

The Diabetes Surgery Summit Consensus Conference

Recommendations for the Evaluation and Use of Gastrointestinal Surgery to Treat Type 2 Diabetes Mellitus

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Objectives: To develop guidelines for the use of gastrointestinal surgery to treat type 2 diabetes and to craft an agenda for further research.

Background: Increasing evidence demonstrates that bariatric surgery can dramatically ameliorate type 2 diabetes. Not surprisingly, gastrointestinal operations are now being used throughout the world to treat diabetes in association with obesity, and increasingly, for diabetes alone. However, the role for surgery in diabetes treatment is not clearly defined and there are neither clear guidelines for these practices nor sufficient plans for clinical trials to evaluate the risks and benefits of such “diabetes surgery.”

Methods: A multidisciplinary group of 50 voting delegates from around the world gathered in Rome, Italy for the first International Conference on Gastrointestinal Surgery to Treat Type 2 Diabetes–(the “*Diabetes Surgery Summit*”). During the meeting, available scientific evidence was examined and critiqued by the entire group to assess the strength of evidence and to draft consensus statements. Through an iterative process, draft statements were then serially discussed, debated, edited, reassessed, and finally presented for formal voting. After the Rome meeting, statements that achieved consensus were summarized and distributed to all voting delegates for further input and final approval. These statements were then formally critiqued by representatives of several scientific societies at the 1st World Congress on Interventional Therapies for T2DM (New York, Sept 2008). Input from this discussion was used to generate the current position statement.

Results: A Diabetes Surgery Summit (DSS) Position Statement consists of recommendations for clinical and research issues, as well as general concepts and definitions in diabetes surgery. The DSS recognizes the legitimacy of surgical approaches to treat diabetes in carefully selected patients. For example, gastric bypass was deemed a reasonable treatment option for patients with poorly controlled diabetes and a body mass index ≥ 30

kg/m². Clinical trials to investigate the exact role of surgery in patients with less severe obesity and diabetes are considered a priority. Furthermore, investigations on the mechanisms of surgical control of diabetes are strongly encouraged, as they may help advance the understanding of diabetes pathophysiology.

Conclusions: The DSS consensus document embodies the foundations of “diabetes surgery,” and represents a timely attempt by leading scholars to improve access to surgical options supported by sound evidence, while also preventing harm from inappropriate use of unproven procedures.

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Diabetes mellitus represents an expanding pandemic that contributes markedly to worldwide morbidity and mortality.¹ Currently, approximately 240 million people are afflicted, 90% to 95% with type 2 diabetes mellitus (T2DM), and that number is expected to exceed 380 million by the year 2025.² Tight glycemic control minimizes microvascular complications³; however, macrovascular complications and cardiovascular mortality remain difficult to address even with intensive glucose-lowering therapy.^{4–8} Furthermore, despite substantial advances in pharmacotherapy and disease management, a large number of patients remain inadequately controlled, and complete remission of hyperglycemia and the associated metabolic alterations is rare.

Faced with the escalating global diabetes crisis, health care providers require as potent an armamentarium of therapeutic interventions as possible. In addition to behavioral and medical approaches, various types of surgery on the gastrointestinal (GI) tract constitute extremely powerful options to ameliorate diabetes in severely obese patients, often normalizing blood glucose levels without diabetes medications. These effects occur not only as a consequence of major weight loss, but also in some cases as the result of additional weight-independent mechanisms. Whereas diabetes is traditionally viewed as a chronic, relentless disease in which delay of end-organ complications is the major treatment goal, GI surgery offers a novel end point: the concept of complete disease remission. The role for GI surgery in diabetes treatment, however, is not clearly defined. Here we describe the results of the first International Conference on Gastrointestinal Surgery to Treat Type 2 Diabetes—commonly known as the *Diabetes Surgery Summit*—in which a multidisciplinary group of experts from around the world gathered to develop consensus guidelines and recommendations for the use and study of GI surgery to treat diabetes.

RATIONALE FOR THE DIABETES SURGERY SUMMIT

Increasing evidence demonstrates that several types of GI surgery, including conventional bariatric operations as well as newer experimental procedures, dramatically ameliorate T2DM, leading to complete remission of the disease in a large proportion of cases.^{9–11}

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Dr. Rubino conceived the idea of the DSS. Drs. Rubino, Kaplan, Schauer, and Cummings served as co-directors of the DSS and equally participated in the planning and execution of the conference. They all have contributed to the preparation of the manuscript and have reviewed and accepted its current version.

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Following some GI procedures, T2DM typically resolves within days to weeks, long before major weight loss has occurred.¹² Growing evidence suggests that the antidiabetic impact of these operations cannot be explained by their effects on food intake and body weight alone.^{13–15}

Not surprisingly, therefore, various GI operations are now being used throughout the world to treat diabetes in association with obesity, and increasingly, for diabetes alone.^{10–11} Clinicians are performing GI operations to treat diabetes without clear parameters or indications sufficiently supported by scientific evidence. This emerging practice includes not only the use of conventional bariatric procedures but also experimental new GI operations that have often not been adequately tested in animals before being applied to humans.

Conversely, given that certain operations cause complete remission of T2DM in a substantial number of cases and can reduce mortality attributed to diabetes,^{16,17} it may be clinically appropriate to expand the indications for these procedures to patients with diabetes who do not meet existing obesity-based criteria for bariatric surgery. Given its dramatic effects, GI surgery offers valuable research opportunities to improve knowledge of diabetes pathogenesis and to facilitate the development of less invasive procedures and novel pharmaceuticals. However, despite these possible gains in research and the pressing need for improved outcomes in diabetes management, there are neither guidelines for these practices nor sufficient plans for clinical trials to evaluate the risks and benefits of such “diabetes surgery.”

For these reasons, a multidisciplinary group of leading scholars in the field converged in Rome, Italy to critically review available evidence regarding GI operations to treat T2DM. The intent of this conference was to raise awareness of the nascent discipline of diabetes surgery and to help set standards for the clinical use and scientific investigation of this practice. Formally titled the International Conference on Gastrointestinal Surgery to Treat Type 2 Diabetes, the meeting has come to be known as the Diabetes Surgery Summit (DSS). It was organized primarily by the 4 authors of this article, with advice and assistance from an International Organizing Committee (indicated in Table 1).

The overarching aims of the DSS were to develop guidelines for the use of GI surgery to treat type T2DM and to craft an agenda for further research. It was recognized by the meeting organizers that weight-loss surgery (“bariatric surgery”) was initially developed largely without formal oversight or guidelines. The first official consensus conference pertaining to this discipline did not convene until bariatric operations had been in clinical use for nearly 4 decades.¹⁸ Although bariatric surgery has now evolved into a safe and highly effective therapeutic option for severe obesity, during its development, patients were subjected to numerous experimental operations that ultimately proved to be ineffective or even harmful. For example, jejunoileal bypass was performed for many years before its life-threatening complications¹⁹ were recognized and the procedure ultimately abandoned. By contrast, because the practice of diabetes surgery is in its infancy, a body of interested investigators acting proactively could help this potentially exciting discipline develop in accordance with sound scientific principles. The DSS was intended to be the first step toward establishing a rational, multidisciplinary approach to help guide the development of diabetes surgery from its outset, and accordingly, avoid some of the mishaps that have impeded bariatric surgery.

GOALS OF THE DIABETES SURGERY SUMMIT

The DSS was designed with the following specific aims.

- To critically review available data describing the impact on T2DM of established bariatric operations (gastric bypass, gastric banding, bil-

TABLE 1. Diabetes Surgery Summit Voting Delegates			
DSS Delegate	Affiliation	Nationality	Surgeon?
Ted D. Adams	University of Utah	USA	No
Stephanie Amiel	King's College, University of London	UK	No
Garth H. Ballantyne	Hackensack University	USA	Yes
Guenther Boden	Temple University	USA	No
Camillo Boza	Catholic University of Santiago	Chile	Yes
Henry Buchwald	University of Minnesota	USA	Yes
Marco Castagneto	Catholic University of Rome	Italy	Yes
Ricardo Cohen	Hospital Sao Camilo	Brazil	Yes
David E. Cummings*	University of Washington	USA	No
David A. D'Alessio	University of Cincinnati	USA	No
Aureo L. DePaula*	Hospital de Especialidades	Brazil	Yes
John Dixon	Monash University	Australia	No
Franco Favretti	Ospedale Maggiore	Italy	Yes
Ele Ferrannini	University of Pisa	Italy	No
David R. Flum	University of Washington	USA	Yes
Gema Fruhbeck	University of Navarra	Spain	No
Michel Gagner	Cornell University	USA	Yes
Giovanni Ghirlanda	Catholic University of Rome	Italy	No
Allison B. Goldfine	Harvard University	USA	No
Peter J. Havel	University of California Davis	USA	No
William H. Herman	University of Michigan	USA	No
Kelvin D. Higa	University of California San Francisco	USA	Yes
Jacques Himpens	Saint Pierre University	Belgium	Yes
Jens Holst	University of Copenhagen	Denmark	No
Lee M. Kaplan*	Harvard University	USA	No
David E. Kelley*	University of Pittsburgh	USA	No
Samuel Klein*	Washington University	USA	No
Judith Korer	Columbia University	USA	No
Antonio Lacy	University of Barcelona	Spain	Yes
Harold E. Lebovitz	State University of New York	USA	No
Carel LeRoux*	Imperial College of London	UK	No
Michael Meguid	State University of New York	USA	Yes
Geltrude Mingrone*	Catholic University of Rome	Italy	No
Jerry P. Palmer	University of Washington	USA	No
Antonio Pontiroli	University of Milan	Italy	No
Walter J. Pories*	East Carolina University	USA	Yes
Eric Ravussin	Pennington Institute	USA	No
Denis Richard*	Laval University	Canada	No
William O. Richards	Vanderbilt University	USA	Yes
Francesco Rubino*	Catholic University of Rome	Italy	Yes
Donna H. Ryan	Pennington Institute	USA	No
Christopher D. Saudek	Johns Hopkins University	USA	No
Philip R. Schauer*	Cleveland Clinic	USA	Yes
Nicola Scopinaro*	University of Genoa	Italy	Yes
Randy J. Seeley	University of Cincinnati	USA	No
April D. Strader	University of Southern Illinois	USA	No
Richard Stubbs	Wakefield Gastroenterology Centre	New Zealand	Yes
Harvey J. Sugerman*	Editor-in-Chief, SOARD	USA	Yes
Tessa Van der Merwe	University of Pretoria	South Africa	No
Bruce M. Wolfe	Oregon Health and Science University	USA	Yes

*Members of the DSS International Organizing Committee.

iopancreatic diversion) and newer experimental procedures and devices (eg, duodenal bypass, ileal interposition, sleeve gastrectomy).

- To discuss plausible mechanisms, based on animal and human data, by which GI operations might ameliorate T2DM, independent of their effects on food intake and body weight.
- To identify indications and contraindications for the current use of GI surgery to treat T2DM in obese and nonobese persons.
- To develop recommendations for the development of maximally influential and ethical clinical studies of diabetes surgery.
- To define the appropriate role of surgery within the broader medical strategy for diabetes care.

ENDORSEMENTS OF THE DSS FROM INTERNATIONAL SCIENTIFIC SOCIETIES

To facilitate participation by a broad spectrum of clinicians and scientists focused on T2DM, the meeting organizers sought support for the concept of the DSS from diverse international societies with relevant interests. Table 2 lists the 21 professional organizations that endorsed the DSS. The endorsement of scientific societies recognizes the quality of experts involved and the appropriateness of methods and aims of the DSS, but not necessarily its conclusions. The final DSS position statement reported here has been submitted to several scientific societies. At the time of this writing, 3 endocrinology societies and 2 surgical societies (indicated by asterisks in Table 2) have officially endorsed the DSS position statement, and formal conclusions from several other societies are pending.

The Summit was also awarded High Patronage status from both the President and the Prime Minister of Italy, the host country for the meeting, and it was endorsed by the Department of Health of the European Union.

TABLE 2. Scientific Organizations That Endorsed the Diabetes Surgery Summit

ADA	American Diabetes Association
ASMBS*	American Society for Metabolic and Bariatric Surgery
ACS	American College of Surgeons
ACN	American College of Nutrition
AGA	American Gastroenterological Association
ASN	American Society for Nutrition
ASO	Association for the Study of Obesity
ASPEN	American Society for Parenteral and Enteral Nutrition
Diabetes UK*	Diabetes United Kingdom
EAES	European Association for Endoscopic Surgery
EASD	European Association for the Study of Diabetes
EASO	European Association for the Study of Obesity
IASO*	International Association for the Study of Obesity
IFSO*	International Federation for the Surgery of Obesity and Metabolic diseases
TOS*	(formerly NAASO)-The Obesity Society
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
SAH	Shaping America's Health
SIC	Società Italiana di Chirurgia (Italian Society of Surgery)
SICOB	Società Italiana di Chirurgia dell'Obesità e delle Malattie Metaboliche
SID	Società Italiana Diabetologia (Italian Society of Diabetology)
SSAT	Society for Surgery of the Alimentary Tract

*Indicates societies that in addition to endorsing the concept and methods of the DSS have also officially endorsed the final DSS position statement at the time of this writing.

METHODS

Participants in the Summit and Selection Criteria for Voting Delegates

Participants were chosen to represent a diversity of medical and surgical disciplines, major scientific societies, and leading journals. Four major groups of thought leaders were represented among the DSS delegates who voted on consensus statements: (1) endocrinologists and gastroenterologists with relevant scholarship; (2) diabetologists with specific expertise in pertinent research methods; (3) surgeons with relevant scholarship and experience; and (4) basic science investigators working in this area. Additional voting delegates included experts in epidemiology, health economics and clinical trial design, as well as representatives of pertinent societies and journals.

In total, 50 voting delegates participated in the DSS (Table 1). The composition of this group was intentionally weighted toward nonsurgeons (58%), given that surgeons' clinical practice could theoretically be affected by the outcomes of the summit. To ensure a high level of scholarship, basic and clinical investigators were heavily represented in the voting body, with 92% employed as university faculty. No one employed in industry was included as a DSS voting delegate. In addition to the voting delegates, several dozen international scholars with relevant expertise were invited to participate in the discussion ("guest experts"). To ensure transparency of all proceedings, the DSS was open to the public. Nonvoting attendees were encouraged to participate in the extensive discussion sessions throughout the meeting, as well as to observe the voting sessions. However, they did not have any input or influence on the drafting and/or editing of statements that were subject to voting. In total, approximately 400 people from 27 countries on 6 continents participated in the DSS.

Evaluation of Relevant Evidence

Before the DSS convened, all voting delegates were provided with educational packets containing key papers in this field as well as several synopses of relevant research topics compiled by appropriate experts. Voting delegates and other DSS participants convened at the Catholic University of Rome on March 29–31, 2007. During the first 2 full days of the meeting, experts from diverse disciplines presented data on diabetes-related surgical outcomes and mechanisms of action, derived from human and animal studies. Evidence was examined and critiqued by the entire group in a series of open discussions led by panels of scholars with relevant expertise. To ensure that ample input was obtained from everyone present, these discussions comprised ~40% of the formal meeting time, and all conference attendees were encouraged to participate.

Generation of Consensus Statements

A primary goal of the Summit was to develop a series of position statements, recommendations, and guidelines pertaining to diabetes surgery that were designed to capture most accurately the consensus of the group. To initiate this process, delegates were asked to assess the strength of evidence supporting specific assertions related to each day's scientific presentations. These voted assessments were then used to guide the development of draft consensus statements, which were presented to all DSS participants for discussion and scrutiny. The degree of support for statements was assessed using a computerized audience-response system that allowed delegates to vote for or against each item as it was publicly presented. Outcomes were tallied and displayed in real time, and based on these results, draft statements were serially discussed, debated, edited, and reassessed in an open forum. The ultimate goal of this iterative process was to maximize delegates' acceptance of, and enthusiasm for each statement. On the last day of the Summit, all of the refined candidate consensus statements were presented again to DSS participants for final discussion, editing, and formal

voting. Consensus for each statement was defined as acceptance by >2/3 of delegates in the final vote; however, language was iteratively modified to maximize agreement. After the Rome meeting, viewpoints that achieved consensus were summarized and distributed to all voting delegates for input and approval. The document generated through this process was distributed to several scientific societies with relevant interest and expertise in the field and was formally analyzed and critically reviewed by official representatives of these societies during a dedicated session at the 1st World Congress on Interventional Therapies for Type 2 Diabetes (New York City, September 2008). The input from this discussion was used to craft a final DSS position statement (Table 3), which is reported in this manuscript.

TABLE 3. Position Statement From the Diabetes Surgery Summit

GI surgery (ie, RYGB, LAGB, or BPD) should be considered for the treatment of T2DM in acceptable surgical candidates with BMI ≥ 35 kg/m ² who are inadequately controlled by lifestyle and medical therapy (A). [*] A surgical approach may also be appropriate as a non-primary alternative to treat inadequately controlled T2DM in suitable surgical candidates with mild-to-moderate obesity (BMI 30–35 kg/m ²) (B). RYGB may be an appropriate surgical option for diabetes treatment in this patient population (C).
Although novel GI surgical techniques (eg, duodenal-jejunal bypass, ileal interposition, sleeve gastrectomy, endoluminal sleeves) show promising results for the treatment of T2DM in early clinical studies, they should currently be used only in the context of IRB-approved and registered trials (A).
To improve quality of medical evidence, the development of standards for measuring clinical and physiological outcomes of surgical treatment for T2DM is a high priority (A).
Randomized controlled trials are strongly encouraged to assess the utility of GI surgery to treat T2DM (A). In patients with BMI <35 kg/m ² , determining the appropriate use of GI surgery for the treatment of T2DM is an important research priority (A). Controlled clinical trials in these patients should be performed to determine the safety and efficacy of GI metabolic surgery (A) as well as to identify parameters other than BMI as criteria for appropriate patient selection (A). Development of a standard registry/database is a high priority for research in this area (A). In addition to clinical trials, animal studies can provide useful information about the efficacy and mechanisms of GI metabolic surgery to treat T2DM (A).
The study of GI metabolic surgery provides valuable, new opportunities for investigating contributions of the GI tract to glucose homeostasis and the pathophysiological mechanisms of T2DM (A). Available data from animal and clinical studies suggest that weight loss alone explains diabetes control after LAGB (A). In contrast, intestinal bypass procedures such as RYGB, BPD, and duodenal-jejunal bypass appear to engage additional anti-diabetes mechanisms beyond those related to reduced food intake and body weight (A). Furthermore, anatomic modifications of various regions of the GI tract ameliorate T2DM through distinct physiological mechanisms (B). Collaboration among endocrinologists, surgeons, and basic scientists should be encouraged to facilitate greater understanding of GI mechanisms of metabolic regulation and to allow use of these insights to improve the treatment of T2DM (A).
The establishment of a multidisciplinary taskforce to guide the study and development of diabetes surgery is a high priority. This taskforce should include endocrinologists, surgeons, clinical and basic investigators, and bioethicists, among others (A).

^{*}Capital letters in parentheses indicate the levels of consensus for individual statements, defined as follows: "Grade C" (67%–77% agreement), "Grade B" (78–89% agreement), and "Grade A" (90%–100% agreement).

RESULTS

Summary of Available Evidence Reviewed and Presented at the Summit

A detailed description of the results of the review of the literature and of new data shown during the DSS will be reported elsewhere.^{19a} Here we summarize the main findings.

Bariatric Surgery in Patients With Type 2 Diabetes and Severe Obesity (BMI ≥ 35 kg/m²)

A substantial body of evidence has accumulated showing that a variety of bariatric operations result in highly significant, reproducible, and long-lasting improvement or remission of T2DM in severely obese patients.^{9,12,12a} One randomized trial²⁰ and one long-term, well-designed comparative study (SOS)¹⁷ also show that surgery is superior to conventional management of T2DM in severely obese subjects, yielding better glycemic control and improving survival.^{16,17} Contrary to some common perceptions, bariatric surgery is associated with low operative mortality. Several studies have reported bariatric surgery mortality rates ranging from 0.25% to 0.5%.²¹ In fact, these mortality rates are on average lower than those of many elective major abdominal procedures, comparing well for example with mortality rates of laparoscopic cholecystectomy, which ranges from 0.26% to 0.6% in the US.²²

Procedure-related complications have declined in recent years as more centers have moved towards predominantly laparoscopic approaches, implemented system-wide controls, and incorporated multidisciplinary teams.^{23,24} The most common complications are anastomotic leak (3.1%), wound infection (2.3%), pulmonary events (2.2%), and hemorrhage (1.7%).^{24,25} Laparoscopic procedures in general have lower complication rates, with the most common being hemorrhage (1.7%) and anastomotic leak (1.4%).²⁵ Overall, nutritional deficiencies can occur in both restrictive and malabsorptive approaches but are far more pronounced with malabsorptive procedures such as the biliopancreatic diversion (BPD).^{26–30} The most common nutritional deficiencies include protein, iron, vitamin B12, folate, calcium, and fat-soluble vitamins. Most deficiencies can be prevented by implementing supplements after surgery.²⁸ Following Roux-en-Y gastric bypass (RYGB) or BPD, close patient follow-up is required to monitor the development of nutritional deficiencies and to provide adequate treatment if they occur. It is important for patients to be placed on multivitamins as well as iron, calcium, folate, and B12 supplements if necessary.

Bariatric Surgery and Other Gastrointestinal Operations in Patients With BMI <35 kg/m²

Overall, published studies and new investigations presented at the DSS indicate that a variety of GI operations including both conventional bariatric surgeries^{31,32} and novel procedures (ie, duodenal-jejunal bypass, ileal interposition, sleeve gastrectomy)^{10,11,33,34} can achieve improvement or remission of T2DM in patients with BMI <35 kg/m², apparently with low rates of complications and mortality in the short- to mid-term. However, sample sizes and duration of postoperative follow-up of these studies are insufficient at this time for a thorough assessment of the long-term efficacy and safety of surgery in this patient population, particularly for novel procedures. The interpretation of findings concerning novel GI procedures and surgery in general in patients with BMI below 30 kg/m² remains particularly problematic because of the small number of patients studied and the short duration of follow-up data. Nevertheless, available evidence suggests that a precise BMI cut-off at 35 kg/m² is not an accurate parameter to predict the potential of surgery to induce glycemic and metabolic control. Furthermore, no existing studies have shown evidence of excessive weight loss following

conventional bariatric operations in moderately obese patients (BMI: 30–35 kg/m²).

Mechanisms of Diabetes Resolution Following GI Surgery

The effects of GI surgery on glucose metabolism and the metabolic syndrome represent a clinically impressive and scientifically interesting phenomenon, which may have significant implications for understanding the pathophysiology of diabetes. Elucidating the mechanisms of action of GI surgery on diabetes may help identify new targets for diabetes medications. The review of available evidence does not allow conclusions regarding the exact molecular mechanisms behind the dramatic improvement of diabetes after GI surgical procedures. However, there seems to be sufficient evidence in support of the fact that rearrangement of the anatomy of the GI tract can influence glucose homeostasis by mechanisms that are additive to, and independent of, body weight loss.^{14–15} Beyond the few gut hormones whose changes after bariatric surgery have been studied to date,^{13,35–37} the GI tract produces dozens of biologically active peptides,³⁸ and possibly other yet-to-be-discovered substances. This suggests the possibility that various types of anatomic rearrangements of the GI tract may activate several distinct mechanisms that influence glucose homeostasis, possibly explaining the gradient of efficacy among procedures. Further research is warranted to help clarify the agents responsible for the beneficial effects of GI surgery on glucose homeostasis.

Consensus Statements From the Diabetes Surgery Summit

Table 3 represents the final position statement of the DSS delegates with a set of consensus recommendations and declarations that address both clinical and research issues, as well as general concepts and definitions. In some cases, statements with stronger language and bolder determinations were achieved at the expense of lower levels of consensus; however, by design, it was decided that the position statement should only include the declarations with the highest degree of consensus. Two major proposals did not achieve consensus and are therefore not included in the position statement. Consensus regarding LAGB to treat diabetes in patients with BMI <35 kg/m² was not quite achieved, as only 66% of delegates endorsed its use in this setting (ie, marginally below our predetermined threshold of 67% agreement to define “consensus”). Also, only 33% of delegates felt that BPD may be suitable to treat diabetes in patients with BMI <35 kg/m².

DISCUSSION

The DSS consensus document embodies the foundations of “diabetes surgery,” emphasizing 2 fundamental aspects of this emerging discipline: the importance of multidisciplinary approaches to guide its development from the outset and the value of investigating antidiabetes GI operations mechanistically. DSS represents a timely attempt by leading scholars to improve access to surgical options supported by sound evidence, while also preventing harm from inappropriate use of unproven procedures.

To ensure a multidisciplinary expertise for the assessment of clinical and mechanistic data about surgical aspects and diabetes-specific issues, the expert panel of the DSS was intentionally larger in size (50 delegates) and more multidisciplinary than most other consensus-developing groups (typically composed by 10–12 members who usually meet under the auspices of only 1 or 2 organizations). Due to the professional and financial ramifications of the subject, a consensus conference to assess the role of surgery to treat diabetes is particularly vulnerable to professional biases and potential conflicts of interest. Given that surgeons’ clinical practice could

theoretically be affected by the outcomes of the summit, the panel was intentionally weighted toward nonsurgeons (58%). Surgeons were not entirely excluded from the group, however, to balance the potential for a highly conservative stance of some nonsurgeons whose clinical practice might also be theoretically affected, though in an opposite manner. This also ensured adequate competence of surgical aspects in the voting panel, as many of the leading scholars in the field are surgeons. Furthermore, given the global epidemic growth of diabetes and the relevance of ethnic and socioeconomic aspects for diabetes surgery, geographical criteria were also considered in the selection of delegates to ensure appropriate representation of regional issues. These methods make the DSS less vulnerable to potential sources of bias and conflicts of interest that might have compromised acceptance and enthusiasm for guidelines established by a smaller group reflecting the position of a single organization.

The endorsement of the DSS by 21 diverse professional and scientific organizations recognizes that the goals, selection of experts, and program of the conference were scientifically appropriate and free of substantial bias. It is important to note that the endorsement for the DSS by these societies does not necessarily translate into an up-front endorsement of its conclusions. At the time of this writing, 5 scientific and professional societies, which represent endocrinologists, internists, and obesity scientists (Diabetes UK, T.O.S. and I.A.S.O.), as well as surgeons and bariatric allied health care professionals (A.S.M.B.S., I.F.S.O., and Brazilian Society of Bariatric and Metabolic Surgery) have concluded their reviews of the findings of the Summit and have officially endorsed the final DSS position statement. More organizations will have the opportunity to consider this document after its publication and, if they wish to do so, contribute their support for the dissemination and application of these findings.

Although conservative because of its goal to evaluate evidence cautiously, the DSS Position Statement recognizes for the first time a revolutionary concept: the legitimacy of GI surgery as a dedicated treatment for T2DM in carefully selected patients. There was 98% consensus that certain intestinal bypass operations engage antidiabetes mechanisms beyond reduced caloric intake and body weight. This and the remarkable clinical efficacy of GI surgery justify considering it as a specific diabetes intervention, rather than viewing diabetes remission merely as a collateral effect of weight-loss surgery. DSS recommendations also call for research into GI-surgical antidiabetes mechanisms, to help elucidate diabetes pathophysiology and identify novel pharmacotherapeutic targets.

Delegates unanimously agreed that patients with inadequately controlled diabetes and BMI >35 kg/m² should be considered for GI surgery. This concurs with existing NIH guidelines and with the 2009 American Diabetes Association standards of care position statement,³⁹ and it further emphasizes the role of GI surgery in severely obese patients, where mounting evidence shows that surgery improves overall survival.^{16,17} Although an antidiabetes efficacy gradient probably exists among bariatric operations (BPD >RYGB >LAGB),⁹ no randomized controlled trials have compared these procedures head-to-head. Hence, definitive prioritization for their use to treat T2DM in severely obese patients seems premature.

There was strong consensus that adopting the strictly BMI-based criteria used for bariatric surgery would be inadequate to select candidates for diabetes surgery. Pending evidence identifying more appropriate parameters, however, available long-term safety and efficacy data in nonseverely obese patients were judged insufficient to advocate routine clinical use of GI surgery for diabetes in this setting. However, based on the results of recent trials showing glycemic benefit of surgery in patients with type 2 diabetes and BMI <35, there was good consensus regarding the legitimacy of GI surgery as a nonprimary therapeutic alternative to treat mild-to-

TABLE 4. International Diabetes Surgery Task Force Members

Member	Affiliation, Country
Sir George Alberti	Imperial College of London, UK
Stephanie Amiel	Kings Cross College, London, UK
Steven H. Belle	University of Pittsburgh, USA
David E. Cummings	University of Washington, USA
John Dixon	Monash University, Australia
Bob H. Eckel	University of Colorado Denver, USA
Ele Ferrannini	University of Pisa, Italy
David R. Flum	University of Washington, USA
Lee M. Kaplan	Harvard Medical School, USA
Francine R. Kaufman	Keck School of Medicine-USC, USA
Sam Klein	Washington University, St. Louis, USA
Carel LeRoux	Imperial College, London, UK
Walter J. Pories	East Carolina University, USA
John Q. Purnell	Oregon Health and Science Institute, USA
Eric Ravussin	Pennington Institute, USA
Bob A. Rizza	Mayo Clinic, USA
Francesco Rubino	Weill Cornell Medical College, New York, USA
Philip R. Schauer	Cleveland Clinic, USA
Lars Sjostrom	University Hospital Gothenburg, Sweden
Paul Zimmet	Baker-IDI Institute, Australia

moderately obese patients (BMI: 30–35 kg/m²) with T2DM inadequately controlled by lifestyle and medications. Formal consensus regarding which operation should be used in these patients, however, was only achieved for RYBG. Consensus regarding LAGB in this context was not quite achieved (66% agreement), because delegates felt that, in contrast to RYGB, LAGB does not activate weight-independent antidiabetes mechanisms. Although delegates concurred that BPD does engage such mechanisms and effectively ameliorates T2DM, its higher risk profile prevented its acceptance in patients with BMI <35 kg/m². While recognizing the fascinating potential of novel GI interventions, DSS established that evidence does not yet support their routine clinical usage; thus, they should be performed only in IRB-approved trials.

DSS delegates recommended that a multidisciplinary taskforce be established to help guide the study and development of diabetes surgery. Accordingly, the International Diabetes Surgery Taskforce was created as a nonprofit organization of 20 members (Table 4), representing diverse expertise in diabetes, obesity, surgery, gastroenterology, and clinical-trials development. The taskforce promotes DSS recommendations, collaborating with professional societies to expand and disseminate evidence-based knowledge of diabetes surgery.

CONCLUSIONS

The DSS recognizes a valuable role for GI surgery in the treatment of T2DM in patients with severe obesity (BMI >35 kg/m²) as well as in carefully selected, moderately obese patients (BMI: 30–35 kg/m²) who are inadequately controlled by conventional medical and behavioral therapies. Based on available evidence, the DSS recommends that conventional and novel GI procedures in nonobese patients be performed at this time only in clinical trials with IRB approval. Further clinical investigations designed to identify new and more appropriate parameters for surgical indications and the appropriate role of surgery in less obese or overweight patients should be considered an important research priority. Finally, the DSS strongly encourages research into the mechanisms of action

in GI metabolic surgery, as this represents an extraordinary opportunity to advance the understanding of diabetes pathophysiology and ultimately improve the treatment of this disease.

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