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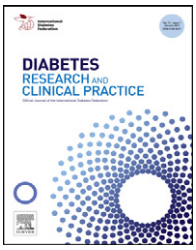

Parachutes for diabetes: Bariatric surgery beyond evidence?

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Bariatric surgery has dramatic effects on type 2 diabetes (T2DM) [1,2] and it has been argued that we do not need more evidence for those with BMI $\geq$ 30 kg/m^2 and with inadequately controlled T2DM [3]. To require more evidence would be the same as to demand RCTs for the effect of parachutes on death and major trauma [4].

But does ''diabetes surgery'' merit a ''parachute approach''? The question is pertinent as the effect of bariatric surgery on T2DM has been shown through a series of studies and meta-analyses [5,6]. It seems unethical to conduct and wait for results from long term RCTs when the success is dramatic and the operation is strikingly safe [3]. Performing high quality RCTs are time consuming, resource demanding, and difficult to fund. Awaiting more evidence will deprive many vulnerable patients from treatment that many studies show to be highly beneficial. Furthermore, it will be difficult to obtain equipoise as surgeons and patients seem to be convinced that surgery is the best approach.

On the other hand some consider that our overall knowledge is based on small short-term studies of questionable quality [7], and published (positive) research findings may be misleading due to publication bias and lack of independent testing [8]. Long term studies are non-randomized and do not contain data specifically on diabetes care [9].

It is well known that new methods are introduced into clinical practice before high quality evidence is available [10], and there are double standards for evidence: ''If surgery were a pill, it would be monitored much more carefully'' [11]. Hence, there is a danger of putting a futile or even detrimental treatment into clinical practice that cannot be verified by randomized studies later because that would be considered to be unethical.

Furthermore, skeptics and critics claim that the ''surgery bandwagon'' [12] is a part of the ''weight loss industry'' established against a socially constructed ''obesity epidemic'' [12]. It is forcefully argued that ''[t]here is currently little or no scientific or ethical justification for offering bariatric surgery to patients with a BMI of <35 kg/m^2 outside the context of a controlled clinical trial'' [11].

So, should we cut or should we study? Is surgery for diabetes as parachutes are for sky divers? Obviously not. There are significant differences.

First, for the very obese (e.g., BMI $\geq$ 40 kg/m^2) it can be argued that no parachute approach is needed. Although more high quality evidence is required, many accept the effectiveness of bariatric surgery on T2DM for this group. Besides, few relevant alternatives exist. The hard question appears for BMI < 35.

Second, the functions of parachutes are well known, whereas the mechanisms behind the various forms of bariatric surgery are still to be verified. There is a difference between *modus operandi* of air and human beings. Hence, the belief in the effect of parachutes is better founded than

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the belief in bariatric surgery. In treatments with unknown mechanisms, we need empirical evidence of higher quality.

Third, the parachute approach presumes what still has to be shown, i.e., that surgery is effective. This is a *petitio principia* (begging the question), which is but one of many quite prevalent fallacies in the arguments for new technologies in health care [13].

Hence, ''diabetes surgery'' does not warrant a ''parachute approach''. We need well-designed long-term controlled trials comparing bariatric surgery with non-surgical interventions [2,14]. Long term studies exist [9], but they are non-randomized and do not specifically assess diabetes outcomes. Despite accumulated knowledge, no general agreement as to the optimal surgical procedure has been reached, and analysis of results of surgical alternatives is hindered by a lack of comprehensive data collection, poor long-term patient follow-up, and lack of standardization of the procedures and of reporting of results [11]. Therefore, well controlled studies should be performed for the various surgical procedures in use [11]. The recent statement on bariatric surgery in the treatment of diabetes Type 2 from the International Diabetes Federation underlines this [15].

Such studies may be difficult to conduct. They may be costly and hard to fund, it may be challenging to obtain equipoise and real consent, and it will require collaboration among professionals and institutions that may not be used to teaming up. However, we do have moral obligations to existing patients in terms of long-term follow up, and to future patients to provide solid evidence.

The debate on bariatric surgery is about more than finding the most appropriate procedures for a threatening disease. It is about social norms involving issues of life-style, self-control, self-esteem, prejudice, fatism, and discrimination. Professional terms such as ''diabetes surgery'', ''metabolic surgery'', and ''diabetes cure'' are far from value-neutral. Cutting in otherwise well-functioning organs in order to regulate metabolism and discipline people's behavior merits high quality evidence.

Conflict of interest

The author declares that he has no conflict of interest.

REFERENCES

[1] Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Leccesi L, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. N Engl J Med 2012;366(17):1577–85.

[2] Schauer PR, Kashyap SR, Wolski K, Brethauer SA, Kirwan JP, Pothier CE, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012;366(17):1567–76.

[3] Rubino F, Kaplan LM, Schauer PR, Cummings DE. The Diabetes Surgery Summit consensus conference: recommendations for the evaluation and use of gastrointestinal surgery to treat type 2 diabetes mellitus. Ann Surg 2010;251(3):399–405.

[4] Potts M, Prata N, Walsh J, Grossman A. Parachute approach to evidence based medicine. BMJ 2006;333(7570):701–3.

[5] Buchwald H, Estok R, Fahrbach K, Banel D, Jensen MD, Pories WJ. Weight and type 2 diabetes after bariatric surgery: systematic review and metaanalysis. Am J Med 2009;122:248–56.

[6] Sjöström L, Lindroos AK, Peltonen M, Torgerson J, Bouchard C, Carlsson B. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. N Engl J Med 2004;351(26):2683–93.

[7] Colquitt JL, Picot J, E. Loveman E, Clegg AJ. Surgery for obesity. Cochrane Database Syst Rev 2009;2. http://dx.doi.org/10.1002/14651858.CD003641.pub3 [Art. No.: CD003641].

[8] Ioannidis J. Why most published research findings are false. PLoS Med 2005;2(8):e124.

[9] Sjostrom L, Peltonen M, Jacobson P, Sjöström CD, Karason K, Wedel H, et al. Bariatric surgery and long-term cardiovascular events. JAMA 2012;307(1):56–65.

[10] Ross S, Robert M, Harvey MA, Farrell S, Schulz J, Wilkie D, et al. Ethical issues associated with the introduction of new surgical devices, or just because we can, doesn't mean we should. J Obstet Gynaecol Can 2008;30(6):508–13.

[11] Pinkney J, Johnson A, Gale E. The big fat bariatric surgery bandwagon. Diabetologia 2010;53:1815–22.

[12] Oliver JE. The politics of pathology: how obesity became an epidemic disease. Perspect Biol Med 2006;49(4):611–27.

[13] Hofmann B. Fallacies in the arguments for new technology: the case of proton therapy. J Med Ethics 2009;35(11):684–7.

[14] Lautz D, Halperin F, Goebel-Fabbri A, Goldfine AB. The great debate: medicine or surgery: what is best for the patient with type 2 diabetes? Diabetes Care 2011;34(3):763–70.

[15] International Diabetes Federation. Bariatric surgical and procedural interventions in the treatment of obese patients with type 2 diabetes. A position statement from the International Diabetes Federation Taskforce on Epidemiology and Prevention. New York: International Diabetes Federation; 2011.