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Original Article

Effect of a Food for Special Medical Purposes for Preoperative Carbohydrate Loading on the Well-Being, Clinical Characteristics, and Adherence of Patients Undergoing Elective Hip and Knee Arthroplasty

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Abstract

Background & Objectives: Preoperative fasting, together with surgical trauma, leads to perioperative insulin resistance, increased risk of complications, morbidity, and even mortality in major surgery patients. Oral preoperative carbohydrate loading (PCL) has been shown to reduce postoperative insulin resistance and improve perioperative patient well-being. However, the relatively high volume of currently available PCL, the disparity of total volume prescribed, and the low-rated taste, hinders adherence to, and thus, efficacy of, PCL. This audit investigated the effectiveness and safety of a newly developed, low-volume-high-carbohydrate PCL product (MediDrink OpLoad) on the well-being and postoperative orthostatic hypotension of replacement surgery patients. ***Patients and Methods:*** Ninety consecutive hip and knee arthroplasty patients participated a randomized, controlled, open-label, single centre clinical audit. Patients either received MediDrink OpLoad in the evening and in the morning up to 2 hours prior to surgery (n=45) or were instructed to fast and drink clear fluids only from midnight prior to surgery (n=45). Well-being, adherence, and clinical parameters (systolic and diastolic blood pressure, heart rate, symptoms of orthostatic hypertension) were measured. Linear mixed-effects models, likelihood ratio tests, and Benjamini-Hochberg correction were used in the statistical analysis. ***Results:*** Twenty-five patients undergoing hip replacement surgery and 20 patients with total knee replacement surgery were included in both patient groups. Compared to preoperative fasting, PCL with MediDrink OpLoad significantly decreased thirst ($p=0.001$), hunger ($p=0.023$), anxiety ($p=0.023$), postoperative intravenous fluids need ($p<0.001$), and symptoms of orthostatic hypotension at the first mobilisation ($p=0.025$). The most common AE reported was feeling full (38.1%), followed by bloating (28.6%), burping (14.3%), flatulence (9.5%), and nausea (4.8%). All AE were deemed mild by the treating physicians. Adherence to MediDrink OplOad was 97%. ***Conclusion:*** PCL with MediDrink OpLoad generated a high adherence rate so far unreported with other PCL products. Moreover, with improving patients' well-being, postoperative hypotension, and costs related to intravenous fluid use, PCL with MediDrink OpLoad may serve as an important part of the preoperative preparation of major surgery patients.

Keywords: ***preoperative carbohydrate loading, well-being, intravenous fluid need, safety, adherence, hip arthroplasty, knee arthroplasty.***

Introduction

The traditional preoperative management for surgery patients is fasting from midnight of the evening prior to surgery. Modern medical guidelines, including those from the American Society of Anesthesiologists (ASA) and many National Health Service (NHS) trusts, allow patients to consume clear fluids up to two hours before their scheduled surgery or anaesthetic procedure [1]. The rationale behind this treatment is to decrease the risk of pulmonary aspiration and pneumonia after surgery [2].

Preoperative fasting, in combination with surgical trauma, leads to increased gluconeogenesis, skeletal muscle breakdown, hyperglycaemia, and perioperative insulin resistance [2-4] resulting in increased risk of surgical complications, postoperative morbidity, and mortality [5-7]. Preoperative carbohydrate loading (PCL) has been shown to decrease postoperative insulin resistance [8], and improve perioperative well-being [9,10], while being safe when administered at least 2 hours before elective surgery [11], since after the consumption of 50 g oral carbohydrate load, gastric emptying has been completed within 90 minutes [12].

PCL is recommended by the guidelines of the European Society for Clinical Nutrition and Metabolism (ESPEN) [13,14], the European Society of Anaesthesiology (ESA) [11], the American Society of Anesthesiologists (ASA) [15], the American Society for Enhanced Recovery (ASER) [16] and the Enhanced Recovery After Surgery Society (ERAS) [17]. PCL continues to be recommended across diverse surgical fields, including liver surgery [18], pancreatoduodenectomy [19], gastrointestinal surgery [20], colorectal surgery [21], gastrectomy [22], gynaecologic oncology surgery [23], vulvar and vaginal surgery [24] and cytoreductive surgery [25].

Regarding surgeries affecting different joints, PCL reduced postoperative length of stay and the need for certain narcotic medication in total hip arthroplasty patients [26] and was proven safe even in older patients undergoing total hip or knee arthroplasty [27]. According to recent meta-analyses of clinical studies, oral PCL in patients with arthroplasty may reduce the related complications, decrease postoperative anxiety, thirst, and hunger [28,29].

Some of the guidelines describe clinical studies that used 800 ml of 12.5% carbohydrate solution to be consumed within 5 minutes in the evening prior to surgery, and 400 ml of the same solution in the morning of the surgery [11,13,14,20,21,25]. A meta-analysis of 67 studies involving 6551 patients highlights the lack of standardization in the use of PCL: in 49.3% of the studies PCL was applied the evening before surgery and the morning of surgery but in 47.8% only in the morning of surgery. The mean prescribed carbohydrate concentration was 13.5%, and the total volume prescribed was 648.2 ml [30]. In another study, 400 ml of a carbohydrate solution (2 cans of a 100-kcal solution) was used 2 hours prior to anaesthesia in colorectal cancer surgery patients [31].

Though PCL is deemed beneficial, the volume of the liquid to be consumed may disadvantageously affect adherence to, and thus, effectiveness of the method. The adherence to different PCL protocols widely varies: 71.6% in patients with fresh fracture [32], 81.1% in bariatric surgery patients [33], 66.7% - 87% in colorectal surgery patients [34-36], 71.7% in elective colorectal cancer resection patients [17], 79.4% in open gynaecologic surgery patients [37], and 43% - 88.6% in diabetic patients undergoing surgery [38,39]. Higher compliance (≥80%) to ERAS including PCL has been associated with lower rates of complications, of 30-day hospital readmission, and decreased length of stay [17,33,37]. The main barriers against PCL adherence were early satiety and hyperviscosity of the drinks. Taste was rated only 5.3/10 in an elective colorectal surgery trial [35].

In this audit, the efficacy and safety of and adherence to a low-volume carbohydrate rich drink (MediDrink OpLoad) were investigated. We compared this novel intervention against standard dietary preoperative management (standard preoperative fasting) in a cohort of patients scheduled for elective knee and hip total arthroplasty. Our primary objective was to determine whether this low-volume approach maintains the metabolic benefits of PCL while ensuring superior patient adherence and safety.

Patients and Methods

Consecutive patients at or above the age of 18 years scheduled for total hip or knee replacement at the Practice Plus Group Hospital Barlborough between January and December 2025 were enrolled in the audit. Based on their order of appearance, patients were randomly assigned to either PCL with MediDrink OpLoad, or to standard preoperative dietary management. To ensure surgical consistency, each groups included the same number of patients. Patient demographics and clinical parameters were recorded at baseline, including age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status classification, mental status, and preoperative ambulation levels.

Patients with pregnancy, diabetes or impaired glucose tolerance, medication influencing insulin sensitivity, >10% weight loss in the past 6 months, active cancer treatment, proven gastrooesophageal reflux, conditions slowing gastric emptying, comorbidity with special dietary requirements, use of oral or parenteral steroid (expect local and inhalation steroids) within 1 month prior to surgery, known intolerance or allergy to any component of MediDrink OpLoad, and participating in any other clinical trial were excluded from the audit.

The audit has been approved by the Practice Plus Group Governance Team. Informed consent has been obtained from all participants.

Preoperative carbohydrate loading with MediDrink OpLoad

In addition to the standard dietary preoperative protocol, patients receiving PCL had to consume 2 packs of MediDrink OpLoad (400 kcal, 100 g carbohydrates in 400 ml) 1 hour after the last meal at the night prior to surgery, and 1 additional pack (200 kcal, 50 g carbohydrates in 200 ml) within 2 to 3 hours prior to surgery. Patients in the control group were instructed to follow the standard preoperative dietary protocol (not to eat after 00:00 AM on the day of surgery). Patients in each group were encouraged to consume clear liquids, preferably water for more than 2 hours before surgery.

Data collection

The audit process was structured into five distinct clinical visits (**Figure 1**).

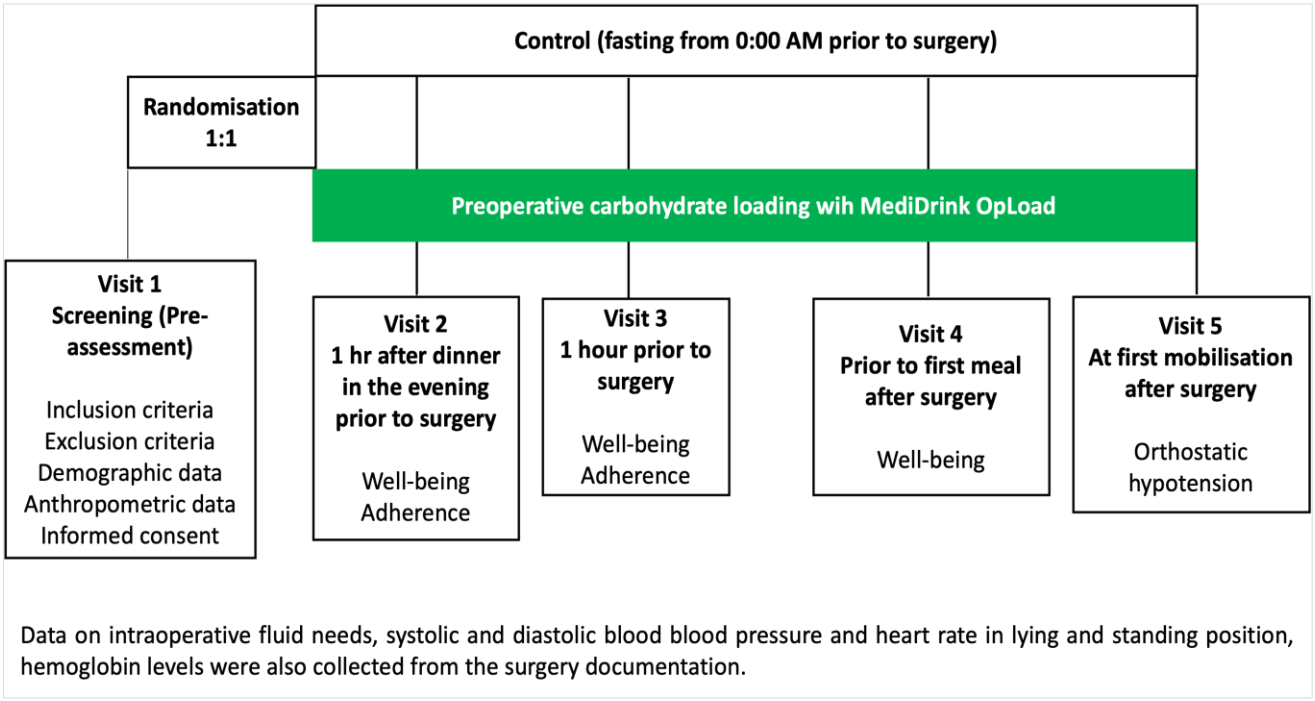


Figure 1: Flowchart of clinical audit procedures

Data on subjective well-being and adverse events were recorded at Visit 2 (1 hour after dinner on the evening preceding surgery), Visit 3 (1 hour prior to surgery), and Visit 4 (prior to the first meal after surgery, well-being only). Evaluation happened with using a 10-point Visual Analogue Scale (VAS), where 0 represented the absence of symptoms and 10 represented the maximum severity. Patients' self-reported scores were collected for thirst, hunger, anxiety, fatigue, nausea and weakness via a standardised questionnaire. The timing of data collection was structured as follows:

- PCL group: Patients completed the questionnaire one hour after consuming the carbohydrate-rich drink, the evening before surgery, and the morning of surgery.
- Control group: Patients completed the assessment at two specific intervals: one hour after the final preoperative meal (the evening prior to surgery) and two hours before the scheduled procedure.

Patients in the PCL group used an adverse event reporting questionnaire to record any adverse events such as diarrhoea, constipation, nausea, vomiting, abdominal discomfort, abdominal pain, feeling fullness, burping, flatulence, bloating, regurgitation.

At first mobilisation after surgery (visit 5), systolic and diastolic blood pressure and pulse rate were recorded. Additionally, patients were screened for clinical symptoms of orthostatic hypotension. Orthostatic hypotension was assessed by recording symptoms of blurred vision, dizziness, light-headedness, tremor, muscle weakness, fainting, and confusion upon first rising from bed after surgery. The presence of the symptom was scored as 1 and the absence of the symptom as 0. At the same time, hemodynamic parameters of orthostatic hypotension were assessed. Systolic and diastolic blood pressure as well as heart rate were recorded in both supine and standing positions to monitor orthostatic changes. From a hemodynamic perspective [40], orthostatic hypotension was defined as a decrease in systolic blood pressure of ≥20 mmHg or diastolic blood pressure of ≥10 mmHg within 3 minutes of standing. A heart rate increase of more than 20 beats/min in the standing position was considered a sign of orthostatic hypotension.

Patient adherence to the audit protocol was evaluated using a self-administered questionnaire. To verify intake, the investigator quantified the volume of the PCL product consumed. In cases of non-compliance or incomplete consumption, patients were interviewed to identify specific barriers, including forgetfulness, loss of appetite, nausea, vomiting, abdominal pain, diarrhoea, bloating, feeling of fullness, bad taste, malaise.

Upon hospital discharge, total intravenous (IV) fluid requirements and a comparison of pre- and postoperative haemoglobin levels were collected from the patients' medication charts. Haemoglobin levels were obtained through routine clinical monitoring. Data points were extracted from laboratory tests conducted during the preoperative assessment and on the first postoperative morning.

Statistical analysis

Full models were compared with reduced linear mixed-effects models that excluded the time effect and the treatment-by-time interaction. Likelihood ratio tests were used to calculate p-values associated with the treatment effect and the treatment-by-time interaction. Because multiple tests were conducted, p-values were adjusted using the Benjamini–Hochberg correction method. As the models were not fully independent, separate p-value corrections were applied for the main treatment effect and for the treatment-by-time interaction.

Blood pressure and pulse were also analysed using linear mixed-effects models. Systolic and diastolic blood pressure were modelled separately, and mean values as well as ranges were evaluated for both lying and standing positions. These analyses were considered independent and exploratory; therefore, p-value correction was applied separately from the analyses of well-being parameters.

Postoperative other symptoms were grouped and analysed using logistic regression to assess their occurrence after surgery. IV fluid volume was analysed using linear regression. In both models the above-mentioned covariates were included. P-values for both

mental symptoms and fluid volume were corrected independently from the other outcome measures.

Stratifying patients by type of surgery was not pursued, as the resulting subgroup sizes would have been too small to yield reliable or meaningful results.

Results and Discussion

Patients

Ninety patients scheduled for elective total hip or knee arthroplasty participated in the clinical audit. Forty-five patients (25 with hip and 20 with knee surgery) were randomized to receive PCL, while 45 patients (25 with hip and 20 with knee surgery) were instructed to follow standard preoperative dietary management (control group).

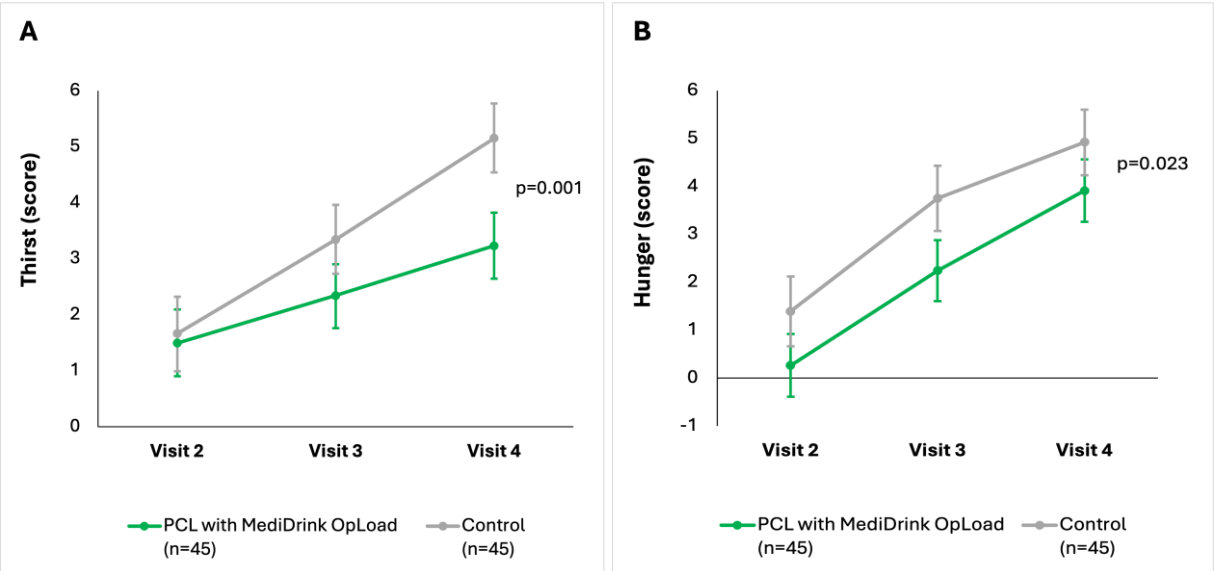
Patients had a mean age of 67.1±8.1 years in the PCL group and 69.6±7.0 years in the control group. Of the PCL patients, 44%, while of the control patients, 40% were male. Mean BMI was 28.9±4.9 kg/m^2 of PCL, and 30.6±6.0 kg/m^2 of control patients. According to the American Society of Anesthesiologists (ASA) Physical Status Classification System, 8 of 45 patients (18%) were ASA grade I and 37 patients (82%) ASA grade II in the PCL group, while in the control group, 5 of 45 patients (11%) belonged to ASA grade I, 37 patients (82%) to ASA grade II, 2 patients (4%) to ASA grade III, and for 1 patient (2%) ASA grade information was missing. In the PCL group, 20 patients (44%), while in the control group, 22 patients (49%) had one or more serious underlying medical condition (e.g. hypertension, cancer, hypothyroidism, COPD, asthma, aortic valve replacement, former spinal surgery) at the time of pre-assessment. Gastrointestinal disorders (gastric ulcer, gastro-oesophageal reflux, irritable bowel syndrome, hemicolectomy, diverticulosis) was present in 3 patients (6.7%) in the PCL, and in 9 patients (20%) in the control group. Among PCL patients, 6 (13.3%), and in the control group, 4 patients (8.9%) suffered from some mental issues (e.g. anxiety, depression, low mood, panic attacks). No significant difference has been found in the initial patient characteristics between the PCL and the control groups (**Table 1**).

Table 1: Baseline characteristics of hip and knee arthroplasty patients.

	PCL (n=45)	Control (n=45)	p
Age, years ± SD	67.1±8.1	69.6±7.0	0.120
Gender male, n (%)	20 (44)	18 (40)	0.831
BMI kg/m^2 ± SD	28.9±4.9	30.6±6.0	0.162
ASA grade, n (%) I II III Missing	 8 (18) 37 (82) 0 0	 5 (11) 37 (82) 2 (4) 1 (2)	0.262
Underlying medical condition present, n (%)	20 (44)	22 (49)	0.833
Gastrointestinal condition present, n (%)	3 (6.7)	9 (20)	0.121
Mental condition present, n (%)	6 (13.3)	4 (8.9)	0.737

Efficacy

Of the well-being parameters, consumption of MediDrink OpLoad (PCL) prior to surgery significantly decreased thirst (p=0.001), hunger (p=0.023), and anxiety (p=0.023) compared to preoperative fasting (**Figure 2**). Tiredness, nausea, and weakness were not significantly different between the PCL and the fasting groups (**Figure 2**).



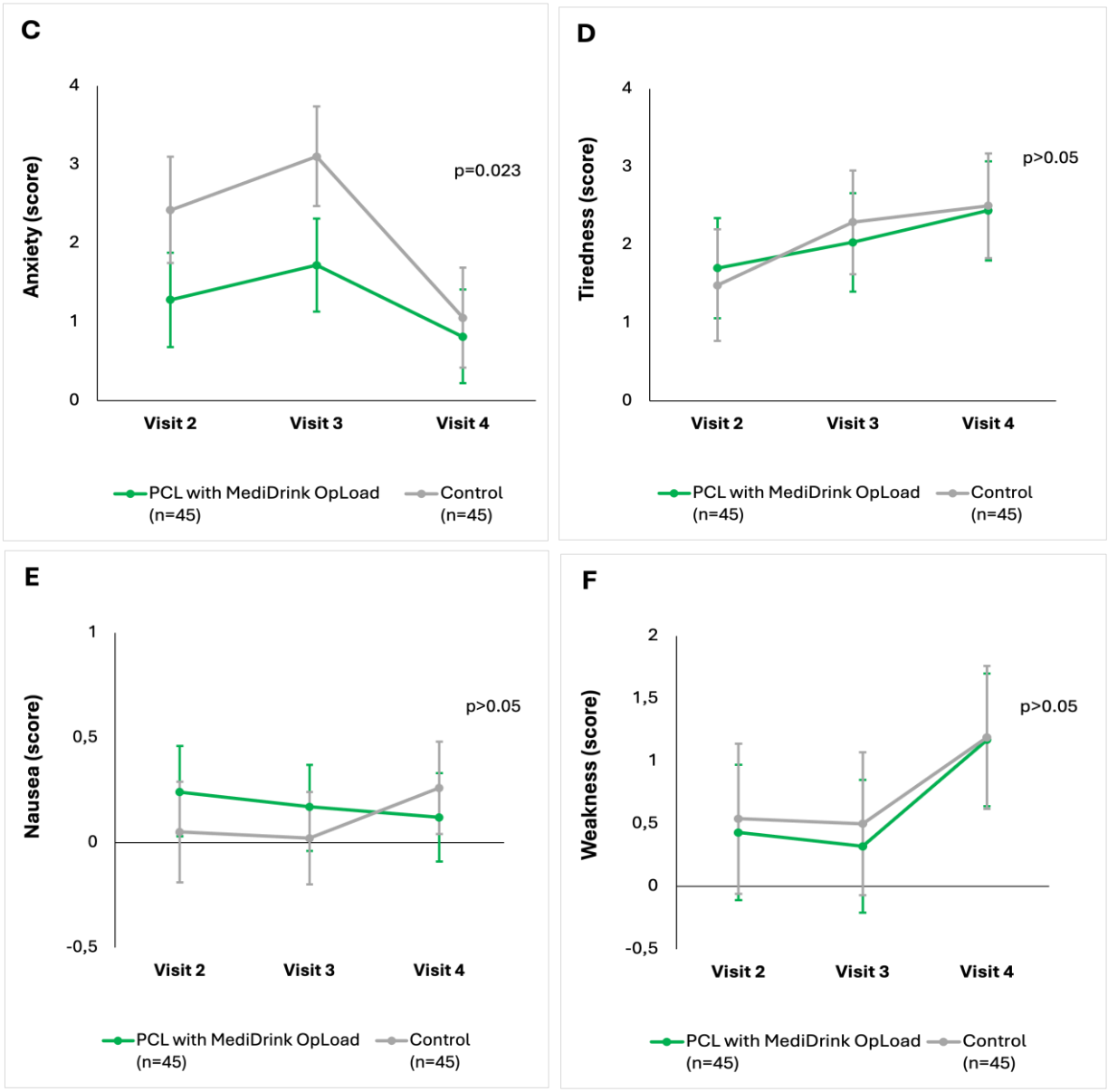


Figure 2: PCL with MediDrink OpLoad significantly improved thirst (A), hunger (B) and anxiety (C), but had no effect on tiredness (D), nausea (E), and weakness (F) in hip and knee arthroplasty patients.

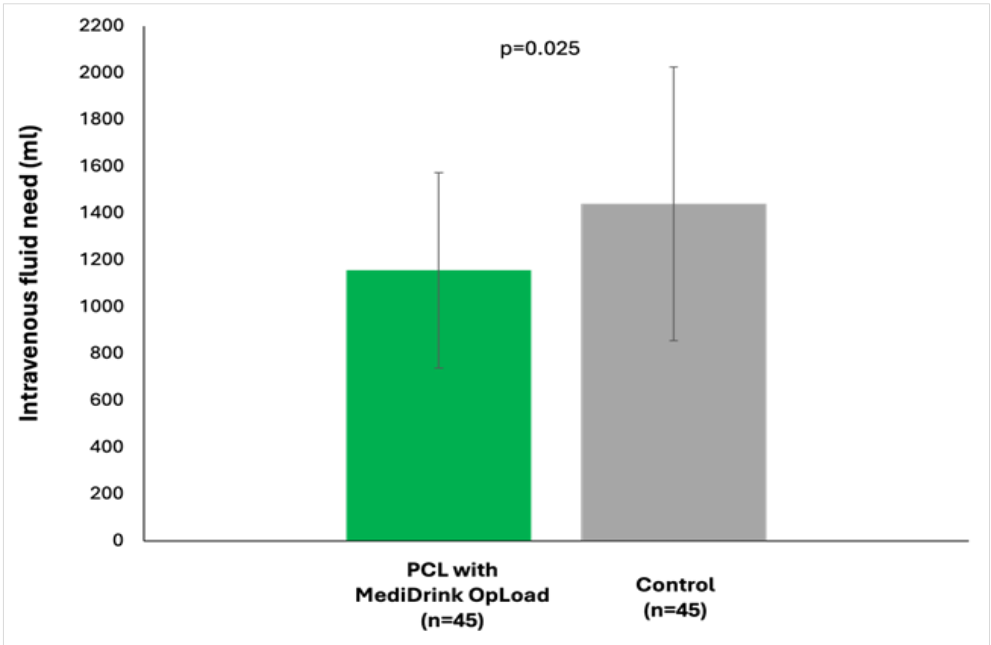


Figure 3: PCL with MediDrink OpLoad significantly decreased intravenous fluid need in hip and knee arthroplasty patients.

Furthermore, PCL with MediDrink OpLoad significantly decreased the amount of postoperative IV fluids need compared to controls (1157 ± 418 ml *vs* 1441 ± 585 ml, p<0.001) (**Figure 3**). Symptoms of orthostatic hypotension, such as blurry vison, dizziness, light-headedness, tremor/muscle weakness, fainting, and mental confusion, at the first mobilisation were significantly less frequent after PCL with MediDrink OpLoad than after fasting (p=0.025).

Systolic and diastolic blood pressure and heart rate in standing and lying position showed no significant change with PCL compared to fasting.

Safety

Of the 45 patients receiving PCL with MediDrink OpLoad, 15 patients (33.3%) reported 21 adverse events (AE) in total at Visit 2 (1 hour after dinner in the evening the day before surgery), with 4 patients (8.9% of all PCL patients) reporting 2 AE, and 1 patient (2.2% of all PCL patients) experiencing 3 AE. One patient (2.2%) reported feeling fullness at Visit 3 (1 hour prior to surgery) - this patient reported feeling fullness at Visit 2 as well. The most common adverse event reported was feeling full (42.9% of all AE), followed by bloating (28.6% of all AE), burping (14.3% of all AE), flatulence (9.5% of all AE), and nausea (4.8% of all AE). All reported AE were deemed mild by the treating physicians. Since patients had dinner before Visit 2, the causative role of dinner for the reported AE cannot be ruled out. No death, serious, or other significant AE occurred during the PCL therapy with MediDrink OpLoad.

Adherence

Adherence to PCL with MediDrink OpLoad was 95.6% in the evening prior to surgery. No patient reported missed drinks, while adherence data were missing for 2 patients. All patient consumed the prescribed MediDrink OpLoad prior to surgery, adherence was reported as 100% at this timepoint.

In total, adherence to MediDrink OplOad was calculated as 97%, since missing data on adherence was considered as if the drinks had not been consumed.

Discussion

PCL has been shown to decrease postoperative insulin resistance [8,10,41,42], improve perioperative well-being [9,10], improve postoperative muscle loss [43,44], and function [45], decrease the rate of postoperative complications [46,47], and improve outcomes [45,48-51] in patients undergoing a wide variety of surgical procedures. Therefore, PCL is recommended by several non-ERAS and ERAS guidelines [11,13,14,16,18-25]. However, the disparity of PCL prescriptions [29,30] and of adherence to PCL [17,32-39] may result in decreased efficacy. Most commercially available PCL products contain a carbohydrate solution of 12.5%, therefore, the recommended intakes in the evening before surgery (800 ml to be consumed within 5 minutes) and in the morning prior to surgery (400 ml) are quite high [11,13,14,20,21,25]. The main barriers against PCL adherence are early satiety, hyperviscosity of the drinks, and low-rated taste (5.3/10) [35]. A study of 30 patients undergoing gastrointestinal surgery found that only 53% of patients who had received PCL were willing to take it again if indicated [52]. Therefore, a PCL FSMP with the same carbohydrate amount but decreased volume and improved taste may lead to higher adherence and thus better efficacy in surgical patients.

Our clinical audit demonstrated that the administration of MediDrink OpLoad, a low-volume-carbohydrate-rich FSMP, significantly reduced preoperative thirst, hunger and anxiety compared to standard fasting protocol. These results are consistent with a previous clinical trial of MediDrink OpLoad [53]. Moreover, a novel finding with the use of MediDrink OpLoad as PCL, namely, a significant reduction in postoperative IV fluid requirements was seen, similarly to a study with a carbohydrate drink in plastic surgery patients [54]. This finding may have special importance when due to resource constraints, IV fluids are not as readily available [54].

The symptoms of orthostatic hypotension, such as blurry vison, dizziness, light-headedness, tremor, muscle weakness, fainting, and mental confusion were significantly less frequent at the time of first postoperative mobilisation after PCL with MediDrink OpLoad than after standard dietary management. This finding indicates that PCL with MediDrink OpLoad may contribute to an easier mobilisation with less difficulties and complications in patients undergoing major orthopaedic surgery.

MediDrink OpLoad was safe to use, with 33.3% of PCL patients reporting a total of 21 AEs (fullness, bloating, burping, flatulence and nausea), all of which were considered mild by the treating physicians and did not significantly affect the procedure. Due to the lack of serious adverse events such as apparent or proven aspiration during or after procedure [55], PCL is generally considered safe despite some minor adverse events that may cause discomfort to patients.

Since the greatest barriers for adherence to PCL are early satiety, hyperviscosity of the drinks, and low-rated taste [35], MediDrink OpLoad was developed as a low-volume-high-carbohydrate FSMP, based not solely on maltodextrin, but on low-glycaemic-index isomaltulose and some saccharose that make the drink more palatable. Adherence to MediDrink OpLoad was high, 97%, since missing data on adherence in case of 2 patients were considered as if the drinks had not been consumed. This adherence rate is higher than the ones found in studies with other clear carbohydrate PCL products [17,32-39].

The so far highest adherence rate to PCL seen in this clinical audit may have a direct causative role in the improved well-being of patients and reduced symptoms of orthostatic hypotension. In addition, the reduction in intravenous fluid requirements can also represent cost savings for hospitals, even if the costs of PCL MediDrink OpLoad must be covered. While of the 12.5% PCL products 1200 ml should be procured (and consumed by the patient), only 600 ml of MediDrink OpLoad ensures the same PCL effect. However, determination of the financial aspects of PCL with MediDrink OpLoad would require further studies designed to analyse costs.

The main limitation of the present clinical audit is that no separate analyses were performed for hip and knee arthroplasty patients due to the relatively low number of individuals enrolled into the clinical audit.

Conclusion

The preoperative oral carbohydrate loading with MediDrink OpLoad resulted in high patient compliance rate and significantly improved patient well-being. Moreover, it reduced the incidence of postoperative orthostatic hypotension, and intravenous fluid requirements in patients with hip and knee replacement surgery. Based on these findings, MediDrink OpLoad may serve as an important and possibly cost-saving step in the preoperative management of major surgery patients.

Data Availability

The data underlying the findings of this clinical audit are available upon request. The following e-mail address can be used for such requests: Ferenc.Toth@practiceplusgroup.com.

Conflicts of Interest

Edit Nádasi, and Gellért György Cseh are affiliated with Medifood International Trading Kft., part of the Medifood group that developed, manufactures, and holds marketing authorisation for MediDrink OpLoad FSMP.

Ferenc Tóth, György Lovász, Marco La Malfa, Attila Aros, Charles Ayekoloye, and Nawar Hilmi declare no conflict of interest regarding the publication of this clinical audit.

Authors' contributions

Ferenc Tóth, György Lovász, Marco La Malfa, Attila Aros, Gellért Cseh, and Edit Nádasi contributed to the development of the protocol.
Ferenc Tóth coordinated the clinical audit.
Ferenc Tóth, György Lovász, Charles Ayekoloye, and Nawar Hilmi performed data collection.
Ferenc Tóth, György Lovász, Gellért Cseh, and Edit Nádasi developed, finalized and proofread the manuscript.

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