

Circular versus Linear versus Hand-Sewn Gastrojejunostomy in Roux-en-Y-Gastric Bypass: Data Analysis from a Quality Assurance Study of the Surgical Treatment of Obesity in Germany

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Received 30 April 2014; revised 26 May 2014; accepted 22 June 2014

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Abstract

Background: Since January 12005, the outcomes of bariatric surgeries have been recorded in Germany. All data are registered prospectively in cooperation with the Institute of Quality Assurance in Surgery at Otto-von-Guericke University Magdeburg. **Methods:** Data are collected in an online data bank. Data collection began in 2005 for the results of Roux-en-Y Gastric Bypass (RYGB). In addition to primary bariatric operations, data regarding the complications and the amelioration of comorbidities have been analyzed. Participation in the quality assurance study is required for all certified centers in Germany. **Results:** Roux-en-Y Gastric Bypass is the most popular bariatric operation in Germany. There were 5115 operations performed from 2005 to 2010. A circular anastomosis was performed in 1587 patients, and a linear anastomosis was performed in 2734 patients. In 783 patients the hand-sewn technique was used. The leakage rate for the linear technique is 1.6%, and the leakage rate is 1.2% for circular anastomosis and 1.4% for hand-sewn technique. The overall postoperative complication rate was significantly higher using the circular technique than using the linear or hand-sewn approach. **Conclusion:** RYGB is a popular procedure in Germany. The complication rate has decreased since 2005. A comparison of hand sewn versus

How to cite this paper: Stroh, C., *et al.* (2014) Circular versus Linear versus Hand-Sewn Gastrojejunostomy in Roux-en-Y-Gastric Bypass: Data Analysis from a Quality Assurance Study of the Surgical Treatment of Obesity in Germany. *Surgical Science*, 5, 280-289. <http://dx.doi.org/10.4236/ss.2014.57048>

linear and versus circular anastomosis indicated a higher complication rate in circular gastrojejunal junctions.

Keywords

Roux-en-Y-Gastric Bypass, Circular versus Linear versus Hand-Sewn Anastomosis, Complications

1. Introduction

Obesity is one of the greatest challenges to health in the 21st century. According to data from the International Association for the Study of Obesity (IASO), Germany ranks first in the prevalence of obesity for both genders [1]. The Federal Office of Statistics revealed that in 2011, 67.1% of men and 53% of women were overweight [2].

Laparoscopic Roux-en-Y-Gastric Bypass (RYGB) was introduced in Germany in the mid-1990s. The long-term durability of RYGB has been shown in different studies. The effects of long-term follow-up over a period of more than 10 years and long-term outcomes after RYGB have recently been published [3]. Due to the high BMI of patients in Germany and the high prevalence of comorbidities, the use of RYGB has rapidly increased in Germany in recent years.

In Germany, a stapled anastomosis is more common than the hand sutured anastomosis of the gastrojejunal junction (GJA). In the literature, anastomotic leak rates reach 5.1% with linear staplers and up to 6.6% with circular devices [4]. All methods have technical advantages and disadvantages, especially with respect to developing strictures and leakage of GJ (gastrojejunal) anastomosis.

Due to the high leakage and stenosis rates of GJA, this study investigated the outcomes and complications for patients undergoing RYGB with linear or circular staples based on an analysis of data from the German Bariatric Surgery Registry (GBSR). The primary goal of the study was to compare the complication rates of primary RYGB.

2. Method

Since January 1, 2005, data from a quality assurance study of the surgical treatment of obesity in Germany have been registered prospectively in an online database at the Institute of Quality Assurance in Surgical Medicine of the Otto-von-Guericke University Magdeburg [5] [6]. All patients provided informed consent prior to entering the study.

This study evaluates the outcomes of RYGB as a primary operation for data collected between 2005 and 2010. The data studied include patient's demographics, surgical parameters, complications and mortality following RYGB for circular versus linear anastomosis with respect to the incidence of leakage, short-term morbidity and mortality. The results are compared with other findings in the literature.

The paper analyzed data of GBSR without any selection criteria for the patients to several stapling techniques for gastrojejunal anastomosis or hand-sewn anastomosis. Decision of depends on the experience of the different centers in Germany.

To ascertain completeness of data entry, participation in the study is a pre-requisite to an institution's certification as a center for bariatric surgery, and reported case numbers are verified against hospitals' clinical and billing documentation. The anonymized data is provided to the institutions and serves a center's quality control in regards to surgical indication, complication rates, outcome, and follow-up in comparison with other centers. To optimize quality and integrity of registry data (e.g. minimize missing data and ensure adherence to eligibility criteria), statistical plausibility checks are employed and regular random audits are conducted by the study director.

The study period ranged from January 1, 2005 to December 31, 2010 96 centers participated. Patients who underwent a primary bariatric procedure were included in a descriptive statistical analysis performed by an independent statistics consulting firm (StatConsult, Magdeburg, Germany).

The study was conducted according to the Recommendations of the Declaration of Helsinki for Biomedical Research and the Guidelines and Standards of the Institutional Review Boards. All patients provided informed consent prior to entering the study.

3. Statistical Analysis of Data

Statistical analysis was performed by StatConsult GmbH using the SAS® 9.2 software program. The descriptive statistical analysis was specified by presentation of absolute and relative frequencies for categorical data and mean, standard deviation, minimum and maximum values for continuous variables. The median was presented for continuous variables with high variation. For further verification of differences between groups in categorical data, the χ^2 test was used or the Fisher's exact test was applied for rare events. Continuous variables were compared between two groups using a two sample t-test. Multivariable analysis of several influence parameters in parallel for a dependent binary variable was performed using logistic regression. p-values were determined for two-sided tests, with a value of $p < 0.05$ indicating a statistically significant difference. All tests were deliberately carried out to the full level of significance.

4. Results

There were 5115 RYGBs performed as a primary approach between 2005 and 2010. In relation to gender distribution there were 3993 female patients and 1122 male patients. In 2734 (53.6%) patients, the GJA was performed with linear staplers, and in 1587 (31.1%) patients, circular staplers were used. 783 patients were operated using the hand-sewn technique. For 11 patients no valid statement could be made.

4.1. Demographic Data

The mean age of patients with circular anastomosis was 41.5 years and was not significantly higher than the mean age for patients in the linear group, which was 40.9 years ($p = 0.084$). Patients with a hand-sewn technique had a mean age of 40.2 years.

The mean BMI of the patients in the linear group was 47.6 kg/m² (23.1 - 73.8 kg/m²), and this value was significantly lower than that of the circular stapled group, which had a mean BMI of 49.8 kg/m² (31.6 - 85.2 kg/m²) ($p < 0.001$). Patients with hand-sewn had a mean BMI of 48.6 kg/m² (27.1 - 86.0 kg/m²) (**Table 1**).

4.2. Comorbidities

Comorbidities were recorded for all patients in the study. The overall incidence of comorbidities was 84.3% ($n = 4303$). Patients with circular anastomosis suffered significantly more comorbidities than patients with linear anastomosis ($p < 0.001$). The occurrence of the different comorbidities is shown in **Table 2**.

4.3. Complications

The intraoperative complication rate for circular anastomosis was not significantly different from that for linear anastomosis (2.02% vs. 2.67%; $p = 0.178$). The overall intraoperative complication rate for using stapler devices (2.43%; $n = 105$) was not significantly different from hand-sewing technique (1.66%, $p = 0.187$). As intraoperative complications spleen injuries, liver injuries and bleeding were reported. The multivariable model detected significant influence of comorbidities on intraoperative complication rate ($p = 0.047$) but no influence of suture ($p = 0.142$), which corresponds to the unadjusted descriptive analysis.

General complications for stapler devices occurred in 268 patients (6.20%) when considering linear and circular staplers. In detail, for patients with circular anastomosis, the complication rate was 9.07% ($n = 144$) which is significantly higher than a rate of 4.54% ($n = 124$) in the linear anastomosis group ($p < 0.001$) (**Table 2**). The overall general postoperative complications for hand-sewn (2.68%, $n = 21$) was significantly less than the complications for stapling devices given above. In the multivariable model a statistically significant effect of suture ($p < 0.001$) could be verified. Furthermore, an effect of BMI ($p = 0.004$) and age ($p < 0.001$) on the general postoperative complication rate could be detected. In pairwise comparisons, hand-sewn procedure revealed to have a significantly lower overall complication rate than the circular ($p < 0.001$) and the linear stapler anastomosis ($p = 0.041$), respectively. Comparing the stapler anastomosis the linear technique had significantly less complications than circular stapler ($p < 0.001$).

The overall specific complication rate for stapler was 5.83% (252 patients) which includes the development of bleeding, leakage or insufficiency, sepsis or postoperative ileus. The incidence of specific complications was significantly higher for patients with circular stapled anastomosis (7.69%, $n = 122$) than for patients with linear anastomosis (4.75%, $n = 130$) ($p < 0.001$). But in general, the hand-sewing procedure had significantly less spe-

Table 1. Demographic data.

		Linear	Circular	Stapled [total]	Hand-sewing
Total number of patients	[n]	2734	1587	4321	783
Body-mass-index	[kg/m ²]	47.6 ± 6.7	49.8 ± 7.4	48.4 ± 7.1	48.6 ± 7.8
Age	[years]	40.9 ± 10.8	41.5 ± 10.5	41.1 ± 10.7	40.2 ± 10.3
Male	[%]	21.8	22.1	21.9	22.2
Body-mass-index	[kg/m ²]	48.1 ± 6.6	49.9 ± 7.3	48.8 ± 6.9	49.7 ± 8.0
Age	[years]	43.6 ± 11.4	42.6 ± 10.9	43.2 ± 11.2	43.3 ± 10.2
Female	[%]	78.2	77.9	78.1	77.8
Body-mass-index	[kg/m ²]	47.5 ± 6.8	49.8 ± 7.4	48.3 ± 7.1	48.3 ± 7.7
Age	[years]	40.1 ± 10.6	41.2 ± 10.3	40.5 ± 10.5	39.2 ± 10.1

Table 2. Comorbidities for linear versus circular stapled anastomosis and stapled vs hand-sewing in RYGB.

		Anastomosis			
		Linear (N = 2734)	Circular (N = 1587)	Stapled [total] (N = 4321)	Hand-sewing (N = 783)
Total number of patients with comorbidities	[n]	2283	1390	3673	630
	[%]	83.5	87.6	85.0	80.5
Overall comorbidities	p-value		<0.001		0.001
Male	[%]	88.4	89.4	88.8	87.4
	p-value		0.619		0.584
Female	[%]	82.1	87.1	83.9	78.5
	p-value		<0.001		<0.001
Hypertension	[%]	56.4	59.8	57.7	52.4
	p-value		0.031		0.006
Insulin-dependent diabetes mellitus type II	[%]	8.0	12.2	9.6	8.6
	p-value		<0.001		0.367
Non-insulin dependent diabetes mellitus type II	[%]	20.6	23.6	21.7	18.6
	p-value		0.020		0.054
Sleep apnea	[%]	17.3	22.7	19.3	18.6
	p-value		<0.001		0.680
Gastroesophageal reflux disease	[%]	18.8	17.8	18.4	14.2
	p-value		0.446		0.004
Cardiac disease	[%]	5.6	12.9	8.3	5.7
	p-value		<0.001		0.015
Pulmonary disease	[%]	13.8	25.6	18.1	19.9
	p-value		<0.001		0.231
Skeletal disease	[%]	39.1	54.8	44.9	27.4
	p-value		<0.001		<0.001

cific complications (2.81%) then using stapler devices (Table 3). For the overall specific complication rate the multivariable model detected a statistically significant effect of suture ($p < 0.001$) and age ($p < 0.001$). In pairwise comparison, the hand-sewn procedure showed a significantly lower rate than the circular ($p < 0.001$) and the linear stapler anastomosis ($p = 0.038$), respectively. For comparison of stapler anastomoses, the linear technique had less specific complications than the circular stapler ($p < 0.001$).

The overall rate of hemorrhage for stapler technique was 0.88% ($n = 38$) for transfusions and 0.88% ($n = 38$) for re-operations. The risk of hemorrhage requiring transfusion was significantly lower for the linear stapled GJA patients than for circular stapled GJA patients ($p < 0.001$).

The total rate of leakage at the gastrojejunal junction (GJA) using stapler devices was 1.46% ($n = 63$). Stenosis

Table 3. Overall complication rates by operation technique.

Complication		Anastomosis			
		Linear (N = 2734)	Circular (N = 1587)	Stapled [total] (N = 4321)	Hand-sewing (N = 783)
Overall intraoperative complications	[n]	73	32	105	13
	[%]	2.7	2.0	2.4	1.7
	p-value	0.178		0.187	
Male	[n]	18	9	27	4
	[%]	3.0	2.6	2.9	2.3
	p-value	0.840		1.000	
Female	[n]	55	23	78	9
	[%]	2.6	1.9	2.3	1.5
	p-value	0.193		0.229	
Overall general postoperative complications	[n]	124	144	268	21
	[%]	4.5	9.1	6.2	2.7
	p-value	<0.001		<0.001	
Male	[n]	30	39	69	5
	[%]	5.0	11.1	7.3	2.9
	p-value	<0.001		0.030	
Female	[n]	94	105	199	16
	[%]	4.4	8.5	5.9	2.6
	p-value	<0.001		<0.001	
Overall specific postoperative complications	[n]	130	122	252	22
	[%]	4.8	7.7	5.8	2.8
	p-value	<0.001		<0.001	
Male	[n]	38	32	65	8
	[%]	5.6	9.1	6.9	4.6
	p-value	0.045		0.318	
Female	[n]	97	90	187	14
	[%]	4.5	7.3	5.5	2.3
	p-value	<0.001		<0.001	

at the gastrojejunal junction was reported in 0.32% of patients (n = 14). A comparison of leakage and stenosis at the GJA in circular or linear stapled anastomosis did not show any significant difference (**Table 4**). The median circular staple size in GBSR was 25 mm. The stenosis rate did not show any significant difference when comparing 25 mm (0.80%) vs. 21 mm (0.58%) circular staples.

4.4. Mortality

For stapler operations between January 1, 2005 and December 31, 2011, the 30-d mortality rate was 0.26% (n = 11). Three further patients died after the 30 days postoperative. The mortality rate for patients with circular stapled anastomosis (0.70%) was significantly higher than for patients with linear stapled anastomosis (0.04%) (p < 0.001). But for patients with hand-sewing procedure the 30-day mortality rate (0.26%, n = 2) did not differ from patients with stapler (p = 1.000) (**Table 5**). Reasons for mortality are shown in **Table 6**. In multivariable analysis, this influence of suture (p = 0.037) could be verified. Furthermore, BMI (p < 0.001) and gender (p = 0.003) could be identified as predictive variables for mortality where a higher BMI and male gender increased the risk of mortality. More detailed analysis of influences on mortality in comparison of linear vs. circular stapler devices are not possible due to the fact of that there was 1/2734 death in linear and 10/1587 deaths in circular stapled group.

5. Discussion

Since January 1, 2005, primary and revisional bariatric procedures have been recorded within the framework of

Table 4. Specific complication rate by operation technique.

			Anastomosis			
			Linear (N = 2734)	Circular (N = 1587)	Stapled [total] (N = 4321)	Hand-sewing (N = 783)
Total		[n]	23	44	67	3
		[n]	8	30	38	2
		[%]	0.29	1.89	0.88	0.26
Hemorrhage		p-value	<0.001		0.077	
		[n]	18	20	38	1
		[%]	0.66	1.26	0.88	0.13
Reoperation		p-value	0.061		0.023	
		[n]	44	19	63	11
		[%]	1.61	1.20	1.46	1.40
Leakage		p-value	0.276		1.000	
		[n]	11	3	14	1
		[%]	0.40	0.19	0.32	0.13
Stenosis		p-value	0.234		0.716	
		[n]	8	12	20	3
		[%]	0.29	0.78	0.46	0.38
Sepsis		p-value	0.037		1.000	
		[n]	11	34	45	2
		[%]	0.40	2.14	1.04	0.26
Wound infection		p-value	<0.001		0.039	

Table 5. Mortality rate.

		Anastomosis			
		Linear (N = 2734)	Circular (N = 1587)	Stapled [total] (N = 4321)	Hand-sewing (N = 783)
30-d mortality	[n]	1	10	11	2
	[%]	0.04	0.64	0.26	0.26
	p-value	<0.001		1.000	
Male	[n]	0	7	7	1
	[%]	0.00	2.02	0.74	0.57
	p-value	<0.001		1.000	
Female	[n]	1	3	4	1
	[%]	0.05	0.24	0.12	0.16
	p-value	0.141		0.565	

Table 6. Reasons for mortality.

Reasons for mortality	Number of patients*
Insufficiency at GJA with severe peritonitis	6
Postoperative ileus	3
Hemorrhage	2
Abcess	1
Without exact information	1

*10 of these patients developed sepsis with multiorgane dysfunction syndrome.

a quality assurance study of the surgical treatment of obesity by the Institute for Quality Assurance in Surgical Medicine at the Otto-von-Guericke University Magdeburg with the aim of improving the quality of care [5] [6].

RYGB is one of the most frequently performed bariatric operations worldwide. For RYGB complications, a leak at the GJA is the most critical aspect to judge the integrity of the anastomosis. The presence of bleeding, marginal ulceration or anastomotic strictures are of secondary importance.

5.1. Leak of GJA

The development of anastomotic leak is well described after RYGB, which has a leak rate of 0% - 6.6% for circular staples and 0% - 5.1% for linear staple devices [4] [7] [8].

A comparison of linear with circular stapled GJA in RYGB is only documented in single center trials and two meta-analyses [7] [8]. The literature reported a leakage rate of 1.1% (n = 514) for linear staples and a 1.0% (n = 140) rate in circular stapled GJA in a single center study [4]. Data in the literature report a leakage rate of 0.1% to 5.25% (Table 7). Meta-analysis has not shown a lower incidence of leakage for linear stapled anastomosis. Data from the Michigan Bariatric Surgery Collaborative also support these investigations [9].

In GBSR patients, the overall leakage rate of stapled GJA in RYGB was 1.46% (n = 63). The leakage rate in linear stapled GJA is 1.61% (n = 44/2734), and in circular GJA, the rate is 1.20% (n = 19/1587). Leakage rate of hand-sewn anastomosis was 1.40% (n = 11). The rates are not significantly different. The data from GBSR showed the results for surgery time using linear staplers (106.4 min) was significantly shorter than circular stapled GJA, which was 149.9 min (p < 0.001). For hand-sewn GJA mean operation time was 103.8 min.

5.2. Hemorrhage

Early postoperative hemorrhage is an infrequent complication with a reported incidence of 0.6% - 4.4% [10].

Table 7. Leakage rate on literature.

Author	Number of operations linear	BMI	Leakage rate		Number of operations circular	BMI	Leakage rate	
	[n]	kg/m ²		[%]	[n]	[kg/m ²]		[%]
Abdel-Galil [18]	30	45 ± 1.7		3.33	30	45 ± 1.8		6.66
Bohdjalian [17]	75	47 ± 6.2		0	75	48 ± 6		1.33
Gonzalez [19]	8			0	13			0
Leyba [20]	40	44 ± 1.9		0	40	45 ± 1.9		0
Szeponiak [21]	100	46 ± 1.3		1.00	124	46 ± 1.2		0.80
Shope [22]	29	47 ± 5.7		6.89	32	49 ± 5.2		0
Bendewald [4]	514	47.8		0.97	140	52.5		0
Finks [9]	2109	47.3 ± 7.8		0.33	5944	48.1 ± 7.9		0.57
Giordano [7]	41	47.7 ± 6.9		4.87	30	45.6 ± 6.4		6.66
Total	2916		16/2916	0.55	6428		40/6428	0.63
GBSR	2734	47.6 ± 6.7	44/2734	1.61	1587	49.8 ± 7.4	19/1587	1.20

Giordanos meta-analysis data did not find a significant difference between the two techniques for risk of post-operative bleeding [7]. In contrast to these data, the GBSR has shown a significantly higher incidence for bleeding using circular stapler devices than linear devices. Similar data were also reported in meta-analysis performed by Penna. In this study bleeding was significantly reduced for linear stapled anastomosis (odds ratio 0.46) [8].

A meta-analysis of literature has shown a significant advantage of linear anastomosis for operation time, hemorrhage and wound infection rate [7]-[10].

5.3. Wound Infection

The use of linear stapler devices is associated with a shorter operation time and a lower rate of wound infection by meta-analysis [7]. The literature describes a higher incidence of wound infection for circular anastomosis [11], but the linear stapling technique is more variable [11]. Higher wound infection rates are caused by contamination during extraction of the stapler or longer operative times [12]. The infection rate can be reduced using a protective plastic sheet [11].

One bias of the evaluation in this study is that patients with circular anastomosis suffered significantly more comorbidities than patients with linear stapled GJA.

The wound infection rate in GBSR was 0.4% with linear stapler devices and 2.1% for circular devices ($p < 0.001$). In comparison of wound infection rate using stapler devices versus hand sewn GJA there was also a significant difference for hand-sewn GJA ($p = 0.039$). Data of meta-analysis also report the reduced wound infection rate of linear stapler devices (odds ratio 0.32) [8].

GBSR patients with circular anastomosis had a higher incidence of specific complications than patients treated with linear GJA. The rates of bleeding, sepsis and wound infection were significantly greater for patients with circular stapled GJA than for patients with linear GJA.

5.4. Stricture of GJA

The etiology of stricture formation is multi-factorial and includes local ischemia, tension of anastomosis, sub-clinical leaks, gastric acid, and small stapler devices as factors considered to play a causal role.

The literature reports a stenosis rate for circular anastomosis ranging from 4.3% to 8.8% and a rate for linear anastomosis ranging from 0% to 7.3% [7]. Data from GBSR have an overall stenosis rate of 0.32%, with a 0.40%

rate for circular and 0.19% rate for linear stapled GJA with an increasing incidence and the necessity of dilatation of 0.66% during follow-up in patients with circular anastomosis. Thus, the evaluated rate of stenosis is lower than that published in the literature.

Literature data report a higher stenosis rate for circular (1.6% - 40%) than for linear (3% - 14.6%) anastomosis [13]-[15]. One important influence on the stenosis rate is the diameter of the stapler. Studies report an increasing incidence for 21 mm staplers compared to 25 mm staplers [16]. Data from the GBSR did not find this effect. According to published data, the GBSR did not detect an influence of the stapler device (linear vs. circular) on stenosis of the GJA [15].

6. Conclusions

The data from the GBSR on the surgical treatment of RYGB have not shown any significant differences in the leakage and stricture rates of gastrojejunal anastomosis when comparing linear versus circular techniques according to data published from the meta-analysis [7] [9].

The number of patients with RYGB in this study is lower than that in a meta-analysis published by Penna *et al.* [8]. GBSR is a multicenter observational register without standardized stapling techniques of linear versus circular GJ anastomosis. Additionally, the GBSR does not consider any aspects of a learning curve. We found that the usage of linear versus circular staplers is subjected to center effects. These results may be supported by the investigations of Bohdjalian [17].

The bias and limitations of the GBSR include the evaluated center effect, the high BMI, and the incidence of comorbidities of patients in Germany. Further studies are necessary to evaluate the complication rates of different stapler devices and assess the impact on comorbidities and their long-term effects.

Claim

The German Nationwide Survey on Bariatric Surgery is supported by the Ministry of Research and Education Germany (BMBF) grant number 01GI1124. The responsible investigator is Christine Stroh.

There is no conflict of interest.

Christine Stroh, Grigorij Nesterov, Rudolf Weiner, Frank Benedix, Christian Knoll, Matthias Pross and Thomas Manger confirm that there are no links to firms whose products are mentioned in the article or to firms marketing a competing product. The topic is presented in an independent manner, and the information outlined is product neutral.

The following firms support the GBSR without any relation to their products: Johnson & Johnson MEDICAL GmbH, Ethicon Endo-Surgery Deutschland, Norderstedt Covidien Deutschland GmbH Neustadt/Donau.

We thank all of the hospitals that participated in the study for their active engagement.

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