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LETTER TO THE EDITOR

Findings of YOMEGA Trial Need to Be Interpreted with Caution

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Abbreviations

OAGB	one anastomosis gastric bypass
RYGB	Roux-en-Y gastric bypass
SAE	serious adverse event
BP	bilio-pancreatic

Dear Editor,

Findings of YOMEGA trial published recently in The Lancet [1] will undoubtedly need to be examined in-depth by the bariatric community. I, therefore, seek your permission to not only congratulate the authors of this extremely important study but also to highlight some of its salient aspects for the readers of "Obesity Surgery".

Authors of this multicentre, non-inferiority, randomised controlled trial found One Anastomosis Gastric Bypass (OAGB) to be not inferior to Roux-en-Y gastric bypass (RYGB) in terms of weight loss and metabolic outcomes at 2 years but found OAGB to be associated with significantly higher serious adverse events (SAE)—42 in the OAGB group compared with 24 in the RYGB group. But behind these headline figures, there actually was no significant difference in the proportion of patients with at least one serious adverse event (22% with OAGB vs 19% with RYGB; $p = 0.19$).

On deeper analysis of the data, it is further obvious that this difference in SAE was due to higher nutritional complications (ten with OAGB vs zero with RYGB; one patient needed conversion to RYGB for Wernicke's encephalopathy), higher diarrhoea/anal fissure (six with OAGB vs zero with RYGB), gall stones (eight with OAGB vs five with RYGB), and reflux (five with OAGB vs zero with RYGB; two needed conversion to RYGB). Given that authors used 200-cm Bilio-Pancreatic (BP) limb for OAGB patients, the higher rate of nutritional complications and diarrhoea is hardly surprising. It may be worth mentioning here that our group (as also noted by the authors of YOMEGA trial) has been advocating a standard BP limb length of 150 cm for OAGB for some time now [2–4]. Though we saw a definite prevalence of diarrhoea in our patients when we were using 200-cm BP limb, this complication has almost disappeared from our practice with the use of 150-cm BP limb. Similarly, though we have seen severe protein-calorie malnutrition requiring parenteral nutrition support with 200-cm BP limb, we have yet to see any with 150-cm BP limb.

It is further worth noting here that the definition of SAE in this study was different from that of a complication. When it comes to complications, OAGB group had half the early complication rate (3.4% vs 6.8%) but had a slightly higher late complication rate (16.2% vs 12.8%). If we combine the early and late complications, both OAGB and RYGB had exactly the same complication rate of 19.6% ($n = 23$). It is further worth noting that two patients needed 30-day reoperation in the RYGB compared to one patient in the OAGB group. It is possible that the higher early complication rate with RYGB could translate into higher early mortality—a difference this study was not powered to examine. But we know from other studies in the literature that RYGB has approximately twice early mortality of 0.2% compared with 0.1% seen with OAGB or sleeve gastrectomy [5, 6].

Authors do not provide clear late reoperation data for the two groups though they mention that 4 patients in OAGB group needed conversion to RYGB for various reasons. The outcome of 5 patients with abdominal pain in the RYGB group remains unclear—a complication not seen in the OAGB group. In our experience, there seems to be a bit of a tradeoff between the two procedures when it comes to long-term complications. OAGB patients report more reflux symptoms and some undoubtedly need conversion to Roux-

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en-Y configuration whereas RYGB patients seem to be at a higher risk of internal hernia and chronic abdominal pain. The internal hernia can often lead to disastrous life-altering consequences, and chronic abdominal pain is not always easy to treat and often associated with a very poor quality of life. On the other hand, reflux associated with OAGB can be managed medically in the vast majority and by conversion to Roux-en-Y configuration in those who remain symptomatic on best medical management.

Quality of life is an important outcome measure. This study found BAROS score to be poor (failure) or fair in 9/63 patients in the RYGB group at 2-year compared with 4/67 in the OAGB group. The difference was not significant ($p = 0.15$) but there might be a trend towards superiority with OAGB.

Authors further report 19% (11/58) gastritis and 10% (6/58) oesophagitis in the OAGB group compared with 6% (4/63) gastritis and 3% (2/63) oesophagitis in the RYGB group. But it is obvious that their visual impressions were incorrect because, on biopsy, gastritis was found in 17.5% (11/63) patients in the RYGB group compared with 20.5% (12/58) patients in the OAGB group with an insignificant difference. Similarly, oesophagitis was seen on oesophageal biopsies in 12.7% (8/63) patients in the RYGB group compared with 20.5% (12/58) in the OAGB group. Once again, the difference was not significant. Only one patient in the OAGB group had intestinal metaplasia on both gastric and oesophageal biopsies and no patient had dysplasia in either group. Neither of these was significantly different between the two groups. I, therefore, find authors' cautionary note about the carcinogenic potential of bile unnecessary and even unscientific especially because we have examined this in detail in the past [7, 8] and more recently, in a consensus statement, experts rejected this notion with a significant consensus [9].

Another significant aspect of this study that needs highlighting is that 60% of diabetic patients underwent complete remission with OAGB compared with 38% with RYGB. Partial remission rates were 10% and 6%, respectively. Though there was no significant difference between the groups, the authors suggest a potential for type II error due to the small number of diabetic patients in this study. Finally, the authors found the operating time to be significantly shorter with OAGB (85 min vs 111 min; $p < 0.0001$).

To conclude, this study [1] found that in comparison with RYGB, OAGB takes less time to be performed, delivers lower early complication rates, and a lower early reoperation rate whilst delivering non-inferior weight loss and metabolic outcomes and exactly the same overall (early + late) complication rates. Reporting of complications in surgical literature is a recognised problem [10] and bariatric surgeons need to agree on a consistent format. Authors of this study [1] do not report all complications using the Dindo-Clavien system and instead lay much more emphasis on their own definition of an SAE. Much higher nutritional complication rates and diarrhoea rates, seen with OAGB in this study [1], could be addressed by using a 150-cm BP limb.

I would, therefore, humbly suggest that future trials on this topic use 150-cm BP limb for OAGB patients and report complications using universally agreed formats in surgical literature such as the Dindo-Clavien classification system for a fair comparison.

Compliance with Ethical Standards

Conflict of Interest The author declares that he has no conflict of interest.

Statement on Human and Animal Rights This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent Informed consent is not applicable.

Ethical Approval Ethical approval is not applicable.

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