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*Marginal ulcers after one anastomosis (mini) gastric bypass: a survey of surgeons.* Clinical Obesity.

**What is already known about this subject:**

One Anastomosis (Mini) Gastric Bypass (OAGB/MGB) is an increasingly performed bariatric surgical procedure, but there are concerns that this operation is associated with high rates of marginal ulceration, and that these ulcers may be associated with higher complications in comparison with Roux-en-Y Gastric Bypass. There is no study in current scientific literature that specifically focuses on Marginal Ulcer (MU) after OAGB/MGB.

**What this study adds:**

- The majority of participants (82.4%, n=69) use routine proton pump inhibitor (PPI) prophylaxis, but there are significant variations in the drugs used, dosage and duration of therapy.
- The total number of OAGB/MGB procedures collectively reported was 27,672, revealing 622 MU, giving an MU rate of 2.24 %.
- There was no reported mortality associated with marginal ulceration after OAGB/MGB procedures from this survey.

**Abbreviations:**

**OAGB/MGB:** One Anastomosis (Mini) Gastric Bypass

**MU:** Marginal Ulcer

**RYGB:** Roux-en-Y Gastric Bypass

**PPI:** Proton Pump Inhibitor

**Abstract:**

**Background:** Many surgeons believe One Anastomosis (Mini) Gastric Bypass (OAGB/MGB) is associated with a high Marginal Ulcer (MU) rate and that this is associated with complications in a significant number of patients. The purpose of this survey was to find out the participant-reported incidence of MU after OAGB/MGB and its complications. We also aimed to understand practices in this cohort concerning prophylaxis, diagnosis, treatment, and management of complications.

**Methods:** Bariatric surgeons who perform OAGB/MGB procedures were invited to participate in a confidential, on-line survey using SurveyMonkey®.

**Results:** Eighty six surgeons performing OAGB/MGB procedures participated. The total number of OAGB/MGB procedures reported was 27,672, revealing 622 MU, giving an MU rate of 2.24 %. Most participants (69/84, 82.4 %) routinely use PPI prophylaxis but there was variation in drugs, dosages, and duration. The majority (49/85 57.6 %) of participants 'always' use endoscopy for diagnosis, 48.1 % (39/81) 'always' perform an endoscopy to ensure healing. Most (49/55) perforated ulcers were treated with laparoscopic repair +/- omentoplasty +/- drainage. Most (55/59, 93.0 %) of the bleeding ulcers were managed with PPI +/- blood transfusions +/- endoscopic intervention (23/59, 39.0 %). Non-healing ulcers were treated by conversion to RYGB in 46.5 % of patients (n = 20/43). The participants did not report any MU related mortality but described a number of risk factors for it.

**Conclusion:** This survey is the first detailed attempt to understand the incidence of MU following OAGB/MGB, its complications and practices concerning prophylaxis, diagnosis, treatment, and management of complications.

**Background:**

One Anastomosis (Mini) Gastric Bypass (OAGB/MGB) is rapidly gaining acceptance as bariatric surgical procedure globally [1, 2] following a detailed attempt to examine the controversy surrounding it [3] and publication of studies over a period of time by respected groups of bariatric surgeons [4-6].

Critics claim that this procedure is associated with a high incidence of Marginal Ulcers (MU) which do not heal on medical management due to the constant exposure of gastro-jejunostomy to bile and pancreatic juices[7]. This conflicts with a recent systematic review [1] of 5095 procedures published between September 1997 and May 2011 which found an overall MU rate of 5.6 %, which appears to be similar to that seen with the Roux-en-Y Gastric Bypass (RYGB) [8].

There were no significant differences in MU rates in the only randomised comparison of OAGB/MGB and RYGB [9]. In a large retrospective comparison of the two procedures, the same group found no difference in revisional surgery rates associated with MU (both 0.6 %) between the two procedures [10]. MU related complications are also rare [4-6] suggesting that majority of these ulcers respond well to medical management. There is as yet no adequately powered, published study comparing the incidence of MU rates and its complications between these two procedures as the primary end point.

There is a paucity of published literature on prophylaxis, diagnosis, treatment, and management of complications for MU after OAGB/MGB. No published studies which specifically address MU after OAGB/MGB were identified. This survey of OAGB/MGB surgeons is the first attempt to explore the surgeon-reported incidence of MU, its complications, and its various other aspects.

**Methods:** A confidential, voluntary, on-line survey using SurveyMonkey® [see Table 1] was disseminated using snowball sampling in order to reach as many potential participants as possible globally. The survey was emailed to known OABG/MBG surgeons who were invited to participate and also asked to circulate the link to colleagues. The link was also posted on professional bariatric surgical social media sites inviting voluntary and anonymous participation. The survey went live on 18<sup>th</sup> April 2016 and closed on 31<sup>st</sup> July 2016. Descriptive statistics were used to analyse data.

**Results:** A total of 86 surgeons participated in the survey. Out of these 72 surgeons reported 622 MU in 27, 672 patients (10 – 3309) giving an overall MU rate of 2.24 % (0 % - 10.5 %). Respondents were advised to skip this question if they did not know the exact number. For the purposes of calculating ulcer rates, the denominator was used as the number for which the ulcer rates were clearly provided.

When asked about prophylaxis, 69/84 (82.1 %) participants stated that they 'always' used prophylaxis for MU. A further 6/84 (7.1 %) used prophylaxis 'sometimes'. A minority of participants (9/ 84; 10.7 %) did not use any prophylaxis [see Table 2]. The majority of these respondents (n = 51/84, 60.7 %) used Proton Pump Inhibitor (PPI) prophylaxis for ≤ 6 months (range 2 weeks – lifelong). There was a self-reported large variation in the drugs and dosages used.

When asked about diagnostic procedures, 49/85 (57.6 %) participants stated they would 'always' use endoscopy to diagnose an ulcer and a further 22/85 (25.8%) would use it 'sometimes' [see Table 3]. Every respondent reported using PPI to treat these ulcers +/- Sucralfate (18/86, 21.0 %) +/- the eradication of Helicobacter Pylori (6/86, 7.0 %). There were significant variations in the drugs, dosages, routes of administration (with some recommending initial intravenous treatment), and duration of PPI treatment. When asked regarding use of endoscopy to ensure healing of the ulcer, 39/81 (48.1 %) would 'always' perform this and a further 21/81 (25.9 %) would perform it 'sometimes' [see Table 4].

The respondents reported a total of 55 (9.0 %) perforated ulcers, with the majority (49/55, 89.0 %) treated with laparoscopic repair +/- omentoplasty +/- drainage. Participants stated that some patients (6/55, 11.0 %) were converted to RYGB and a total of 59 bleeding ulcers (9.5 %) were reported. The findings showed that the majority of patients responded to conservative treatment with PPI with or without blood transfusions or endoscopic intervention (23/59, 39.0 %). Four patients underwent surgery (1 enterotomy and underrunning; 3 resections and conversion to RYGB). It was reported that a further 43 patients (6.9 %) had persistent ulcers unresponsive to medical management; 20 were converted to RYGB, 5 underwent revision of the anastomosis, 2 underwent reversal, 3 underwent a Braun's anastomosis, 1 reversal, 1 total gastrectomy, 1 conversion to sleeve gastrectomy and 10 underwent thoracoscopic vagotomy).

None of the respondents reported any mortality attributable to MU in their patients. Comments deemed to be important are summarised in Table 5. Respondents reported a number of risk factors for MU with OAGB/MGB in their experience [see Table 6].

## **Discussion:**

With increasing adoption of OAGB/MGB as a bariatric surgical procedure, there is an emergent need to understand the different aspects in closer detail. There is wide variation in published literature regarding MU rates with this procedure [1, 6] which may be attributed to differences in patient population, preoperative preparation, surgical technique, prophylaxis used and aggressiveness concerning its diagnosis. For example, MU rates would differ depending on whether every patient with suggestive symptoms was first subjected to a diagnostic endoscopy as opposed to reserving endoscopy for only those who have failed a therapeutic trial of PPI.

Only 72 participants reported ulcer rates in this survey, as they were asked not to answer this question if the rate of ulceration was not known. The ulcer rate of 2.24 % reported in this survey is not vastly different from our own experience [11, 12] and what has been found in a recent systematic review [1].

Though the majority of participants used prophylaxis, there was considerable self-reported variation regarding the drug, dosage, and duration of the prophylaxis regime. This is significant considering recent data suggesting a significant decline in marginal ulceration rate in RYGB patients with routine use of Pantoprazole 40 mg daily for 6 months (1.2 % in the prophylaxis group compared 7.3 % in historical control without prophylaxis) [13]. The impact of PPI prophylaxis and its duration on marginal ulceration after OAGB/MGB has not yet been studied carefully. In this context, it would also be worth finding out if longer duration of prophylaxis such as 12 or 24 months would be associated with further reduction in ulceration rates with both types of bypass procedures.

We noted that approximately 12.0 % of participants would 'almost never' or 'never use' endoscopy to diagnose ulcers. As stated above, this would then artificially decrease the ulcer rates reported. At the same time, it is worth noting that majority

of participants would 'always' or 'sometimes' carry out an endoscopy to diagnose ulcers. Similarly, there was a discrepancy regarding the use of endoscopy for ensuring of healing of these ulcers. We have previously suggested, in the context of ulcers after RYGB, that all patients undergo a check endoscopy to ensure healing [14]. It might be reasonable to also recommend this approach for OAGB/MGB patients.

The survey findings provide insight into the complications of marginal ulceration in these patients and how these are currently managed. It would appear that majority of participants manage perforation and bleeding associated with these ulcers similarly to RYGB patients, but for persistent ulceration, respondents seemed to favour conversion to RYGB rather than a simple revision of the gastrojejunostomy retaining a loop configuration. Future studies comparing RYGB and OAGB/MGB will need to address if ulcers after OAGB/MGB are more prone to developing these complications to address the concerns raised by the critics of this procedure.

Smoking emerged as the risk factor implicated by most respondents which is similar to RYGB patients. Interestingly, the survey respondents described a number of other risk factors. Given that we have no formal data on potential risk factors for marginal ulceration after OAGB/MGB, the findings of this survey could prove useful in exploring risk factors in future studies.

There is little published research on prophylaxis, diagnosis, treatment, and complications of marginal ulcers on this topic. Table 7 [4, 6, 10-11, 15-19] attempts to summarise the information available in major published studies on this. Most authors do not provide clear information regarding ulcer prophylaxis, whether a trial of PPI therapy before diagnostic endoscopy was used, and if routine check endoscopies to ensure healing were carried out. Furthermore, because of relatively rare occurrence of complications after MU, individual studies in literature cannot provide any meaningful information on this aspect.

On the basis of studies on patients undergoing RYGB [20], one would expect a higher ulceration rate in patients undergoing OAGB/MGB because the gastric pouch is



much larger. However, this was not found to be the case in this survey and other studies examining this procedure. Although it is difficult to understand the reasoning behind this observation, less tension on the anastomosis because of a considerably longer pouch in comparison with RYGB and neutralisation of gastric acid by alkaline bile and pancreatic juices might be relevant.

In addition to reporting MU rates on a much larger cohort than is currently published, this survey highlights several important aspects concerning prophylaxis, diagnosis, and treatment of MU after OAGB/MGB. It also gives an estimate of expected complication rates and the preferred options for management. As shown in Table 7, there is little published information available concerning MU after OAGB/MGB in current scientific literature and this study contributes additional information on this topic.

There are several limitations to this study. Owing to the snowball sampling techniques used in order to reach a wide, global population of surgeons performing OAGB/MGB procedures in practice, an accurate response rate could not be provided. The authors moderate a Google group of OAGB/MGB surgeons and are also members of an International OAGB/MGB club which has a specific population who would have had an interest in the topic and would therefore be receptive to taking part in the survey. We estimate the number of surgeons performing this procedure at the time of this survey would likely have been in the region of 125 – 150. Given this information, we suggest this survey is likely to capture the views of the majority of the global community of OAGB/MGB surgeons.

Though the respondents were asked to leave the survey if they did not know the exact numbers for various questions for their patients, recall bias still remains a significant limitation of this study. It is possible that the actual numbers in each surgeon's practice are different to what they have provided us. One could also criticise that the way these questions were framed would not capture all the information regarding this complication. To overcome this weakness, the survey asks the respondents for 'any other thoughts' relevant to this survey in the end. The

value of this study is obviously limited by the fact that it is a survey of surgeons and not a direct study of patients.

The procedures used to diagnose ulcers pose a further problem. Routine endoscopy diagnoses even those ulcers that will never become clinically relevant. Most surgeons hence use endoscopy selectively in patients with suggestive clinical picture to confirm the ulcer diagnosis. It is hence interesting that only 57.6 % of the surgeons in this survey would 'always' use endoscopy to confirm the diagnosis of the ulcers. It is difficult to challenge this pragmatic approach in parts of the world with limited access to diagnostics, but it may potentially affect the ulcer rates reported in this survey. However, this practice may over-, not under-report the ulcer rates. Alternatively, the survey may have also under-reported ulceration rates as many patients might report to other surgeons or gastroenterologists as opposed to bariatric surgeons.

Another weakness of the study is that it cannot tell us about the timing of the ulcers. This information was not collected as we thought this information could not be reliably obtained for each MU patient from a survey data without specifically studying the patient population. Finally, this study may suffer from recall bias, with surgeons underreporting ulcers and over reporting complications.

**Conclusion:**

This survey of OAGB/MGB surgeons is the first attempt to further understand routine practices concerning prophylaxis, diagnosis, treatment, and management of complications associated with marginal ulceration after OAGB/MGB. It reveals an overall marginal ulceration rate of 2.24 % after OAGB/MGB and identifies a need to standardise prophylaxis, diagnosis, treatment, and management of complications of these ulcers.

**Conflict of Interest Statement:** The authors declare that they have no conflict of interest.

**Statement of Human and Animal Rights:** Not Applicable

**Statement of Informed Consent:** Not Applicable

**Author Contribution:**

KM conceived the idea, conducted the survey, data analysis and led on the writing of the manuscript. YG assisted with manuscript writing and critical review of it. AR assisted with manuscript writing. All authors were involved in writing the paper and had final approval of the submitted and published version.

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