

Manuscript version: Author's Accepted Manuscript

The version presented in WRAP is the author's accepted manuscript and may differ from the published version or Version of Record.

Persistent WRAP URL:

http://wrap.warwick.ac.uk/110202

How to cite:

Please refer to published version for the most recent bibliographic citation information. If a published version is known of, the repository item page linked to above, will contain details on accessing it.

Copyright and reuse:

The Warwick Research Archive Portal (WRAP) makes this work by researchers of the University of Warwick available open access under the following conditions.

Copyright © and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable the material made available in WRAP has been checked for eligibility before being made available.

Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

Publisher's statement:

Please refer to the repository item page, publisher's statement section, for further information.

For more information, please contact the WRAP Team at: wrap@warwick.ac.uk.

Effective Implementation of Peri-Operative Local Guidelines for Metabolic Surgery in Patients with Diabetes Mellitus in a Tier 4 Setting Demonstrate Improved Work Efficiency and Resource Allocation

Shah N; Abraham, J; Goodwin, W; Kahal, H; Menon, V; Lam, FT; Barber, TM

Word count: 2,543

Abstract

Background: Dynamic changes in glycaemia predominate peri-operatively in patients with type 2 diabetes mellitus (T2DM) undergoing metabolic surgery. There is a lack of consensus and clear guidance on effective glycaemic management of such patients. The aim of this study was to design, pilot and implement a proforma to improve consistency of glycaemic management, and clarity of communication with healthcare professionals following metabolic surgery in patients with T2DM, thereby reducing unnecessary Diabetes Specialist Nurse (DSN) referrals.

Methods: A proforma was designed and piloted for 12-months to guide healthcare professionals on managing glycaemic therapies for T2DM patients undergoing metabolic surgery. Glycaemic control (HbA1C) and glycaemic therapies were reviewed 3-weeks pre-operatively and a proforma was completed accordingly.

Results: Of the patients with T2DM (n=34) who underwent metabolic surgery prior to the new proforma being implemented, 71% (n=24) had a DSN referral. Half of these referrals were deemed unnecessary by the DSNs. Of the patients with T2DM (n=33) who underwent metabolic surgery following implementation of the proforma, 21% (n=7) had a DSN referral. Only 10% of these were deemed unnecessary. Despite the reduced DSN input, no diabetes related complications were reported.

Conclusion: Implementation of our proforma effectively halved the proportion of patients with T2DM requiring a DSN referral. Additionally, there was a 40% absolute reduction in the proportion of unnecessary DSN referrals. The proforma improved clarity of communication and guidance for healthcare professionals in the glycaemic management of patients. This also facilitated improved work-efficiency and resource allocation.

Keywords: Type 2 Diabetes Mellitus; Metabolic surgery; Glycaemic control, Sleeve Gastrectomy

2

Introduction

Over recent decades, metabolic surgery has risen to prominence globally as an effective and durable therapeutic option for patients with morbid obesity [1]. The effectiveness and utility of metabolic surgery is manifest primarily in the resultant weight-loss. Importantly however, it is well-established through much literature, including meta-analyses on many thousands of patients who have undergone metabolic surgery, that this therapeutic option is an excellent choice for patients with weight-related conditions that are reversible with weight-loss, such as Obstructive Sleep Apnoea (OSA) and Type 2 Diabetes Mellitus (T2DM). In some of the largest meta-analyses published to date, it was demonstrated that in those patients with OSA, resolution of this condition occurs in 86% of patients following metabolic surgery [2], and an equivalent proportion of those with T2DM experience substantial improvement in glycaemic control [3]. Furthermore, a large proportion of patients who undergo metabolic surgery in the UK (25% of women and 45% of men) have an established diagnosis of T2DM at the time of their surgery (data from the UK National Bariatric Surgery Registry) [4].

Improvements in glycaemic control in patients with T2DM who undergo metabolic surgery often occur quite rapidly following the procedure, and usually precede any reduction in weight [5]. The magnitude of glycaemic effects following metabolic surgery is procedure-specific, with those that increase the rapidity of nutrient transit into the distal ileum (including gastric bypass procedures, and to a lesser degree sleeve gastrectomy) having the greatest effect on glycaemia [6-7]. Whilst the mechanisms that mediate improvements in glycaemia in patients with T2DM following metabolic surgery are incompletely understood, the 'hind-gut hypothesis' (faster post-prandial release of incretin hormones that include PYY and GLP1) is widely accepted as an important contributor [8-13]. Another important mediator may simply relate to reduced caloric (including glycaemic) intake in patients following

metabolic surgery, and the reduced need for glycaemic therapies. Whatever the actual mechanisms of glycaemic improvement however, it is important that glycaemic therapies (including oral and injectable options such as insulin) are adjusted appropriately within the metabolic surgical peri-operative period, to pre-empt the expected dynamic improvements in post-operative glycaemia, and avoid wide fluxes of glycaemia (including hypoglycaemia) [14-15].

Unfortunately, there is a general lack of consensus regarding correct adjustments to glycaemic therapies for T2DM in the metabolic surgical peri-operative period. Furthermore, clear guidelines from esteemed societies on this topic are lacking, with a dearth of evidence from the literature within this field [15]. Direct anecdotal feedback from the DSN's who are involved in metabolic surgical peri-operative glycaemic management of patients with T2DM in our own Tier 4 obesity service, revealed inconsistent management practices amongst wardbased health-care specialists, and frequent unnecessary DSN referrals, thereby compromising both work-efficiency and ultimately optimal patient care. We identified a clear need for development and implementation of local guidance, to unify and improve glycaemic management of patients with T2DM in the metabolic surgical peri-operative period. This provided a rationale for our study.

Our aim was to design and implement our own proforma to improve consistency of glycaemic management, and clarity of communication with ward-based teams in the perioperative period following metabolic surgery in patients with T2DM. Through such a strategy, we also aimed to reduce and limit the number of unnecessary referrals to our DSN team. We reasoned that successful implementation of our proforma would improve both understanding and confidence in effective glycaemic management in the metabolic surgical

4

peri-operative period. This in turn would reduce the need for DSN input. In this way, the number of DSN referrals (total and unnecessary) was a barometer of the effectiveness of our implemented ward-based proforma, and was used as the main outcome variable for our study.

Methods

Research environment: Within the UK, the NHS Commissioning Board has published guidance on clinical commissioning of obesity management, based on a four tier model. This includes guidance on complex and specialized obesity surgery (by definition, tier 4) [16]. Regional weight management services are provided based on local needs and priorities. Whilst definitions vary locally, the obesity pathway consists of 4 four defined tiers: tier 1 covers universal public health-based services; tier 2 covers lifestyle management typically administered in a primary-care based setting; tier 3 covers a multi-disciplinary specialist team-based approach, typically administered in a hospital setting, and; tier 4 covers bariatric surgery [17]. Whilst tier 2 services are usually commissioned by local authorities, tier 3 services are usually commissioned by either local authorities or clinical commissioning groups. Tier 4 services are commissioned currently by NHS England. Prior to referral to a tier 4 service for surgical assessment, all patients need to have attended and complied with a local tier 3-based weight-management service for a minimum of 6 months [18].

Outcome variable: The main outcome variable was the proportion of patients with T2DM undergoing metabolic surgery, for whom a DSN referral was requested by the ward-based team. DSN referral rate was used as a measure of confidence within the ward-based team in the glycaemic management of such patients. In addition, the proportion of DSN referrals that were deemed unnecessary by the reviewing DSN was also assessed. The definition of

5

'unnecessary' was that in the view of the reviewing DSN, the glycaemic issue being referred could and should have been managed easily by the ward-based team. Examples included:

- No current or predicted problems with either hypoglycaemia or hyperglycaemia (blood glucose >15) in the peri-operative period;
- ii) Advice about standard NICE-based glycaemic therapy alterations such as the need to discontinue Metformin in the peri-operative period;
- iii) No need for any changes in current glycaemic therapies.

Baseline assessment of DSN referrals: Prior to development and implementation of our new proforma, baseline data were collected on DSN referrals during the peri-operative period for patients with T2DM undergoing metabolic surgery in our Tier 3 and Tier 4 Obesity service within a tertiary care setting. The duration of data collection for the baseline assessment was a 12-month period, between October 2015 and October 2016. During this period, there were no local guidelines in place for ward-based staff managing such patients.

Proforma development: Prior to commencement of the study, a new proforma was developed by our Tier 3 and Tier 4 Obesity team. This proforma was designed for use by ward-based healthcare professional staff who are involved in the peri-operative management of patients undergoing metabolic surgery in our Tier 3 and Tier 4 Obesity service. Clarity of communication and improved consistency and uniformity of peri-operative glycaemic management were key strategies in the design of the proforma. The proforma provided clear instructions on any modifications required for glycaemic therapies in patients with T2DM, with each class of glycaemic therapy listed. This included guidance on continuation, discontinuation and suggested dosage changes for specific glycaemic therapies. For ease of use, the proforma was designed to fit on one side of A4 paper, and is shown in *figure 1*. Existing NICE guidance and evidence-base from the current literature for each glycaemic therapy was utilized in the process of proforma development [19].

Proforma-based assessment of DSN referrals: Following successful design of the proforma, the main pilot study for its implementation had a duration of 12-months between November 2016 and November 2017. As with the baseline assessment, data were collected on DSN referrals during the peri-operative period for patients with T2DM undergoing metabolic surgery at our tertiary centre, but this time with the developed proforma in place. To ensure adequate usage of the proforma, a copy was placed in the medical notes of each patient with T2DM who was due to have metabolic surgery at our tertiary centre during this period. In the immediate post-operative period, each patient was reviewed by an obesity-specialist Dietitian and Nurse within our Tier 4 team, who also reiterated correct usage of our proforma for glycaemic management by the ward-based staff. In addition to this, current glycaemic control (HbA1C) and glycaemic therapies were reviewed 3-weeks pre-operatively by the Tier 4 obesity team in the pre-surgical group clinic setting. Finally, a letter was sent out to each patient with T2DM (and their GP) at 2-weeks prior to their metabolic surgery, outlining relevant instructions for their glycaemic therapies (based on the guidance in our proforma) in the peri-operative period for their upcoming metabolic surgery. Through this process, awareness of the details in our proforma was maximized for the patient, their GP and the ward-based staff.

Post-operative management: Although not directly assessed during this pilot study, our proforma was also utilized for post-operative glycaemic management by Dietitians and Nurses within our Tier 4 obesity team during the study. Each patient was reviewed by a dedicated Nurse and Dietitian within our Tier 4 team at 7-10 days postoperatively. At this

routine appointment, our proforma was also used as a guide for ongoing post-operative glycaemic management. Patients on insulin were encouraged to undertake regular blood glucose monitoring at home and to contact the team if necessary. Support from our DSN team, and Consultant Diabetologist was available where required, thereby maintaining excellent glycaemic management throughout the patient journey.

Results

Baseline assessment of DSN referrals: During the 12-month period of assessment prior to implementation of our new proforma, there were 34 patients with T2DM who underwent metabolic surgery. Of these 34 patients, the majority (n=24; 71%) had had a referral to the DSN by the ward-based staff during the metabolic surgical peri-operative period. Half of these referrals were deemed unnecessary by the reviewing DSN.

Proforma-based assessment of DSN referrals: During the 12-month period of assessment following design and implementation of our new proforma, there were 33 patients with T2DM who underwent metabolic surgery. Of these 33 patients, a minority (n=7, 21%) had had a referral to the DSN by the ward-based staff during the metabolic surgical peri-operative period. Only 10% of these referrals were deemed unnecessary by the reviewing DSN. In the 12-month period when our new proforma was piloted, there were 17 fewer DSN referrals than during the 12-month period of assessment prior to our proforma being implemented (based on proportions of patients having DSN referral for each of the study periods). There was also a 40% absolute reduction in the proportion of DSN referrals deemed unnecessary following implementation of our proforma.

Discussion

Our data demonstrates a 50% reduction in the proportion of patients with T2DM who had a DSN referral from ward-based staff, during the metabolic surgical peri-operative period within the Tier 4 setting at our tertiary centre, following successful design and implementation of a proforma for management of glycaemia in such patients. There was a substantial absolute reduction (40%) in the proportion of DSN referrals that were deemed unnecessary by the reviewing DSN. To our knowledge, this is the first Tier 4-based centre report on DSN referral data following successful design and implementation of a bespoke proforma for metabolic surgical peri-operative glycaemic management of T2DM. Our data demonstrate that over the course of a year, there were 17 fewer DSN referrals requested with use of our proforma compared with its non-use. Our data show that implementation of a simple management strategy can have quite profound implications for work efficiency, resource utilization, and ultimately optimizing patient-care.

Although not directly measured in our study, we hypothesize that the substantial reduction of both total and unnecessary DSN referrals following implementation of our proforma was reflective of improved clarity of communication of peri-operative glycaemic management strategy with ward-based teams. Improved uniformity of glycaemic management through use of the proforma would have further strengthened confidence amongst ward-based staff in peri-operative management of glycaemia in T2DM, thereby reducing the need for DSN referral. Our strategy for successful implementation of our proforma also included discussion of details related to peri-operative glycaemic management with each patient prior to their surgical date within group-based clinics (based on details within the proforma), and communication of such details with the each patient's GP. These additional communication streams further optimized clarity, uniformity and consistency of communication regarding peri-operative glycaemic management. Direct implications of the successful implementation of our proforma include improved standard and continuity of patient care and safety.

The NHS is a complex system, with many examples of inefficiency [20-21]. Whilst causation for such inefficiency is usually multifactorial, procedure and protocol are often key. Workbased practices often become entrenched, and typically vary between each locality. An example of NHS inefficiency is that of work-based practices, specifically regarding referrals of patients to specialty-based teams, when such a referral is not needed. Improving ward-staff knowledge and having clear treatment guidelines may overcome this problem. Given the current pressures on the NHS, with increasing hospital admissions, ageing population and increased prevalence of chronic disease (including obesity and T2DM), combined with limited resources, it is important to explore how work-based efficiency can be improved, and to implement measures to effect such a change. Our data provide an excellent example of how relatively simple measures (that of implementing simple, easy to use and inexpensive standard and logical guidance for metabolic surgical, peri-operative glycaemic management for patients with T2DM on one side of A4 paper, combined with multi-level and unified communication streams) can have quite profound implications for work-based efficiency and resource allocation. Through substantial reduction in DSN referrals, our DSN time was freed up for more appropriate allocation to other patients with Diabetes Mellitus who would benefit from DSN input. In short, work-based efficiency and effectiveness was substantially improved through successful implementation of our proforma.

An important limitation of our study was that that our proforma was not always made clearly visible in the patient's admission notes whilst on the ward in the peri-operative period. One possible reason for this could be limited awareness of our pilot study amongst ward-based

staff. Increased training of ward-based staff prior to future implementation of the proforma is likely to mitigate this problem. A further limitation was that no assessment of peri-operative glycaemic control or length of hospital stay was performed during our study, the main outcome variable being DSN referral rate. Future studies should focus on the effects of proforma implementation on glycaemic control and variability and length of hospital stay in addition to DSN referral rates. Finally, future studies should also focus on the patient perspective, to strengthen our hypothesis that utilization of our proforma improves the patient peri-operative experience and journey. A small sample size is another limitation of this study. Future studies concentrating on a larger sample size and other centers' experiences in using the proforma, will assist in the generalisability of our findings.

To summarize, we demonstrate for the first time, that successful design and implementation of a bespoke guideline for glycaemic management of T2DM in the metabolic surgical perioperative period within a Tier 4 setting is feasible. Such a simple and inexpensive strategy results in substantial reductions in both total and unnecessary DSN referrals, and has quite profound implications for improved work-based efficiency and resource allocation. A likely mediator of such beneficial effects is the effect of our proforma as an expedient for improved clarity, consistency and uniformity of communication streams to all relevant healthcare professionals, and the patient. We recommend that our proforma is adopted and embraced by other Tier 4 centres, and that further research into its clinical utility is conducted. Scalability of our proforma would maximize potential for work-based efficiency throughout the NHS and other healthcare organizations involved with metabolic surgery, and result in improved patient care, experience and safety. **Conflict of Interest:** The authors declare that they have no conflict of interest

Ethical Approval: This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent: For this type of study formal consent is not required

References

- Cummings DE, Cohen RV. Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery. Lancet Diabetes Endocrinol. 2014;2(2):175– 181.
- 2. Buchenwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004;292(14):1724-37.
- Henry Buchwald et al. Weight and Type 2 Diabetes after Bariatric Surgery: Systematic Review and Meta-analysis. The American Journal of Medicine. 2009; 122(3):248–256.
- Welbourn R, Small P, Finlay I, et al. The Second National Bariatric Surgery Registry Report 2014. Dendrite Clinical Systems, Henley-on-Thames; 2014.
- Chuah, Ling & W Le Roux, Carel. Management of patients with type 2 diabetes before and after bariatric surgery: evolution and microvascular complications Introduction: the obesity epidemic. Nutr Hosp. 2013;28(Supl. 2):17-22.
- Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. Ann Surg. 2000;232:515– 29.
- Lee WJ, Chong K, Ser KH, Lee YC, Chen SC, Chen JC, et al. Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: a randomized controlled trial. Arch Surg. 2011;146:143–8.
- Patriti A, Facchiano EC, Annetti C, Aisa MC, Galli F, Fanelli C, et al. Early improvement of glucose tolerance after ileal transposition in a non-obese type 2 diabetes rat model. Obes. Surg. 2005;15(9):1258-1264.
- Horowitz M, Collins PJ, Harding PE, Shearman DJ. Gastric emptying after gastric bypass. Int. J. Obes. 1986;10(2):117-121.

- Cummings DE, Overduin J, Foster-Schubert KE. Gastric bypass for obesity: mechanisms of weight loss and diabetes resolution. J Clin Endocrinol Metab. 2004;89:2608–2615.
- 11. Strader AD, Vahl TP, Jandacek RJ, Woods SC, D'Alessio DA, Seeley R.J. Weight loss through ileal transposition is accompanied by increased ileal hormone secretion and synthesis in rats. Am. J. Physiol. Endocrinol. Metab. 2005;288(2):E447-E453.
- 12. Nausheen S, Shah IH, Pezeshki A, Sigalet DL, Chelikani PK. Effects of sleeve gastrectomy and ileal transposition, alone and in combination, on food intake, body weight, gut hormones, and glucose metabolism in rats. Am. J. Physiol. Endocrinol. Metab. 2013;305(4):E507-E518.
- Cummings DE, Overduin J, Foster-Schubert KE, Carlson MJ. Role of the bypassed proximal intestine in the anti-diabetic effects of bariatric surgery. Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery. 2007;3(2):109-115.
- Dagogo-Jack, S, Alberti, George. Management of Diabetes Mellitus in Surgical Patients. Diabetes Spectrum. 2002;15:44-48.
- Thorell A, Hagström-Toft, E. Treatment of Diabetes Prior to and after Bariatric Surgery. J Diabetes Sci Technol. 2012;6(5):1226–1232.
- 16. Jennings A, Hughes CA, Kumaravel B, et al. Evaluation of a multidisciplinary Tier 3 weight management service for adults with morbid obesity, or obesity and comorbidities, based in primary care. *Clinical Obesity*. 2014;4(5):254-266.
- 17. Barth J. How should we deliver obesity services? *British journal of Obesity*. 2015;1(4):124–167.
- NICE. Obesity: identification, assessment and management CG189; c2014 [cited 2018 April 27] Available from: https://www.nice.org.uk/guidance/cg189.

- NICE. Type 2 diabetes in adults: management NG28; c2015 [cited 2018 April 27].
 Available from: https://www.nice.org.uk/guidance/ng28.
- 20. Organisation for Economic Co-operation and Development. Tackling Wasteful Spending on Health. Paris: OECD Publishing; 2017.
- 21. Carter P. 2016. Operational productivity and performance in English NHS acute hospitals: unwarranted variations. London: Department of Health; 2017.