



The Birmingham experience of high-pressure methylene blue dye test during primary and revisional bariatric surgery: A retrospective cohort study



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ABSTRACT

Introduction: Leak following bariatric surgery continues to be associated with morbidity and rarely mortality. With improvement in surgical techniques and stapler design, leak rates have reduced drastically. Intra-operative high pressure Methylene blue leak test (HPMB) is one of the techniques employed to confirm integrity of anastomoses and staple lines. Despite this, evidence for its use remains limited. We evaluated the role of HPMB in detecting and preventing leaks.

Methods: A retrospective cohort of consecutive patients who underwent primary or revisional Laparoscopic Sleeve Gastrectomy (SG) or Laparoscopic Roux-en-Y Gastric bypass (RYGB) under the care of five surgeons in three centres across Birmingham, UK, between 2012 and 2016 were assessed. All patients had routine HPMB at the end of the procedure. Demographics, HPMB positivity, and post operative leaks were recorded.

Results: 924 patients underwent bariatric surgery: 696(75.3%) RYGB, and 225(24.3%) SG. 85(9.2%) were revisional procedures.

Two HPMB were positive, which necessitated staple or suture line reinforcement with sutures intra-operatively. The patients had an uneventful recovery. 5 patients had postoperative leaks, all of whom had negative intraoperative HPMB: 3 SG patients; and 2 RYGB patients (gastro-jejunosomy anastomotic leaks). There was no statistically significant relationship between positive HPMB and anastomotic leak (Fishers exact test; $p = 1$).

Conclusion: Despite routine use of methylene blue dye test in 924 patients, there were only two positive tests. Whilst HPMB may demonstrate technical failure, this study suggests that there is no role for its routine use in primary bariatric surgery. Discontinuation of this practice would reduce risk of anaphylaxis to the dye, cost, and intra-operative time.

1. Introduction

Bariatric surgery is an established treatment for obesity and related co-morbidities providing long term weight loss and increase in life expectancy [1]. Although this patient population is high risk, the morbidity and mortality from these operations is low [2]. There has been a plethora of research into the etiology of bariatric complications, including leak, and strategies for their prevention and treatment. Various techniques have been described including larger bougie size in sleeve gastrectomy, reinforcement of staple lines with Fibrin Glue, use of absorbable buttressing material, and oversewing staple lines in an effort to reduce leak rates [3].

Interestingly leaks may occur as a late event, days or even weeks postoperatively [3–5]. High pressure methylene blue leak test (HPMB) has been routinely used to assess anastomotic integrity following

bariatric surgical procedures. Studies have questioned the routine use of leak testing intra-operatively by any technique. Despite the limited evidence supporting the use of HPMB routinely, it continues to be widely used internationally. The International Sleeve Gastrectomy panel failed to reach a consensus as to whether there was any benefit in continuing the routine use of intra-operative leak testing [6].

The aim of this manuscript is to evaluate our practice of routine use of HPMB in Birmingham and analyse the benefit and risk profile of its routine use. Our primary outcome was anastomotic or staple line leak, secondary outcome was procedural complication of HPMB or adverse reaction to methylene blue. This study is registered with the Research Registry and the unique identifying number is: researchregistry2922.

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2. Methods

We undertook a retrospective cohort study of 924 patients undergoing Laparoscopic Sleeve Gastrectomy (SG) or Gastric Bypass (LRYGB), including revisional bariatric surgery (laparoscopic adjustable gastric band to RYGB/SG; Vertical Banded Gastroplasty to RYGB/SG; SG to RYGB) under the care of 5 experienced surgeons between 2012 and 2016. Patient details were identified from a prospectively maintained database. Private and NHS centres were included. All patients undergoing surgery were included. We recorded any postoperative leak before discharge, or during emergency readmission. Routine post operative contrast imaging was undertaken only if clinically indicated.

SG was routinely calibrated over a 34 Fr gastric tube. Transection was commenced 2.5–5 cm from the antrum. Staple line reinforcement using sutures, buttressing material, or fibrin glue was not performed routinely.

Roux-en-Y gastric bypass was performed with a linear stapled gastro-jejunostomy (45 mm) that was closed over a 34 Fr orogastric tube in two layers using 2/0 monocryl. Jejunum-jejunostomy was performed with a 45 mm linear stapler and the enterotomy was closed with a single layer 2/0 monocryl. Intra-operative variations on surgical technique such as retro-colic or ante-colic roux limb were undertaken on surgeon preference and not recorded. The laparoscopic stapling device used was again on individual surgeon choice and were supplied by Medtronic (Dublin, Ireland); and Ethicon (Somerville, USA).

A 34Fr orogastric tube was subsequently used to introduce methylene blue at the completion of surgery to perform the HPMB leak test. In the case of SG the stomach distal to the resection was occluded with a laparoscopic bowel grasper. In LRYGB the jejunum distal to the gastrojejunostomy was occluded. This tests the staple line in SG, and the gastro-jejunostomy anastomosis and blind end of the jejunum in LRYGB. Between 50 and 150 mls of methylene blue was introduced until satisfactory distention was obtained.

Statistical analysis was undertaken with SPSS, IBM. The study was undertaken in line with SROCSS criteria [7]. The analysis was performed as part of a health service evaluation assessing the outcomes of bariatric surgery at our centres, and hence ethical approval was deemed not required.

3. Results

924 patients underwent Laparoscopic Gastric Bypass or Laparoscopic Sleeve Gastrectomy in the five year period between 2012 and 2016 at three institutions. This included revisional surgery, and operations with secondary procedures (synchronous laparoscopic cholecystectomy or repair of hiatus hernia). Two (0.21%) laparoscopic procedures were converted to open surgery: one SG for control of bleeding from a short gastric artery, and one LRYGB for division of adhesions resulting from previous abdominal surgery.

For a breakdown of the procedures undertaken, see Table 1.

839(90.8%) operations were primary bariatric procedures, 85(9.2%) were revisional. 696(75.3%) operations were Roux-en-Y Gastric Bypass, and 225(24.3%) Sleeve Gastrectomy. 3(0.3%) single anastomosis or ‘mini’ gastric bypasses were undertaken. Patient age ranged from 18 to 77 years (median 46 years). 209(22.6%) patients were male, 714(77.4%) female.

HPMB was performed in all cases.

Two HPMB were positive: one in a primary LRYGB with visible contrast extravasation from the gastrojejunostomy; and one in a primary SG from the staple line. In both cases the leaking area was oversewn and the patients made an uncomplicated recovery. 5 patients (0.54%) suffered postoperative leaks. 2 of these had undergone primary SG, 1 primary LRYGB, 1 LRYGB revised from gastric band with intraoperative diagnosis of band erosion, and 1 SG revised from vertical banded gastroplasty. Median time to diagnosis of leak was 2 days

Table 1
Operations Performed.

Procedure	N	Percentage
Primary Procedures		
LRYGB	611	66.1
SG	217	23.5
SG and repair of hiatus hernia	4	0.43
Single anastomosis gastric bypass	3	0.32
SG and cholecystectomy	2	0.22
LRGB and repair of hiatus hernia	1	0.11
LRYGB and cholecystectomy	1	0.11
Revisional Procedures		
Gastric Band to LRYGB	73	7.90
SG to LRYGB	6	0.65
Vertical Banded Gastroplasty to LRYGB	3	0.32
Vertical Banded Gastroplasty to SG	1	0.11
Gastric Band to SG	1	0.11
Revisional SG	1	0.11

(range 1–8 days). All patients were managed operatively, with additional endoscopic stent placement if indicated.

No patient who had a leak had previously had a positive HPMB leak test. Fisher's exact test confirms HPMB leak test does not predict postoperative leak. ($p = 1$). Subgroup analysis of SG and LRYGB again shows no correlation between HPMB positivity and post operative anastomotic or staple line leak for either operation ($p = 1$ in both cases, Fisher's exact test) There was no mortality in the post operative period. There was no procedural complication of the HPMB, and no allergic reaction to methylene blue in our cohort.

4. Discussion

Bariatric surgery provides effective, durable and cost efficient management of morbid obesity and confers an increase in life expectancy, however staple line or anastomotic leak is a dreaded complication which often requires multiple corrective procedures, weeks of recovery for patients, and increased healthcare costs [8–11].

Previous studies by Sethi et al. and Celik et al. found limited benefit of intraoperative leak testing, with minimal effect on eventual outcome on the diagnosis of postoperative leaks or of the management of the leaks when they did happen [4,12]. Similarly, Bingham et al. found intraoperative leak test did not predict leak in SG, and postulated that leak testing may increase the risk of postoperative leak [13]. The international consensus group on sleeve gastrectomy attempted but has not reached a definitive conclusion on whether there is a benefit in the use of routine intraoperative leak tests [6]. A series of systematic analyses failed to support routine use of leak tests at the end of bariatric procedures and also failed to ascertain any cost or risk benefit in their routine use [3,14].

It has been estimated that intra-operative testing takes a mean of 7.6 min and that abolishing this routine could result in a cost reduction of \$855.37 [4]. Other studies have suggested that intra-operative leak test can be negative even when there is a proven leak on CT in patients taken back to theatre, questioning the sensitivity of this test in the first instance [15]. This is further corroborated by Parikh et al. [14] who concluded that performance of the leak test did not seem to impact the leak rate ($P = 0.454$). Some studies have even suggested that intra operative leakage testing was a risk factor for leakage with an odds ratio of 2.26 [16].

Leak tests require the use of nasogastric or orogastric tubes to deliver high pressure dye and there are reported instances of these tubes causing perforations [17]. Whilst methylene blue has a reasonable safety profile and is used widely in a host of surgical techniques it is known to have caused anaphylaxis [18,19].

In our study we detected only two positive intra-operative leak tests. More importantly, all postoperative leaks had a normal HPMB test.

Though our cohort is large, we feel the low number of leaks may have diminished the value of a leak test. We postulate this is due to the experience of the surgeons performing these operations, as this is known to have a positive impact on outcomes [20,21].

This study raises important considerations regarding the confirmation of anastomotic integrity during bariatric surgical procedures. In our study of more than 900 patients who had SG and LRYGB, we did not identify a benefit in the routine use of a high-pressure methylene blue leak test.

In summary, HPMB may demonstrate technical failure in a very small number of patients. A further randomised and controlled study would identify whether it reduces leak rates by identifying these failures, however given the rarity of leak following bariatric surgery the sample size required for a study of this nature is prohibitive. HPMB has no role in predicting post-operative anastomotic or staple line leak and negative leak test should not be taken as false reassurance of staple line or anastomotic integrity in patients whose post-operative course deviates from the norm. Discontinuation of this practice would minimise manipulation of the bowel and stomach; remove the risk of anaphylaxis to the dye; and reduce both cost and operative time.

Ethical approval

Ethical approval not required, evaluation of routine practice.

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Author contribution

G. Kirby: Writing the paper, data collection and analysis.

C. Macano: Writing the paper, data collection.

S. Niyasavajjala: Writing the paper, data collection.

M. Daskalakis: Data collection, review and editing of paper.

M. Richardson: Study concept, data collection, review and editing of paper.

R. Singhal: Study concept, data collection, review and editing of paper.

R. Nijjar: Data collection; project conception; review and editing of the manuscript.

Conflicts of interest

We have no conflict of interest to declare.

Registration of research studies

researchregistry2922.

Guarantor

R. Singhal.

G. Kirby.

Consent

Analysis carried out as part of a health service evaluation of routine

practice, consent not required.

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