#### **ORIGINAL CONTRIBUTIONS**





# Bariatric Surgery Worldwide: Baseline Demographic Description and One-Year Outcomes from the Fourth IFSO Global Registry Report 2018

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#### Abstract

**Background** Since 2014, the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) has produced an annual report of all bariatric surgery submitted to the Global Registry. We describe baseline demographics of international practice from the 4th report.

**Methods** The IFSO Global Registry amalgamated data from 51 different countries, 14 of which provided data from their national registries. Data were available from 394,431 individual records, of which 190,177 were primary operations performed since 2014. **Results** Data were submitted on 72,645 Roux en Y gastric bypass operations (38.2%), 87,467 sleeve gastrectomy operations (46.0%), 14,516 one anastomosis gastric bypass procedures (7.6%) and 9534 gastric banding operations (5.0%) as the primary operation since 2014. The median patient body mass index (BMI) pre-surgery was 41.7 kg m<sup>2</sup> (inter-quartile range: 38.3–46.1 kg m<sup>2</sup>). Following gastric bypass, 84.1% of patients were discharged within 2 days of surgery; and 84.5% of sleeve gastrectomy patients were discharged within 3 days. Assessing operations performed between 2012 and 2016, at one year after surgery, the mean recorded percentage weight loss was 28.9% and 66.1% of those taking medication for type 2 diabetes were recorded as not using them. The proportion of patients no longer receiving treatment for diabetes was highly dependent on weight loss achieved. There was marked variation in access and practice.

**Conclusions** A global description of patients undergoing bariatric surgery is emerging. Future iterations of the registry have the potential to describe the operated patients comprehensively.

Keywords IFSO · Bariatric surgery worldwide · Demographic description · Global registry

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## Introduction

With international prevalence increasing year on year, and corresponding increases in the burden of related disease, it is

Table 1	Database	form	used	for	4th	IFSO	Global	Registry	report
(Version 4	.1)								

	Choices/format
Date of birth	dd/mm/yyyy
Gender	Male/female/unknown
Funding publicly	Funded/selfpay/private insurer
Height	cm
Weight on entry to the weight loss program	kg
Type 2 diabetes on medication	Yes/no
Diabetes medication type	Oral therapy/insulin
Hypertension on medication	Yes/no
Depression on medication	Yes/no
Increased risk of DVT or PE	Yes/no
Musculoskeletal pain on medication	Yes/no
Confirmed sleep apnea	Yes/no
Dyslipidemia on medication	Yes/no
Gasto-esophageal reflux disease	Yes/no
Date of operation	dd/mm/yyyy
Has the patient had a prior gastric balloon?	Yes/no
Weight at surgery	kg
Has the patient had bariatric surgery before?	Yes/no
Date of operation	dd/mm/yyyy
Operative approach	Laparoscopic/lap converted
Type of operation	to open/endoscopic/open Gastric band/gastric bypass/
	sleeve
	gastrectomy/duodenal switch/duodenal switch with sleeve/biliopancreatic with sleeve/biliopancreatic diversion/other
Type of hypers	
Type of bypass	Roux-en-Y/single anastomosis/banded gastric
	bypass
Details of other procedure	Gastric plication/single
	anastomosis duodenal-ileal surgery/vertical banded gastroplasty/other
Leak within 30 days of surgery	Yes/no
Bleeding within 30 days of surgery	Yes/no
Obstruction within 30 days of surgery	Yes/no
Re-operation for complications within 30 days of surgery	Yes/no
Patient status at discharge	Alive/deceased
Date of discharge or death	dd/mm/yyyy
Follow-up data	
Date of follow-up	dd/mm/yyyy
Weight at follow-up	kg
Type 2 diabetes on medication	Yes/no
Diabetes medication type	Oral therapy/insulin
Hypertension on medication	Yes/no
Depression on medication	Yes/no
Increased risk of DVT or PE	Yes/no
Musculoskeletal pain on medication	Yes/no
Confirmed sleep apnea	Yes/no
Dyslipidemia on medication	Yes/no
Gasto-esophageal reflux disease	Yes/no
Clinical evidence of malnutrition	Yes/no
Patient status at discharge	Alive/deceased

clear that obesity is a problem that has to be addressed [1, 2]. Although bariatric surgery has been demonstrated to be a safe, effective and sustainable method of weight loss with associated reduction of obesity-related disease [3, 4], it is only performed on a very small percentage of patients who could benefit from it [5].

Bariatric surgery has the potential to improve health, in a costeffective manner, to a large number of patients. However, accessibility to surgery varies within and between countries. Some information has been gleaned by worldwide surveys of practice of bariatric surgeons, but overall, little is still known about the demographics and trends of patients being operated on around the world [6–11]. Thus, although the surveys demonstrate the different kinds of operations and changes in practice over time in different regions, data on patient-related factors such as age, gender, body mass index (BMI) and obesity-related disease, for example type 2 diabetes and hypertension, are lacking. In addition, there is limited information on variation in surgical outcomes including length-of-stay or reduction in BMI or effect on obesity-related diseases on a national or international basis.

In an effort to answer some of these questions, the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) developed a Global Registry, in association with a software and analysis provider, Dendrite Clinical Systems Ltd., aiming to create a global estimate of bariatric surgery practice. The Global Registry has reported on its findings for the last 4 years [12–15]. In this 4th report, the number of individual patient records has doubled the information available compared to the third report, together with a near doubling in the number of national registries submitting data [14, 15]. In this paper, we summarise the findings of the 4th international analysis of outcomes from bariatric and metabolic surgery.

## Methods

National societies were invited by the IFSO President Dr. Jacques Himpens to participate in the Global Registry as previously detailed [16] and a 4th report was commissioned for distribution at the IFSO World Congress in Dubai 2018 [15].

 Table 2
 Progression of data capture over the four IFSO Global Registry reports

	2014	2016	2017	2018
Operations	100,092	142,748	196,188	394,431
Countries	18	31	42	51
Single centre	8	19	21	18
Multi centre	7	5	13	19
National registries	3	7	8	14

Table 3Countries contributing tothe 4th IFSO Global Registryreport

Contributing country	Contributing centres	Years contributed	Number of cases	Total cases in calendar years 2013–2018 analysed in 4th IFSO Global Registry report
Italy	a		80,364	41,957
United Kingdom	163	> 20	63,340	36,867
Sweden	42	10	63,084	31,480
Netherlands	21	4	40,765	40,765
Israel	33	4	34,125	34,125
India	47	15	15,308	12,901
Belgium	20	<u>&gt;</u> 20	12,549	5412
Chile	3	$\geq 20$ $\geq 20$ $\geq 20$ $\geq 18$ = 6	10,011	2349
Switzerland	2	<u>&gt;</u> 20	7863	2240
Taiwan	3	> 18	7472	1786
United States of America	1	6	6117	5457
Russia	25	15	4265	3970
Saudi Arabia	3	10	4231	3120
China	16	13	4126	3684
France	4	$\frac{>}{11}20$	4080	1015
Kuwait	6		4011	2646
Norway	17	5	3726	3726
Argentina	4	16	3264	1084
Turkey	16	9	3041	3027
Qatar	1	7	2832	2203
Canada	1	11	2143	556
Brazil	23	17	2013	922
Mexico	5	<u>&gt;</u> 20	1838	469
Austria	14	1	1713	1713
United Arab Emirates	6	10	1662	1295
Czech Republic	1	3	1319	1319
Japan	21	4	961	961
Hong Kong	4	17	842	358
Peru	1	7	762	557
Spain	2	15	711	126
Poland	3	3	647	647
Ireland	2	12	572	362
Bahrain	1	5	500	487
Egypt	8	8	481	454
Germany	2	$\frac{>}{9}20$	472	82
Jordan	1		466	378
Portugal	1	11	418	221
Colombia	1	3	356	356
Kazakhstan	1	9	338	319
Australia	2	2	321	321
Guatemala	1	18	278	164
Guadeloupe	1	5	211	211
Venezuela	1	5	148	146
Lithuania	1	1	134	134
Bolivia	1	9	128	95
Belarus	1	4	115	115
Georgia	5	5	110	110
Panama	2	10	96 72	63
Hungary	1	3	73	73
Bulgaria	1	2	19	19
South Korea	3	1	10	10

National registries denoted in italics

<sup>a</sup> Number of centres not provided at the time of submission

The Dendrite Intellect Web database technology platform, an Upload-My-Data web portal and a Direct Data Entry system were used to upload and merge the data. Data were submitted from over 550 hospitals in 51 countries spanning 5 continents, including data from 14 national registries.

Descriptive statistics were used for the analysis of the data. The contributors were reassured that no statistical comparison would be attempted between different units or countries. Data presented in graphs define the number of "valid" records, indicating the number of records where obesity-related disease could be ascertained and cases with "no data", the number of cases unavailable for subgroup analysis.

The dataset, defined by a committee for the 1st report, has since been extended slightly, for instance to include explicitly one anastomosis gastric bypass as a procedure distinct from Roux en Y bypass. The dataset for the current version 4.1 is shown (Table 1) [16]. All operations entered up until 4th July 2018 were included in the analysis. All data presented are in relation to primary procedures. Operative data are presented from 2014 to 2018; follow-up data are presented from 2012 to 2016 to account for the inevitable lag in data capture.

## Results

The registry contained 394,431 individual operation records at the time of last data submission. Numbers of participating countries, national registries, individual centres and submitted cases have steadily increased year on year (Table 2). The number of records submitted ranged greatly from 10 from a single centre to over 80,000 submitted by the Italian national registry (Table 3). We do not have complete country-data on case ascertainment.

The majority of the database records fell in the period 2009–2018 (88.5% of the total) although some countries have submitted data from procedures prior to 2000; 190,177 of primary operations were dated in the calendar years 2014–2018. Forty-six percent of the baseline records were >80% complete in data submitted in the calendar years 2014–2018. Variation in data completion for the whole registry is presented (Table 4).

#### **Patient Demographics**

The following baseline analyses relate to primary operations in the calendar years 2014–2018. The overall proportion of female patients was 73.7% (95% CI: 73.5–73.9%). Although operations were more common in females in all countries, there was also a wide variation in the gender ratios, ranging from 50.9% female in Georgia (55/108) to 93.4% female in Guadeloupe (183/196). For the 16 countries with  $\geq$  1000 submitted patients, the gender ratios were 57.7% female (India; n = 11,088) to 79.4% female (Netherlands; n = 37,818).

The median BMI pre-surgery was 41.7 kg m<sup>2</sup> (interquartile range: 38.3-46.1 kg m<sup>2</sup>); there was a wide variation between different contributor countries, with medians ranging from 34.2 kg m<sup>2</sup> in South Korea to 49.1 kg m<sup>2</sup> in Germany (Fig. 1a). The median age at time of operation was 42 years (inter-quartile range: 33-51 years; Fig. 1b) There was variation between countries with a trend to Middle Eastern and Asian countries having a younger, or adolescent practice, with those in the West more commonly operating at an older age. For the 16 countries with

 Table 4
 Data completeness for selected fields in the complete 4th IFSO
 Global Registry report

Data fields	% of data complete
Age	99.9%
Gender	99.5%
Initial weight	64.8%
Funding	48.6%
Diabetes	69.2%
Hypertension	69.2%
Depression	62.3%
DVT risk	59.3%
Musculo-skeletal pain	51.5%
Sleep apnea	68.8%
Dyslipidemia	60.7%
GERD	60.8%
Weight at operation	88.5%
Previous balloon	41.1%
Prior bariatric surgery	93.3%
Approach	76.8%
Other operation	56.5%
Banded procedure	42.0%
Leak	42.7%
Bleed	42.1%
Obstruction	42.2%
Reoperation	40.0%
Status at discharge	65.9%
Date of discharge	57.1%

 $\geq$  1000 submitted patients, the BMI range was 37.3 (China; *n* = 1939) to 44.5 (Saudi Arabia; *n* = 2119).

#### **Obesity-Related Disease Prior to Surgery**

As expected, a large proportion of patients had obesity-related disease. There was large variation in the reported rates of these conditions between countries. Overall, those on medication for type 2 diabetes made up 19.8% of patients (inter-country variation: 4.5-97.7%); 30.6% were treated for hypertension (10.9-92.6%) and 12.4% of patients were on medication for depression (0.0-54.4%). Also, 24.3% of patients reported requiring treatment for musculoskeletal pain (0.0-65.1%); 18.6% of patients had diagnosed sleep apnea (0.0-74.3%); and 17.0% of patients had gastro-esophageal reflux disease (0.0-54.8%). Amongst those countries with  $\geq 1000$  submitted patients, the respective figures were 19.5% (9.8-43.5%) for type 2 diabetes, 30.2% (15.5–46.3%) for hypertension, 12.5% (0.6–29.1%) for depression, 24.6% (0.0–50.4%) for musculoskeletal pain, 18.4% (0.0-36.8%) for sleep apnea and 17.0% (6.4-40.7%) for GERD. The variation in disease prevalence between regions is shown (Fig. 2a, b).

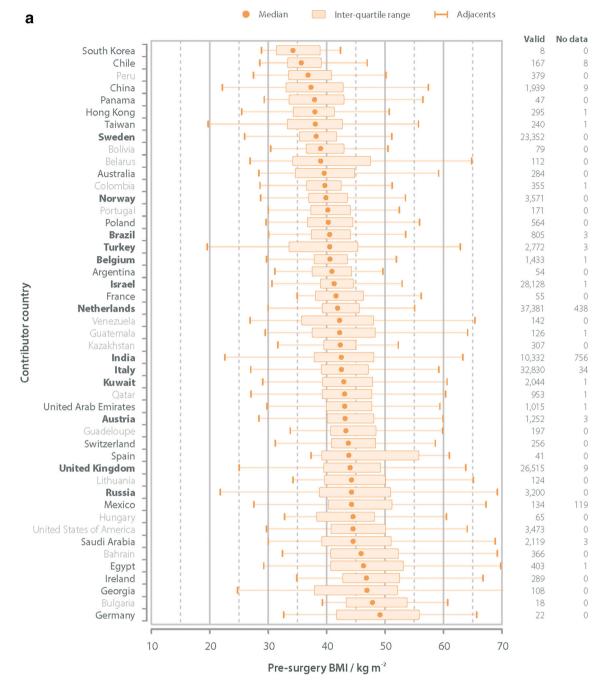


Fig. 1 a Patient's BMI before surgery by country; calendar years 2014–2018 (data for 188,522 of 190,177 cases). b Patient's age at surgery by country; calendar years 2014–2018 (data for 190,080 of 190,177 cases)

## Stratification for Operative Risk

An estimate of operative risk as determined by the Obesity Surgery Mortality Risk Score (OSMRS) varied widely by country (Fig. 3) [17]. Georgia, Bulgaria and Hong Kong had the highest risk patient populations (OSMRS groups B and C: 78.7%, 72.2% and 66.7%, respectively); South Korea, Bolivia and Kuwait show the least risk (OSMRS groups B and C: 12.5%, 20.5% and 22.2%).

#### **Operation Type**

Almost all, 99.3%, operations were performed laparoscopically. In the time period of this analysis, there were 72,645 Roux en Y gastric bypass operations (38.2%), 87,467 sleeve gastrectomy operations (46.0%), 14,516 one anastomosis gastric bypass procedures (7.6%) and 9534 gastric banding operations (5.0%). Although in the whole registry Roux en Y gastric bypass is the most recorded

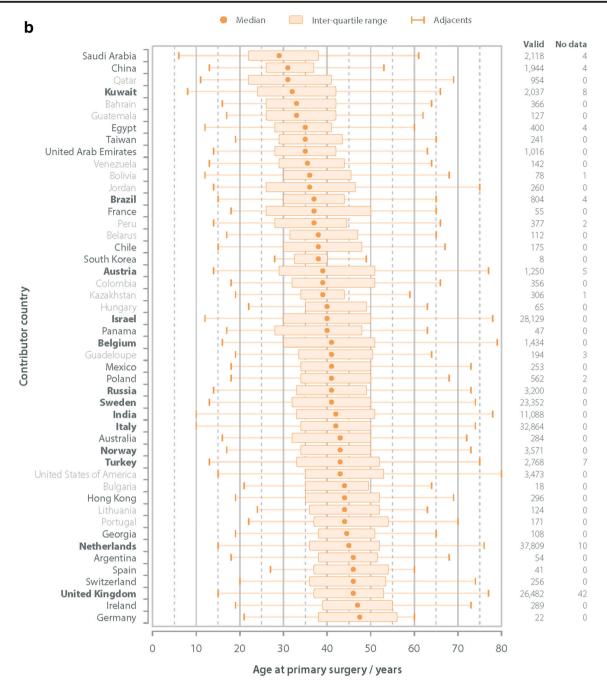


Fig. 1 (continued)

operation, in the last 2years, the number of sleeve gastrectomies recorded is greater than the number of Roux en Y gastric bypasses.

Mexico (205/253, 81.0%), Colombia (282/356, 79.2%) and Brazil (595/808, 73.6%) reported the highest proportions of gastric bypass surgery; Australia (284/284, 100.0%), Saudi Arabia (2122/2122, 100.0%) and Guadeloupe (196/197, 99.5%) reported the highest rates of sleeve gastrectomy operations. Those figures may represent local, rather than national practice since, of these

countries, only Brazil submitted data from a national registry. Region variation in operation type is displayed in Fig. 4 and Table 5.

## Length of Stay

The vast majority of patients who had a gastric band inserted were discharged within 1 day of their operation (88.5%); gastric bypass patients within 2 days of surgery (84.1%); and sleeve gastrectomy patients within 3 days (84.5%). This

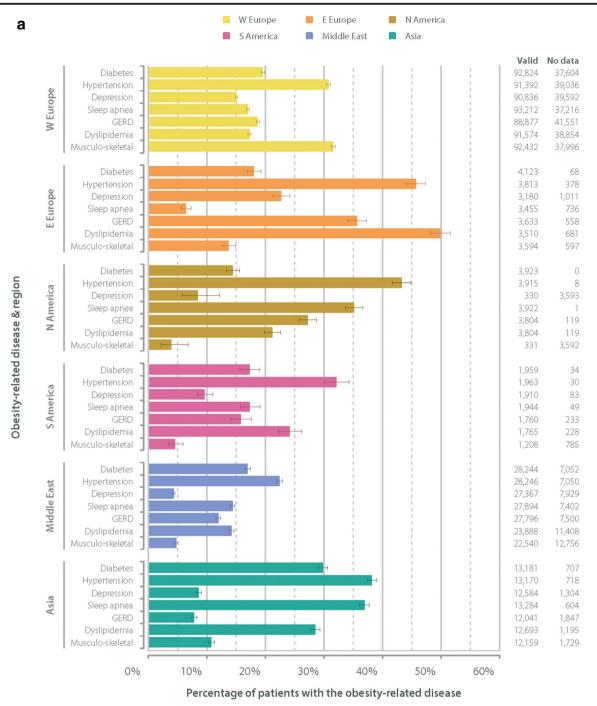


Fig. 2 a Distribution of obesity-related disease by region; calendar years 2014–2018. b Distribution of obesity-related disease ordered by each disease; calendar years 2014–2018

variation in trends was marked between different regions with the shortest lengths of stay being in North America (singlecentre data; Fig. 5).

## **One-Year Follow Up**

For the 184,871 primary operations recorded between 2012 and 2016, 116,431 had follow-up records (63.0%). One-year follow-up was more complete in those patients

having Roux en Y gastric bypass than sleeve gastrectomy (57.4% vs 29.4%). Variation in attainment of follow-up data for the Roux en Y gastric bypass group is shown (Table 6).

Over all types of surgery, the average recorded percentage weight loss was 28.9% a year after surgery: 30.0% for Roux en Y; 29.1% for gastric sleeve; 16.1% for gastric band; and 32.9% for one anastomosis gastric bypass. As would be expected, the percentage weight

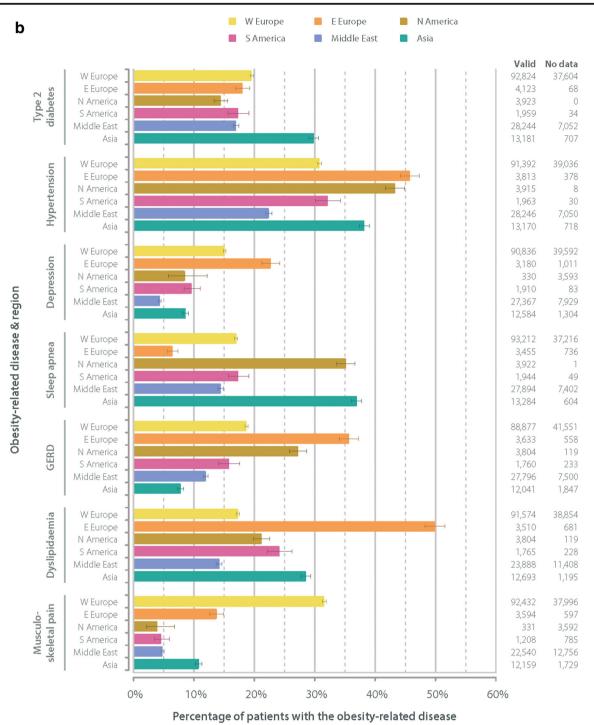


Fig. 2 (continued)

loss at 1 year was greater in those with a higher initial BMI (Fig. 6a).

One year after primary surgery, 66.1% of those taking medication for type 2 diabetes beforehand were no longer on medication; the proportion of patients no longer treated for diabetes was highly dependent on weight loss achieved, with the rate of improvement increasing with higher percentage weight loss (Fig. 6b).

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## Discussion

This dataset derived from the continuing IFSO Global Registry gives an extensive and unique overview of practice in bariatric surgery, demonstrating variations in patient and operation selection in different countries. If the datasets submitted by national registries have accurate case ascertainment, then it is likely that they represent

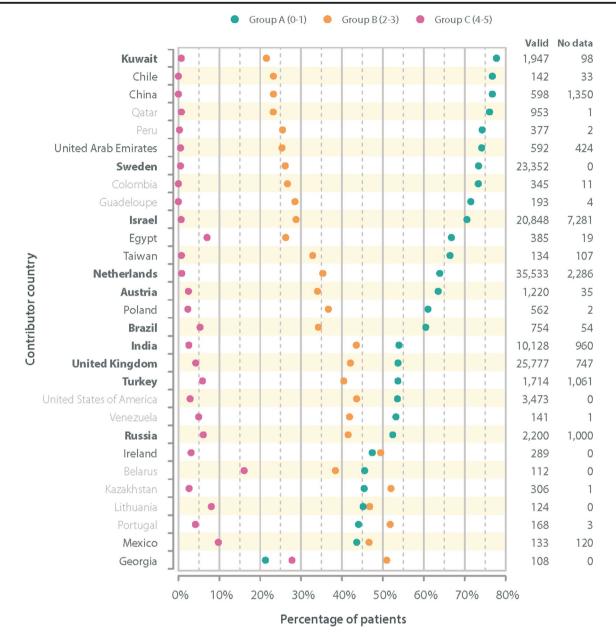
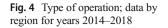
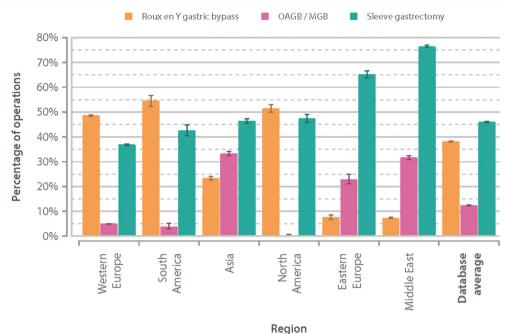


Fig. 3 OSMRS group by country; calendar years 2014–2018. Data are shown for countries with 100 or more qualifying operations

accurately the practice in each country. However, the IFSO Global Registry has no mechanism to check case ascertainment, submission of incomplete or erroneous data, and it is assumed that each submitting society provides this validation. The same assumption is made for all individual hospital submissions. Future iterations of the dataset could include a question about whether the data have been validated before submission. However, even in small datasets, the data submitted appear consistent with known parameters in that country: the number of patients submitted from Germany in this report is only 22 but their median BMI is similar to that of the known caseload in that country [18]. To enable high levels of participation and compliance with the Global Registry, the dataset has purposefully been kept short and minimal, predominantly in the form of 'Yes/No' questions. However, the simplicity of the data collected may miss important outcomes, and it is not in line with recommendations on standardised bariatric surgery outcomes reporting [19]. There is a fine balance between the two approaches to achieve a comprehensive, detailed database with true case attainment: there is more work to be done to achieve the perfect equilibrium.

We noted that the overall completion of the baseline dataset was 63%. Differences in how registries are set





up, for instance the lack of 'Yes/No' answers to identify the absence of surgical complications, may account for some apparent incompleteness. Recently, the Swedish and Norwegian SOReg and the Dutch registry DATO have demonstrated that sharing data elements between registries can allow accurate cross-comparison of surgical complications, an important initiative towards quality assurance between different countries [20]. Qualitative assurance and improvement projects might be a future goal of the IFSO Global Registry. However, thus far, the project has been limited to a description of baseline demographics and 1-year outcomes so as to encourage continuing data submission and recognising the inherent challenges of data validation as described above. In the future, standardising a minimum bariatric dataset could be a goal for national registries and local databases worldwide.

Although this year, the number of national registries submitting data has increased to 14, there are still large areas of the world whose data are unknown. Other countries have large comprehensive registries: in the USA, the MBSAQIP (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program) is a large collaboration between the American College of Surgeon and the ASMBS (American Society for Metabolic and Bariatric Surgery) and the resulting Participant Use Data File (PUF) is released periodically for independent analysis by participating centres. Recent reports from the 2015 PUF provide baseline demographic descriptions that are complementary to the data presented here [21-23]. Many countries have data submitted from only a single centre, which means that this may only reflect local practice rather than national trends. Continued efforts to recruit new centres and obtaining data from existing, and developing, national

	Roux en Y gastric bypass	OAGB/MGB	Sleeve gastrectomy	Gastric band	Other	Total
W Europe	63,395	6468	48,151	7630	4784	130,428
S America	1087	46	849	2	9	1993
Asia	3235	3711	6440	16	486	13,888
N America	2017	7	1858	40	1	3923
E Europe	320	433	2734	285	419	4191
Middle East	2585	3851	26,983	1561	316	35,296

Data from Central America and Australasia excluded due to small numbers *OAGB/MBG* one anastomosis gastric bypass/mini-gastric bypass

**Table 5** Type of operation; databy region for years 2014–2018

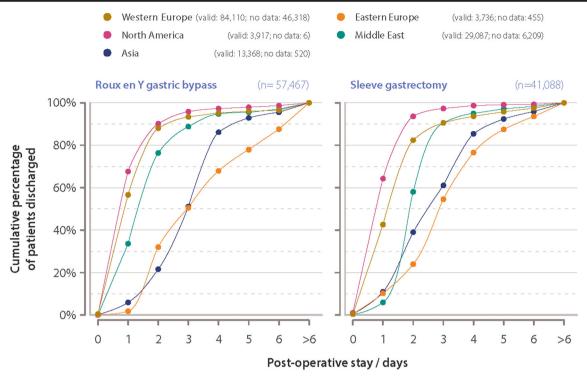


Fig. 5 Post-operative stay and region; calendar years 2014-2018

registries will strengthen the description of baseline demographics in patients operated worldwide.

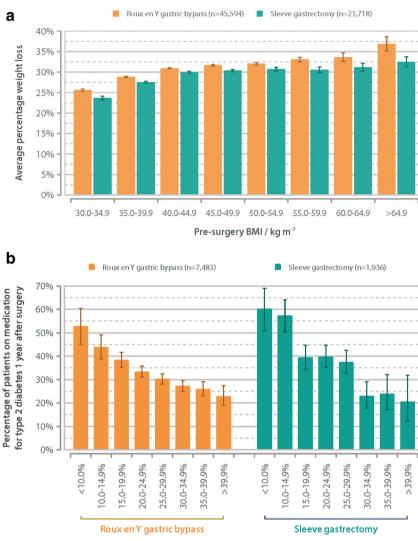
The data collected via the Global Registry mirror the operative trends of the 2016 international survey of practice [11]. The international survey obtains a wider coverage of complete countries than is obtained by the Global Registry; however, where no national registry is available, these numbers may be estimated. In addition, the Global Registry collects a greater depth of data, with patient variables and outcome data within the limitation of the dataset. The estimated international number of operations performed in 2016 was 634,897. This suggests at this time around 7.5% of all international operations are being logged on the global registry, an increase from previous years [16].

Even though the overall attainment of 1-year follow-up data has increased, weight loss and diabetes status are the only variables retrieved with sufficient frequency to allow meaningful comparison, with 32.5% and 23.3% of cases with follow-up, respectively. [16] We note the differences in captured follow-up for patients with diabetes having gastric bypass (41.1%) and sleeve gastrectomy (11.9%). The reasons for this are unknown, but might be due to different follow-up data submitted by the geographically separate centres doing these operations. Also, the data

 Table 6
 Roux en Y gastric bypass; data completeness for obesity-related disease data 12 and 24 months after surgery; operation calendar year 2012–2016

	Patients without condition before surgery			Patients with condition before surgery		
	Data at operation	12-month follow-up	24-month follow-up	Data at operation	12-month follow-up	24-month follow-up
Type 2 diabetes	70,733	33,224 (47.0%)	5391 (7.6%)	19,058	7690 (40.4%)	2012 (10.6%)
Hypertension	60,043	28,038 (46.7%)	4616 (7.7%)	28,571	12,449 (43.6%)	2944 (10.3%)
Depression	72,380	17,395 (24.0%)	202 (0.3%)	12,111	3107 (25.7%)	26 (0.2%)
Sleep apnea	73,701	32,156 (43.6%)	5910 (8.0%)	16,043	6235 (38.9%)	1665 (10.4%)
GERD	68,897	30,671 (44.5%)	5731 (8.3%)	16,069	5801 (36.1%)	1532 (9.5%)
Dyslipidemia	71,199	34,225 (48.1%)	5690 (8.0%)	15,073	6261 (41.5%)	1810 (12.0%)
Musculo-skeletal pain	51,002	21,234 (41.6%)	4313 (8.5%)	22,759	10,777 (47.4%)	2846 (12.5%)

**Fig. 6** a Percentage weight loss at 1 year by pre-surgery BMI: operations in calendar years 2012–2016. b Diabetic medication use in type 2 diabetics 1 year after surgery: operations in calendar years 2012–2016



Type of operation and percentage weight loss one year after surgery

presented in the full 4th report show some promising trends in improvement of hypertension, sleep apnea, depression, and musculoskeletal pain, but with follow-up records available for fewer than 10% of cases, no conclusions can be drawn from these findings [15]. A challenge for this and all registries is how to achieve better follow-up data.

One of the benefits of such a registry enables us in real time to appreciate the changes in practice, initially with the rise in popularity of the sleeve gastrectomy, and now with an emerging increase in the number of one anastomosis gastric bypass operations being performed. Such understanding can help us focus our research questions to make them relevant, as demonstrated by the By-Band study which evolved to become the By-Band-Sleeve randomised controlled trial in the UK, as the number of sleeve gastrectomies performed increased. [24]

Limitations of the paper include lack of generalizability due to incomplete case ascertainment, and inability to assess incomplete or erroneous data submission, as well as incomplete follow-up data. In addition to the limitations of the Yes/No questions, there is unknown selection bias for those patients with recorded follow-up. Swedish, Norwegian and Dutch surgeons have shown that it is possible to amalgamate large datasets with the aim of demonstrating differences in mortality and complication rates between different countries. [20] Over time, future iterations of the IFSO Global Registry might be able to achieve this on a much wider scale. If this became possible, the bariatric community would be able to demonstrate further the safety of bariatric/metabolic surgery on a generalizable basis.

In summary, there is a wide variation in bariatric practice internationally with sleeve gastrectomy now the most commonly performed bariatric procedure. The burden of obesityrelated disease in the operated populations is high but varies greatly between regions. Worldwide, bariatric surgery provides marked weight loss and remission of diabetes at 1 year. Further data are needed to show the effect on other obesityrelated diseases. **Funding Information** The IFSO Global Registry Fourth Report was funded by the International Federation for Surgery for Obesity and Metabolic Disorders.

#### **Compliance with Ethical Standards**

This article does not contain any studies with human participants or animals performed by any of the authors. For this type of study, formal consent is not required.

**Conflict of Interest** Dr. Welbourn reports non-financial support for attending conferences from Ethicon Endo-Surgery, personal fees from consultancy fees from Novo Nordisk, outside the submitted work.

Dr. Cohen reports personal fees from GI Dynamics, grants from Johnson & Johnson Medical, Brazil, outside the submitted work.

Dr. Dixon reports personal fees from NHMRC, during the conduct of the study; personal fees from Apollo Endosurgery, personal fees from Bariatric Advantage, personal fees from Medrontic, personal fees from Nestle, personal fees from Johnson & Johnson, outside the submitted work.

Dr. Himpens reports personal fees from Ethicon, personal fees from Medtronic, outside the submitted work.

Dr. Walton and Dr. Kinsmen reports grants from IFSO, during the conduct of the study; grants from IFSO, outside the submitted work. Dr. Hollyman, Dr. Liem, Dr. Brown, Dr. Ottosson, Dr. Ramos, Dr. Alsabah, and Dr. Våge have nothing to disclose.

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