, it thus seems more difficult to achieve a technical perfect SG. The presented weight loss

is in line with the literature as well as earlier results from SOReg-S on patients operated before 2014 in Sweden.[17, 19] Interestingly, the 1-year %TWL outcome in RYGB seems more uniform and predictable across hospitals and nations than that of SG.

Currently, almost 98% of elective bariatric surgical cases are managed worldwide by laparoscopy.[12] The increased use of laparoscopy in bariatric surgery has reduced postoperative morbidity and mortality.[45-47] In an attempt to further improve quality, a minimum annual procedural volume per hospital of 200 cases has been established in the Netherlands and 100 in Sweden. In Norway, no formal minimum annual procedural hospital volume exists, although most centers perform close to 100 or more procedures annually. Although numerous studies suggest an inverse relation between hospital case load volume and postoperative severe complicated course, recent studies show no significant benefits for choosing a high-volume hospital compared with a low-volume hospital.[38-40, 48, 49] This remains a topic of discussion and accreditation on quality outcomes may be of greater value than that of volume.

Several aspects of long-term outcomes can be monitored in Sweden and Norway by registering the unique identification number given at birth, which allows cross-linking with other nationwide registrations. All Dutch citizens have a similar identification number, but cross-linking between different registries may be more challenging due to legal restrictions. However, the national bariatric registries can learn from one another and allow for international comparison. The SOReg registries include more pre- and postoperative laboratory values, which allow comorbidities to be measured more objectively. On the contrary, registration in DATO is mandatory, whereas registration in SOReg-N is on voluntary basis. In addition, the Netherlands offers a weekly benchmark feedback, while SOReg presents a selection of quality outcomes online and publish annual figures.

Case-mix adjusted outcomes are still controversial in the international literature [31, 32] and deliberately not applied in this study and could imply a possible selection bias as does the heterogeneity of the data, which reflects real-world data. This could be a limitation of this study in a narrower sense of the word.

Nationwide clinical audits provide detailed information on patient characteristics, treatment, and individual hospitals. This information is quickly available for monitoring of quality indicators. These indicators can be used for hospitals to compare their performances relative to a national and an international benchmark analysis. A disadvantage of national clinical audits is that data may not always be complete and directly validated.

The major strength of this study is the international, population-based design, the use of pooled data from 3 high-quality registries including in-depth information, and almost complete coverage of all patients who had bariatric surgery in the Netherlands and Sweden. Standardization of registries and consensus of definitions of measures included facilitate comparisons between countries that may impact quality of the treatment given on an international level.

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