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- building, maintaining & hosting the data entry web portals
- data analysis and
- publishing this report

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Preface: Big Data demands Big Questions

The past 2 decades have seen the world engulfed by a pandemic of overweight and obesity, with the emerging economies as severely affected as the advanced. Beyond the individual toll of disabling illness and reduced lifespan lies a major health-economic and socio-economic burden: it is intuitive that the most severely affected individuals are the greatest contributors to this cost.

Surgical treatment demonstrably improves the health and life expectancy of those who suffer from Severe and Complex Obesity, a protean disease of civilisation. Surgeons and patients alike are convinced of this truth and few can contradict: over 340,000 operations were performed worldwide in 2008.

Such a volume should yield really good information. Several good national registries have emerged, yet at the global level there is such diversity between patients, healthcare systems, preferences of patients and predilections of surgeons that the signal-to-noise ratio in this Big Data has hitherto been poor.

The present report is a bold and outstanding approach to processing this signal: diverse data from around the world have been painstakingly collated and filtered for their similarities. The differences uncovered are intriguing and themselves challenge to lateral thinking, but real persuasive impact comes from the addition of the similar, precisely because it speaks in spite of diversity.

The current project pilot breaks new ground: of course it demonstrates the ability of modern data systems and experienced analysts to filter the background noise of diversity and to offer more secure answers to old questions. Beyond that however the upward shift in magnitude of data that, if collected, can be interrogated challenges to define the new questions that must now be asked.

These are interesting times for the global bariatric community and its representative body, IFSO.

Alberic Fiennes
President of the European Chapter of IFSO
Immediate Past President, British Obesity & Metabolic Surgery Society (BOMSS)
Foundation Chairman of the Data Committee, UK National Bariatric Surgery Registry (NBSR)

Foreword

The epidemics of obesity and metabolic syndromes like type-2 diabetes are not sparing any part of the World. According to the World Health Organization (WHO), non-communicable diseases (NCD) kill more than 36 million persons each year, most before the age of 60; will the United Nations Millennium goal to decrease those estimates be reached? A recent National Institute of Health (NIH) study has reported that extreme obesity is shortening life expectancy in certain groups by 14 years. The economic burden of such health problems is estimated to be 190 billions of dollars per year in the United States alone (Harvard School of Public health, 2005) and rising rapidly in extremely populous countries like India and China. All efforts are needed to control NCDs, and since the WHO is developing a comprehensive global programme for monitoring prevention and control of non-communicable disease, surgical interventions should be counted.

Surgery is the only hope for this decade, and the early part of this century, to decrease this epidemic. We have decided to tackle this in a worldwide fashion, and since IFSO (International Federation For The Surgery of Obesity & Metabolic Disorders) is now 20 years of age, we need to know how extensive is the practice of bariatric and metabolic surgery across the globe, and how effective it is in different regions?

Lack of monitoring, the need for an accurate database from numerous countries, more specifically the outcomes and health systems responses have prompted IFSO to establish a registry. At the start of this project, within 4 months, 3 national registries were uploaded successfully (Sweden, United Kingdom and Russia), with the additions of individual centres and contributors, representing a total of 18 countries, with more than 100,000 patients. Although, at this time, IFSO is made up of 60 national Societies, it is expected that in the near future, this registry will encompass far more countries and a larger cohort of patients (>half a million to 1 million patients).

This was all permitted by a generous grant from Dendrite, under the leadership of Dr Peter Walton and his fantastic team. The Dendrite software technologies have enabled the merging of national, local and individual registries, into a unique merged dataset with intelligent analysis. In fact, the story started by solidifying a concept that took form after a meeting at the Royal Society of Medicine, in Wimpole street in London, on August 9, 2013, and presented to the executive board of IFSO in Istanbul at the end of the same month. By September 13, 2013, the industrious executive board of IFSO, under the presidency of Luigi Angrisani of Napoli, has approved the Dendrite Proposal to commence a Global IFSO Registry Pilot Project with a report to be presented at the 19th World Congress of IFSO in Montreal, Canada (August 26-30, 2014). After some discussion, the founding charter of the IFSO global registry was approved on January 22, 2014, and invitation letters were sent to worldwide participants on February 12, 2014, and data gathered until mid-June.

The present reported analyses, with the expertise of members of the Steering committee Richard Welbourn, Ingmar Naslund, Johan Ottosson, and Peter Walton with a special contribution from Robin Kinsman (Dendrite’s Senior Data Analyst), have taken the data and presented it nicely for readers. With the First IFSO Global Registry report in hand, over 100 pages describe demographics, presence of comorbidities, and type of surgery, post-operative outcomes, and follow up data. We have some description of post-operative stay per country and region, as we know there are regional and cultural differences in this aspect. In addition, this report presents follow up data, outcomes on weight loss are given at 1 year (we know it is short, but it is the beginning!), as well as comorbidity resolution.

But, as the late Canadian economist John Kenneth Galbraith used to say:

*Do not be alarmed by simplification, complexity is often a device for claiming sophistication, or for evading simple truths.*

Congratulations on the first report.

Michel Gagner

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President, IFSO 2014 - 19th World Congress of IFSO, Montreal, Canada
Introduction

IFSO Global Registry: an Australian bariatric physician’s perspective

Surgical registries have had an extraordinary impact on evaluating and positively influencing numerous areas of surgical care. Understanding trends, providing quality assurance, allowing timely evaluation of innovation, monitoring devices, and examining and understanding outliers are all vital roles of registries in delivering positive health outcomes and assuring public and stakeholder confidence. Unlike medical drug therapies, surgery is rarely subjected to large randomized controlled trials: innovation is often incremental, and not all in a positive direction, and long-term post marketing surveillance of surgery is not assured. For example, the collection of sufficient evidence to formally support the change in cholecystectomy from a routine open approach to a routine laparoscopic approach took 20 years from the time the original innovation was introduced 1. The development cycle in bariatric-metabolic surgery is short, generating a need for timely assessment of trends and innovation.

Bariatric surgery provides specific challenges that increase the need for excellent long-term surveillance. Bariatric surgeons are not excising diseased or dysfunctional tissue; blocking, unblocking or repairing a bodily conduit; restoring dysfunctional or damaged anatomy; or implanting a device to restore function. They are treating a chronic metabolic disorder by targeting organs that are neither diseased nor necessarily dysfunctional. The responsibility to understand the consequences of what we are doing is critical to public confidence in this rapidly evolving area of surgery. We have the global challenge of rapidly increasing numbers of eligible patients with modest overall growth in bariatric surgery over recent years, but have many more bariatric surgeons, institutions and countries sharing the load 2-4. The percentage of eligible patients undergoing bariatric surgery is very low, generally less than 2% annually in regions of greatest uptake, and trivial globally. Within countries, regional and socio-economic factors have a major influence on availability and uptake 5, 6. At a public health level any effect would be negligible.

Given the impressive results that we believe bariatric surgery provides, and that it is considered the best, or only, effective therapy available for a range of eligible patients, we must consider some important questions. Why is uptake so low? Why do we not have a group of patients where bariatric surgery would be recommended as responsible best care; a group that caring physicians would be obliged to offer a referral for a surgical opinion? When would not providing access be negligent? We all know of our responsibilities when confronted with patients with other serious chronic conditions, but somehow clinically severe obesity is different. There is clearly an issue of confidence. Those working in the bariatric surgical area may have misplaced confidence in the therapy provided, or a well justified confidence, but have they have not shared, or marketed, this effectively to healthcare providers. What is clear is that broader healthcare providers, payers, health practitioners, and patients do not share the confidence of those working directly in the bariatric surgical area. Our patients and their local stakeholders need to have confidence in bariatric-metabolic surgery, a confidence not derived from model practice in another country. Real world, local data in the context of the big picture is a valuable resource. Simply contributing to a surgical registry inspires confidence, demonstrates integrity, oversight, and quality assurance. Indeed, impressive local results may demonstrate the need for increased bariatric surgery capacity to accommodate a growing demand.

The First IFSO Registry Report has contributions from 18 countries and represents national data from the United Kingdom, Sweden and Russia. This first report clearly demonstrates:

- Commitment to move forward and provide an opportunity to engage the global bariatric community to contribute and share data. This is particularly important for countries and regions without registry access.
- Willingness for many nations to contribute to a global registry.
- Ability for the current registry software to upload data from multiple established sources and provide a data entry platform for those with no current database.
- Capacity to merge data and generate analyses of interest.

This is an exciting start to an important international journey; a commitment that will need to be flexible, innovative, provide leadership, and serve the needs of the global bariatric community in monitoring and improving patient outcomes.

Minimal dataset

Registries need to engage a minimum required dataset for each patient as part of entry. Bringing disparate datasets together has delivered an extremely minimal dataset, and this will need to change. The minimal dataset should only include fundamental elements needed to define critically important outcomes such as early morbidity
& mortality, surgical reoperations and revisions. The composition of any minimal dataset will be controversial, as today there is no consensus in presenting weight loss. We also need to consider the value in collecting poor quality, for example non-objective, data on obesity-related comorbidity, when this quality data can be accurately sourced from a small sub-study. I commend the efforts of the England NHS-funded By-Band RCT study group for taking on the detailed task of developing a minimal dataset for reporting bariatric-metabolic surgery randomized controlled trials as this should provide excellent guidance for the global registry. A minimal dataset does not preclude collecting detailed data on a specific topic; for example, examining in detail the early outcomes of a newly-introduced gastrointestinal device or procedure.

There are limitations to the current data and analysis. Much of the data has been uploaded retrospectively; only limited countries can provide rigorous post-operative mortality data; and the method and integrity of data entry varies. However, this first report sets the scene, enables clear trends to emerge, and provides a roadmap for the future.

**Observations from the current analysis**

Publicly funded bariatric-metabolic surgery dominates in Europe with high levels of privately funded surgery in Asia, the Middle East and South America. Areas with high levels of public funding tend to operate on patients with a higher baseline BMI and are more likely to also report diabetes, hypertension, depression, musculo-skeletal pain and obstructive sleep apnoea. In Asia, BMI levels are generally lower and the proportion of patients with diabetes is higher, as might be expected given the greater propensity for diabetes at a lower BMI in Asian communities. European countries, specifically the United Kingdom, Germany and Spain, operate on a higher proportion of patients with a higher surgical mortality risk, probably reflecting prioritisation within publicly funded health services.

The three most commonly used procedures are almost always performed laparoscopically. There also appears to be extraordinary polarity with regard to procedure selection. In Sweden and the Netherlands the Roux-en-Y gastric bypass dominates (>90%) while in Peru and Saudi Arabia sleeve gastrectomy are performed almost exclusively. Of course, in some countries this may be related to the surgical practices currently contributing to the registry. There is a striking variation in the rate of reported re-operative surgery with 40% from France and less than 1% from Germany and Brazil. Clearly differences are likely to be related to bias generated by national reporting requirements, an issue which needs attention. However, the two large national contributors to the registry (the United Kingdom and Sweden) also have substantial differences in the proportion of re-operative surgery being performed.

**Post-operative results**

Weight loss results at one year demonstrate the overwhelming bias that BMI generates with percentage of excess weight loss. This reporting method, while distorted, implies a uniform ideal weight for all, but, this is not the case, as ideal BMI for mortality varies with age, ethnicity, and state of health. Percentage weight loss provides a more comparable picture and thankfully demonstrates a lower percentage weight loss in those of lower baseline BMI & a trend for the highest loss in the super obese. The weight loss results are as expected from the published literature and provide a real world result that individual practices could use as a standard for one year following surgery.

Changes in the presence of comorbidity or medications used for comorbidity are also as reported in the literature but, speaking as a bariatric physician, we should be very cautious with this approach. All comorbidity must be measured objectively and there is no guarantee that patients who have stopped therapy for diabetes, hypertension, dyslipidaemia, depression, or obstructive sleep apnoea do not need their therapies. The aim of bariatric surgery should be to deliver better health, not to stop other highly effective therapy. There is clear evidence that post bariatric surgery remission of diabetes is not necessarily permanent; incident hypertension is not affected, with weight loss having a modest and variable effect on blood pressure; commonly-used procedures have small, if any, influence on total cholesterol or LDL-cholesterol; and obstructive sleep apnoea can be improved, but is rarely cured by bariatric surgery. Depression levels fall following bariatric surgery, but risk of suicide appears to increase with some modalities. In my view, monitoring comorbidity, while attractive, may not be a core role for bariatric registries. Registries do provide a platform to add on very detailed data collection on a specific topic or comorbidity, within a specific group, or in assessing innovation thereby providing excellent opportunities for high-quality clinical research.

Registries are of greatest value when the fundamental data are complete. Clearly, prospective data need to be sourced from all participating surgical practices on every patient. National registries are ideal and I would encourage all countries or regions to develop registries as a priority, and through these have their data seamlessly extended to the IFSO global registry. There will always be a need to provide direct access to the registry for
individual practices without an alternative. At this stage retrospective data entry from both individuals and registries has been valuable in providing clear evidence of successful data upload, integration and analysis; and is already providing a large enough caseload from many countries to generate interesting comparisons and trends.

In conclusion, I applaud this first report of the IFSO global bariatric surgery registry. It marks an historic first step in bringing together real world data from around the globe. It will provide essential support in understanding risk stratification, and refining those most likely to benefit from surgery. It will allow new procedures to be assessed, devices to be tracked, and provide information regarding surgical learning curves, and may define minimal surgical workloads for surgeons and their institutions. It will enable morbidity, mortality, complications and reoperations to be assessed, allow the development of clinical standards and benchmarks, detection of outliers, and provide valuable quality assurance locally and globally. Ultimately, it informs a broad range of stakeholders of the risk and benefits of surgery, while generating data to inform measurable improvement in the health outcomes of patients. The report strongly endorses the concept of a global registry. Now for extending its reach, refining the prospective data collection, and providing durability of the registry and data collection.

John Dixon

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References

Chairman’s introduction

It is a privilege to present data on baseline obesity-related disease, operation types, operative outcomes and disease status after bariatric surgery in over 100,000 patients accumulated from 25 local and national databases and registries from all over the world. This initiative of IFSO, the first of its kind, could help the bariatric community establish essential benchmark knowledge about the patients we are operating upon, their age and gender distributions, body mass index (BMI) and disease burden, as well as track trends in surgery over time.

The data are presented not as the standard Abstract, Introduction, Methods, Results, Discussion and Conclusions format of a peer-reviewed publication. Rather, using a small and necessarily far from comprehensive dataset, we present the data as simple tables and graphs using usually 2 variables, one for each axis, plus a dedicated commentary for each. Even though this is a very basic presentation of data, many of the results demonstrate clear and important differences in bariatric practice between countries.

A comprehensive Charter of ownership has been set up regarding use and ownership of the accumulated and merged data, and contributors can be assured that we have steered well clear of attempting to make statistical comparisons between different units and countries, and that their submitted data will not be misused. We are also fully aware of the inherent problems of over interpretation and reading too much into the data (see page 25 for a discussion of the challenges of missing, incomplete or erroneous records). Statistical comparison and analysis between countries was not the purpose of data collection (see our aims on page 24) in this first iteration of the process.

If there are to be further developments and reports for the IFSO Global Registry, attractive aims could also include agreeing and developing models of risk stratification and the setting of international benchmarks for post-operative complications or mortality. The Registry could help in these aims by standardizing data collection. As it progresses, the data it contains might also be useful in influencing policy internationally and increasing service provision in countries where there is little or no bariatric surgery.

I encourage all key stakeholders in bariatric surgery (especially surgeons, providers and commissioners of care) to embrace this data collection and reporting process at individual clinics and hospitals, and onwards / upwards at both national and international levels. It will require widespread involvement and on-going commitment from all those involved in the care of the bariatric patient to ensure high-quality data can be collected, properly analysed and shared, so that we will be better able to understand shifts in disease patterns, practice and outcomes on a global scale.

Thank you to all those surgeons who have committed their data for inclusion in this first pilot report, your contribution is very much appreciated.

Richard Welbourn

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President, British Obesity & Metabolic Surgery Society (BOMSS)
Chairman of the Data Committee, UK National Bariatric Surgery Registry (NBSR)
Executive summary

This is the first comprehensive, international analysis of outcomes from bariatric (obesity) and metabolic surgery, gathered under the auspices of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

In overview

- 18 countries from 5 continents contributed 100,092 operation records, with 53,197 in the calendar years 2011-2013
- The number of operations contributed ranged from one individual centre that entered 24 operation records to over 34,000 each from two countries with established national registries (Sweden and the United Kingdom)
- The report details information on 65,636 gastric bypass operations (65.6% of the total operations submitted), 16,735 sleeve gastrectomy operations (16.7%) and 12,365 gastric banding operations (12.4%)
- Most database entries represented operations performed in the period 2011-2013 (53,197, 53.1% of the total) and therefore likely represent the current status of bariatric surgery in these countries

The dataset and completeness of data entry

- A simple dataset of only 30 (23 baseline / 7 follow up) variables was created.
- Overall more than 79.3% of the submitted baseline records were >80% complete, a remarkable achievement for the first iteration of an international collaboration in surgery.

Funding and gender inequality

- Overall 63.1% operations were funded by public health services of each contributor country and 36.9% were funded privately; there was wide variation in the rate of public funding (range: 0.0-100.0%), suggesting inequality of access to surgical services.
- There was also wide variation in the gender ratios of patients having surgery, ranging from 48.2% female patients in China to 80.7% female patients in the Netherlands.

Primary operations in the calendar years 2011-2013 and BMI range

- The average BMI of operated patients was 44.4 kg m$^{-2}$ (inter-quartile range: 38.9-48.7 kg m$^{-2}$), the average age was 42.1 years (inter-quartile range: 34-76 years) and the average proportion of female patients was 74.4% (range: 47.3-80.8%).
- There was wide variation in the average initial body mass index (BMI) between different countries, ranging from 39.6 kg m$^{-2}$ in Chile to 53.4 kg m$^{-2}$ in Germany for male patients; and 36.1 kg m$^{-2}$ in Peru to 49.1 kg m$^{-2}$ in Germany for female patients.
- The centres submitting data from Mexico (92.2%), the Netherlands (94.0%) and Sweden (96.3%) had the highest proportion of gastric bypass operations and those submitting data from Peru (100.0%), Saudi Arabia (100.0%) and India (91.1%) had the highest proportion of sleeve gastrectomy surgery.
- A very large proportion of all operations (97.3%) were carried out laparoscopically and 91.2% of gastric banding patients were discharged by post-operative day 1; 91.6% of gastric bypass patients by day 3; and 88.3% of sleeve gastrectomy patients by day 3.
- The overall reported mortality for all operations was 0.03%.

Comorbidities

- Treatment for type 2 diabetes was reported more frequently in male patients (with the exception of France), but there was wide variation in reported rates. The average rate of diabetes was 30.5% for males (range: 5.4-57.1%) and 16.8% for females (range: 8.3-30.3%).
- Hypertension was more common in male patients in every country, but there was wide variation in reported rates. The average rate of hypertension was 46.9% for males (range: 21.4-67.9%) and 28.1% for females (range: 0.0-48.1%).
• Depression was more common in female patients (with the exception of Saudi Arabia), but there was wide variation in reported rates. The average rate of depression was 11.2% for males (range: 0.0-28.6%) and 19.3% for females (range: 0.0-41.7%).

• Musculo-skeletal pain did not show a significant gender difference, but there was wide variation in reported rates. The average rate of musculo-skeletal pain was 23.3% for males (range: 0.0-68.2%) and 25.1% for females (range: 0.0-48.1%).

• Sleep apnoea was more common in male patients (with the exception of Germany), but, again, there was wide variation in reported rates. The average rate of sleep apnoea was 29.4% for males (range: 3.8-86.5%) and 11.2% for females (range: 0.0-52.9%).

Stratification for operative risk

The Obesity Surgery-Mortality Risk Score (OSMRS) varied widely between the submitting countries. Operated patients in Peru, Chile and United Arab Emirates appeared to have least risk (OSMRS Groups B & C: 21.9%; 23.6%; and 26.2% respectively) while patients from Spain, Germany and the United Kingdom appeared to have the highest risk (OSMRS Groups B & C range: 54.8%; 57.7%; and 57.9% respectively).

Follow-up data derived from some 191,387 follow-up entries show

• One year after primary surgery performed in 2009-2013, the average percentage excess weight loss was 75.9% (inter-quartile range: 58.6-90.5%) for all operations; the equivalent percentage weight loss was 30.5% (range 25.3-36.5%).

• The available two-year data after primary surgery showed the average %EWL was 76.4% (inter-quartile range: 59.2-94.4%) for all operations; the equivalent % weight loss was 31.4% (inter-quartile range: 25.0-38.5%).

• For the severely obese patient these weight loss results are far better than can be achieved by dieting alone. For these people, medical therapy, lifestyle changes and attempts at dieting rarely succeed in maintaining long-term, clinically beneficial weight loss due to the hormonal effects of the obese state, dieting, energy balance and metabolic rate.

• One year after primary surgery 65.8% of patients recorded as taking medication for diabetes beforehand were no longer on medication, implying in practice, that they no longer were considered diabetic. There was no substantial gender difference in recovery in diabetes.

• The rate of diabetes one year after primary surgery was highly dependent on weight loss.

• One year after primary surgery, 46.0% of patients recorded as being on medication for hypertension initially were off medication; there seems to be a near linear relationship between the rate of patients still medicated for hypertension and weight loss.

• There were also reductions in recorded rates of depression (38.1% no longer medicated one year after surgery), musculo-skeletal pain (50.2% no longer medicated one year after surgery) and sleep apnoea (71.6% no longer treated using CPAP/ BiPAP one year after surgery).

• As an example of the type of analysis that can be done, %EWL and %WL at one and two years after gastric bypass were compared between the two largest contributors to the IFSO Global Registry (Sweden and the United Kingdom); there were no significant differences.

Implications for bariatric surgery

• A simple dataset and the willingness of many centres in different countries to contribute can lead to a large body of pooled and merged data.

• This first report quantifies the gender inequality evident worldwide and also shows inequality of access to surgery in many countries.

• For the first time on the scale of a large international collaboration, the data on improvement in diabetes demonstrate the profound treatment effect that bariatric surgery has on this disease.

• Therefore, this initiative may be useful in advancing the status and acceptability of bariatric surgery worldwide and suggests many international research projects that could be undertaken.
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