value of 5% has a PPV of 70% and an NPV of 92%. Although researchers do not intentionally under-power their studies, poor power comes as a consequence of unaccounted measurement error and effect size over-estimation. A recent review of meta-analyses found that approximately 50% of the studies surveyed had a statistical power less than 20%.[8] This is a significant problem if we extrapolate this result across the medical field and logically explains why we observe so little success in the thousands of studies out there.

Where do we go from here?

We suggest that experiments reshape their planning to focus on how meaningful their conclusions are going to be scientifically and statistically.

For single research trials, the following should be planned for and reported either from the study data or past published reports:

1. Strength of the relationship
2. Biological gradient, that is a dose-response relationship
3. Specificity
4. Temporality
5. Similar circumstances reproduce similar results
6. Reversibility
7. A power and *P*-value to meet an assigned study PPV and NPV

For data syntheses of multiple studies, the following are also important:

8. Reproducibility
9. Agreement between laboratory and epidemiological results
10. A credible mechanism exists that can explain the result
11. Experimental evidence supporting the cause–effect

Study design should focus around meeting as many of the Bradford Hill criteria possible, and the power and *P*-value chosen to achieve the highest possible study PPV and NPV using calculations as demonstrated here. A conclusion should be grounded in the same principles. Researchers in the planning phase can use the approaches described in this article to help them achieve this. We must report our statistics better, focusing on how power and sample size analysis is done, including whether the sample and power is achieved in real life. Published studies should clearly state the level of statistical expertise involved in their design and analysis.

In conclusion, we should stop seeking more from the *P*-value than it can provide and move towards a more scientifically robust reporting structure for validating our conclusions.

Authors' contributions

Study concept, theory development: GH
Drafting of the article: GH, RS, BF
Interpretation of statistical approach: RS, BF

Declarations of interest

The authors declare that they have no conflicts of interest.

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British Journal of Anaesthesia, 126 (3): 567–571 (2021)
doi: 10.1016/j.bja.2020.10.023
Advance Access Publication Date: 17 December 2020

Preoperative considerations of new long-acting glucagon-like peptide-1 receptor agonists in diabetes mellitus

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Keywords: anti-hyperglycaemic agents; diabetes mellitus; glucagon-like peptide-1; glucose control; perioperative care

The current preoperative recommendation for the inpatient population regarding use of non-insulin glucose-lowering treatment is to withhold this medication on the day of surgery.[1,2] The reasons are variable for different preparations and involve the risks of hypoglycaemia, lactic acidosis, and ketoacidosis.[3] Until recently, all these drugs had short half-lives, were taken once or multiple times daily, and were eliminated from the body within 1 day. This enabled the one-size-fits-all recommendation that is now well-known and followed.[4] However, recent advances in diabetes treatment include once-weekly preparations of long-acting glucagon-like peptide-1 receptor agonists (GLP-1 RAs). This prompts anaesthesiologists to reconsider their current practice of stopping all antidiabetic medications on the morning of surgery. We argue that the benefits of perioperative continuation outweigh the risk of withholding these medications, and therefore propose a non-withholding policy for all GLP-1 RAs. We focus on the new antidiabetic medication class of GLP-1 RAs (named -natide or -glutide, e.g. exenatide/liraglutide), not to be confused with the recently introduced sodium glucose co-transporter-2 inhibitors (names ending in -gliflozin, e.g. empagliflozin). Although their cardio-reno-protective properties might harbour perioperative potential,[5] they are generally recommended to be withheld before surgery, until more data on perioperative safety are known.[6]

Long-acting GLP-1 receptor agonists

Endogenous GLP-1 is a gut-derived incretin hormone that reduces glycaemia by stimulating insulin production and secretion from pancreatic beta cells and by reducing glucagon secretion from alpha cells.[7] In addition, GLP-1 inhibits gastric emptying, and reduces appetite and food intake which contribute to glucose lowering.[7,8] Importantly, the pancreatic effects of GLP-1 only operate during hyperglycaemia, making the risk for hypoglycaemia extremely low.[7] Endogenous GLP-1 has a half-life of several minutes and is rapidly broken down by dipeptidyl peptidase-4 (DPP-4). The first generation of GLP-1 RAs (e.g. exenatide, lixisenatide) were designed to resist DPP-4-breakdown and could be administered either once or twice daily.[8] Second-generation GLP-1 RAs (e.g. liraglutide, dulaglutide) have a higher protein-binding, thereby reducing their renal clearance, and further prolonging their half-life.[8] In the last decade, GLP-1 RAs came to the market as a second-line treatment option for type 2 diabetes mellitus.[7] Besides established efficacy in improving glucose control, enthusiasm for these medications increased with the findings of large cardiovascular outcome trials.[9–14]

Cardiovascular outcomes in type 2 diabetes mellitus

The long-term cardiovascular outcome trials with GLP-1 RAs were designed to prove cardiovascular safety. All these trials confirmed that GLP-1 RAs were safe and did not increase the long-term risk of major cardiovascular adverse events (MACE).[15] What was even more important from these reports is that several studies actually showed a reduction in risk of MACE with GLP-1 RAs compared with standard treatment. The currently available preparations, their characteristics, and the most important findings from the respective cardiovascular outcome trials are summarised in Table 1.

Cardiovascular effects

The observed cardioprotective effects of GLP-1 RAs have resulted in extensive research on their effects on cardiovascular physiology, with many postulated mechanisms.[16] The most consistently reported finding is the expression of GLP-1 receptors in the sinoatrial node.[15] Although this explains the

Table 1 Overview of currently available glucagon-like peptide-1 receptor agonists. *For superiority. †Originally a once-daily formulation, now available as prolonged release injection for once-weekly. CI, confidence interval; HR, hazard ratio.

	Duration of action		Effectiveness		Reference
Drug	Half-life	Dosing frequency	HbA1c lowering mmol mol^{-1}	Major adverse cardiovascular events (MACE)	Cardiovascular outcome trial
Lixisenatide	2.5 h	Daily 10–20 μg	3 (2–3)	Non-inferior to placebo (HR=1.02, 95% CI=0.89–1.17, P=0.81*)	ELIXA[8]
Exenatide	3 h	Twice daily 5–10 μg/weekly 2 mg†	8 (7–8)	Non-inferior to placebo (HR=0.91, 95% CI=0.83–1.00, P=0.06*)	EXSCEL[11]
Liraglutide	12.5 h	Daily 1.8 mg	5 (4–5)	Superior to placebo (HR=0.87, 95% CI=0.78–0.97, P=0.01*)	LEADER[9]
Albiglutide	5 days	Weekly 30–50 mg	8 (7–8)	Superior to placebo (HR=0.78, 95% CI=0.68–0.90, P=0.006*)	HARMONY[12]
Dulaglutide	5 days	Weekly 1.5 mg	7 (6–7)	Superior to placebo (HR=0.88, 95% CI=0.79–0.99, P=0.026*)	REWIND[13]
Semaglutide	7 days	Weekly 0.5–1.0 mg	11 (10–12)	Superior to placebo (HR=0.74, 95% CI=0.58–0.95, P=0.02*)	SUSTAIN-6[10]

increased HR found in all studies administering GLP-1 RAs, it is unlikely to be the explanation for any of the cardioprotective properties.[15,17] Thus far, cardioprotective mechanisms are poorly understood. Animal studies showed increases in myocardial metabolic efficiency of glucose usage, lower vascular resistances in pulmonary and systemic circulations, and activation of ischaemic preconditioning pathways.[16,17] In humans, the relevance of these findings remains unclear, despite some promising results of improved left ventricular function and reduced infarct size after ischaemic injury in GLP-1 RA-treated subjects.[18,19] What remains, however, are the findings from major cardiovascular outcome trials (Table 1) that found clear cardiovascular benefits with reduced rates of myocardial infarction, stroke, and revascularisation procedures.[10,11,13,14]

Gastrointestinal side-effects

The most commonly reported side-effects of GLP-1 RAs are gastrointestinal, such as nausea, vomiting, and diarrhoea.[7] In the SUSTAIN trial, 52% of patients reported gastrointestinal side-effects in those receiving semaglutide compared with 35% in the placebo group, resulting in discontinuation of medication in 14% and 8% of patients, respectively.[11]

Nausea and vomiting are explained by direct central effects of GLP-1 and delayed gastric emptying. Both effects decrease over time with ongoing treatment because of tolerance and tachyphylaxis.[8,20–24] After 8 weeks of treatment with liraglutide (a long-acting GLP-1 RA), gastric emptying returned to near baseline values.[23] Of note, contrasting effects have been found with shorter acting GLP-1 RAs that retained delayed gastric emptying over time.[23] Although associated with reduced oral intake and a beneficial loss of weight in overweight and obese patients, these effects might worry anaesthesiologists given the theoretically increased risk of aspiration. However, although commonly reported by patients, these symptoms are mostly mild, are rarely a reason for discontinuation of therapy, and seem to decrease over time with ongoing treatment.[7,25–27]

Although gastrointestinal side-effects occurred commonly in the large cardiovascular outcome trials, most were reported in the first weeks after initiation and they only led to discontinuation of treatment in 1–3% of cases.[10,11] On the ICU, GLP-1 was also found to decrease gastric motility, although its effect was minimal when gastric emptying was already delayed.[28] In patients with diabetes mellitus, gastroparesis is a known complication that requires attention and appropriate action by anaesthesiologists. Postoperatively, gastrointestinal upset remains a common concern. Despite the fact that surprisingly few perioperative studies recorded this outcome,[29] it is reassuring that GLP-1 RAs do not appear to further increase the risk of postoperative nausea and vomiting.[30–32] We performed two randomised trials studying preoperative liraglutide administration, including more than 400 patients. In both trials, the liraglutide intervention group did not report higher rates of nausea or vomiting compared with the non-GLP-1 groups, neither before nor after surgery.

GLP-1 in perioperative care

Several recent studies investigated different GLP-1 RAs in the perioperative period, showing their efficacy in improving glycaemic control.[29] The first two studies used a continuous infusion of GLP-1 during coronary artery bypass grafting (CABG) which resulted in lower perioperative glucose concentrations.[33,34] A continuous i.v. infusion of exenatide (first generation, short-acting GLP-1 RA) during CABG also reduced blood glucose concentrations and insulin requirements, during and after surgery.[32,35] Of note, GLP-1 RAs have only been approved for s.c. administration. Liraglutide (second generation, once-daily GLP-1 RA) administered before surgery was effective in lowering glucose and insulin requirements in cardiac surgery and in patients undergoing noncardiac surgery.[30,31] In these studies, adverse events have only been recorded as secondary outcomes, yet no signal of harm has been detected. A recent systematic review and meta-analysis of perioperative trials studying GLP-1 RAs found improved perioperative glycaemic control without increasing the incidence of hypoglycaemia.[29]

Contraindications for GLP-1 receptor agonists in perioperative care

In some specific situations, stopping GLP-1 RAs in patients already taking these should be considered. Post-marketing surveillance reported a possible association between GLP-1 treatment and pancreatitis or pancreatic cancer. However, analysis of all large-scale cardiovascular outcome trials found no increased risk of pancreas pathology. Nonetheless, stopping GLP-1 in patients undergoing pancreatic surgery or with postoperative pancreatitis must be considered. Furthermore, although GLP-1 RAs are safe for use in patients with impaired kidney function, they should be stopped in case of acute kidney injury requiring renal replacement therapy. Finally, we suggest that GLP-1 RAs should be stopped in case of postoperative ileus because of its effects on gastric motility, even though delayed gastric emptying is a problem during therapy initiation that abates over time.

Preoperative recommendations

No perioperative study has yet been performed using a once-weekly GLP-1 RA, although at least one is underway administering dulaglutide before cardiac surgery (NCT 03743025). Nonetheless, use of GLP-1 RAs in patients with diabetes mellitus is growing. As a result, anaesthesiologists will increasingly encounter these medications in their patients. With the introduction of the newer long-acting GLP-1 RAs, taken once-weekly, the advice to withhold antihyperglycaemic treatment preoperatively needs to be reconsidered. Firstly, to stop long-acting GLP-1 RAs before surgery is impractical. Effective discontinuation would require stopping $\geq$2 weeks in advance, affecting glycaemic control for a similar period. As patients are often seen only shortly before surgery, this policy could lead to unnecessary postponement of surgery. In addition, worse preoperative glycaemic control is associated with a higher risk of postoperative complications.[36,37] Secondly, continuation of GLP-1 RAs perioperatively is likely a safe practice. GLP-1 improves glycaemic control by reducing the incidence of hyperglycaemia without increasing hypoglycaemia. Few side-effects have been reported and most are mild. Although anaesthesiologists should be aware of the theoretical side-effects such as delayed gastric emptying and possible nausea and vomiting, GLP-1 RAs can be considered safe and effective in the perioperative period. Although shorter-acting preparations could be withheld, we recommend continuing all GLP-1 RAs throughout the perioperative period. As this is in line with the Association of Anaesthetists for day-case surgery,[38]

we extend this recommendation from ambulatory surgery to all perioperative patients.

Postoperative recommendations

Experts have highlighted the potentially advantageous aspects of using GLP-1 RAs for the in-hospital treatment of hyperglycaemia,[39,40] and several studies have shown this to be a safe and effective adjunct for in-hospital glucose control.[30,31,41] In line with the arguments for preoperative continuation, continuation of GLP-1 RAs during hospital stay should also be considered.

Conclusions

Perioperative studies of long-acting GLP-1 RAs showed better glycaemic control compared with placebo or standard care with insulin in the perioperative period without a higher risk for developing hypoglycaemia. Side-effects, most frequently gastrointestinal in nature, are mostly mild and diminish over time. Historically, non-insulin glucose-lowering medications are stopped on the day of surgery. However, stopping these once weekly preparations would require stopping the medication several weeks preoperatively. This is not only impractical but would also lead to inadequate glycaemic control for a prolonged period. In light of the current evidence, continuation of these drugs is a safe and effective practice with regard to glycaemic control and side-effects. We therefore recommend that all GLP-1 RAs be continued during the perioperative period.

Authors' contributions

Drafted the initial manuscript: AHH
Revised manuscript critically for important intellectual content: JAP, SES, DHvR, JHDV, BP, JH
Approved the final version and are accountable for all aspects of the work: all authors

Declarations of interest

AHH and JH have received funding from Novo Nordisk for investigator-initiated studies. JHDV has received research support from Sanofi, acts as a consultant for Novo Nordisk. DHvR serves on advisory boards of Sanofi Aventis and Merck Sharp & Dohme (all honoraria paid to employer). The other authors declare that they have no conflicts of interest.

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British Journal of Anaesthesia, 126 (3): 571–574 (2021)
doi: 10.1016/j.bja.2020.12.015
Advance Access Publication Date: 5 January 2021

Supraglottic airway *versus* tracheal intubation and the risk of postoperative pulmonary complications

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This editorial accompanies: Supraglottic airway device *versus* tracheal intubation and the risk of emergent postoperative intubation after general anaesthesia in adults: a retrospective cohort study by Hammer et al., *Br J Anaesth* 2021:126:738–45, doi: 10.1016/j.bja.2020.10.040

DOI of original article: 10.1016/j.bja.2020.10.040.