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Original Research Article

Evaluation of preoperative carbohydrate loading compared to preoperative fasting for enhanced recovery after elective gynecological surgeries

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ABSTRACT

Background: This study aimed to evaluate the impact of preoperative carbohydrate loading on insulin resistance and clinical outcomes in patients undergoing elective gynecological surgeries.

Methods: A single-center, parallel-group, randomized controlled study was conducted at the Post Graduate Institute of Medical Education and Research, Chandigarh, India. Thirty-nine patients were randomized into two groups: the carbohydrate loading group (CHO, n=20) received 600 ml of a carbohydrate-rich drink the day before surgery and 200 ml two hours before surgery; the control group (CO, n=19) fasted overnight.

Results: Baseline serum insulin, blood glucose, and insulin resistance levels were similar between the groups. Two hours before surgery, the CO group had significantly higher serum insulin levels (7.5 ± 5.6 IU/ml) compared to the CHO group (4.5 ± 2.9 IU/ml) ($t=2.08$, $p=0.04$). Insulin resistance was also higher in the CO group (1.9 ± 1.6) compared to the CHO group (0.9 ± 0.6) ($t=2.40$, $p=0.02$). Seventy-five percent of the CHO group regained bowel sounds within 24 hours post-surgery, compared to seventy-three percent of the CO group, who achieved bowel sounds after 24 hours ($\chi^2=9.24$, $p=0.02$). No significant differences were observed in postoperative mobilization, urinary catheter removal, fever, nausea, vomiting, length of hospital stay, or surgical site infections.

Conclusions: Preoperative carbohydrate loading reduces insulin resistance and facilitates faster bowel recovery without increasing postoperative complications in elective gynecological surgery.

Keywords: Preoperative carbohydrate loading, Insulin resistance, Elective gynecological surgery, Clinical outcomes, Postoperative recovery, Bowel activity

INTRODUCTION

Enhanced recovery after surgery (ERAS) protocols, also known as 'fast track surgery protocols', consist of multiphasic and multidisciplinary evidence-based interventions aimed at improving postoperative outcomes and recovery in patients undergoing elective surgeries.

Preoperative measures include information, education, and counselling, preoperative optimization, avoidance of bowel preparation, preoperative carbohydrate loading, thromboprophylaxis, antimicrobial prophylaxis, and part preparation. Perioperative interventions by both surgical and anesthesia teams include standard anesthetic protocol, minimally invasive surgery, perioperative normothermia,

appropriate fluid management, and intraoperative analgesia. Prevention of postoperative hypothermia, multimodal antiemetics for postoperative nausea and vomiting, postoperative pain management, and early ambulation are considered under postoperative measures in ERAS.^{1,2}

Traditional overnight fasting places a patient in a catabolic state, aggravating the surgical stress response, thereby leading to increased insulin resistance. An optimal nutritional state is critical in providing successful postoperative outcomes; hence, carbohydrate loading has been considered under ERAS to alleviate the deleterious effects of preoperative fasting and insulin resistance. Consuming carbohydrate-containing drinks the previous evening and two hours before surgery mimics the normal postprandial metabolic response, stimulating the release of endogenous insulin, reducing the surgical stress response, and hence peripheral insulin resistance.³

A recent appraisal of the ERAS protocol in gynecology showed heterogeneity in outcomes and emphasized the need to develop standardized evidence-based guidelines for gynecological patients. Thus, we carried out a prospective randomized study to compare the effect of preoperative oral carbohydrate loading on insulin resistance and clinical outcomes in patients undergoing elective gynecological surgeries. We aimed to assess the effect of preoperative carbohydrate loading on insulin resistance and clinical outcomes among patients undergoing elective gynecological surgeries. Clinical outcomes included postoperative nausea and vomiting (PONV), tolerance to oral diet, the onset of bowel sounds, length of hospital stay, and effect on surgical site infection.

METHODS

We conducted a parallel group randomized controlled trial in the Department of Obstetrics and Gynaecology at Post Graduate Institute of Medical Education and Research, Chandigarh, India from September 2018 to September 2020. The trial was approved by the Institute Ethics Committee and registered under clinicaltrials.gov (CTRI Ref No - CTRI/2019/12/022360).

Sample size and study population

According to the study by Mathur et al, the mean difference in the length of hospital stay between the intervention and control group was found to be 2 ± 2.8 days, which means that the mean length of hospital stay was more by two days in the control arm.

$$\delta = (\mu_2 - \mu_1) / \sigma$$

In the above equation, δ is standardized effect size; $(\mu_2 - \mu_1)$ is the difference in population mean of two groups; and σ is standard deviation ($\delta = 2/2.8 = 0.7$).

$$m = 2c / \delta^2$$

In the above equation, m is sample size in each group, c is 7.9 for 80% power at 95% confidence interval.⁴ Using this formula, m comes to be 33 in each group.

$$\text{Total sample size} = 2 \times m = 66$$

Therefore, the total sample size to be achieved in the current study was 66 (33 in each group) for attaining 80% power and 95% CI. However, due to restriction of cases during the COVID-19 pandemic, the sample size had to be reduced to 40 (20 in each group).

Female patients above the age of 18 undergoing major elective gynecological surgery were randomized. The preferred anesthesia included general anesthesia or spinal anesthesia along with epidural analgesia. Randomization was done using a random number allocation table into 2 groups: the carbohydrate group (CHO) and the control group (CO).

We excluded diabetics, ASA grade III and IV patients, patients undergoing laparoscopic and vaginal surgeries, and those requiring postoperative ICU care and ventilation.

Preoperative preparation

No intravenous fluids were given to patients before surgery. The intervention included a carbohydrate drink of a specified composition: carbohydrate-12.6 g (glucose 0.2 g, fructose 1.3 g, maltose 0.7 g, and maltodextrin 10.0 g), energy-50 kcal, and osmolarity-290 mosm/l, which was locally prepared as per protocol. Study subjects in the CHO group were administered 600 ml (75.6 g carbohydrate load) of the drink orally (PO) on the evening before surgery. After midnight, patients were not allowed anything orally. On the morning of surgery, 200 ml (25.2 g carbohydrate load) of the carbohydrate drink was given PO two hours before surgery. The CO group was kept fasting overnight.

Intraoperative considerations

Pre-medications, antibiotic prophylaxis, intravenous fluids, intra-operative normothermia, and analgesia were given to all the recruited patients as per institutional protocol. Patients were catheterized routinely, and peritoneal drains were placed at the discretion of the surgeon.

Postoperative period

Patients from both groups were mobilized as tolerated within 24 hours following surgery. Clear fluids were allowed 6 hours after surgery in the CHO group, whereas in the CO group, patients were allowed orally on postoperative day 1 as per the routine practice at our institution. Postoperative analgesia was by epidural infusion, and PONV was managed as per institutional protocol in all recruited subjects.

Assessment of outcomes

Outcomes of the trial consisted of the effect of preoperative carbohydrate loading on insulin resistance, postoperative nausea and vomiting (PONV), onset of bowel sounds, tolerance to oral diet, length of hospital stay, and surgical site infection. Blood glucose (BG) was measured by glucose oxidase method with the help of a home blood glucose monitor (CareSens N Blood Glucose Monitoring System, Medical Technology Promedt, Germany). Serum insulin estimation was performed by ECLIA on ROCHE COBAS 6000 (Roche Diagnostics, Switzerland).

Serum BG and insulin levels were measured the evening before surgery (baseline), 2 hours before surgery, 1 hour after incision, immediate post-surgery, and 6 hours post-surgery. Insulin resistance was measured according to the homeostatic model assessment-insulin resistance (HOMA-IR) equation as proposed by Mathew et al.⁵

$$HOMA - IR = \frac{\text{Serum insulin (IU/ml)} \times \text{Blood glucose (mg/dl)}}{405}$$

Patients were monitored for 24 hours postoperatively for PONV, and the need for antiemetics was considered a surrogate marker for PONV. The onset of bowel sounds and tolerance to oral diet were also assessed in both groups. Patients were considered fit for discharge after passing flatus/bowel movement, tolerating oral diet, having adequate pain control on oral analgesia, being afebrile, ambulatory without catheter/drains/intravenous lines, and capable of self-care with minimal assistance. Patients were followed up to 30 days following surgery for evidence of surgical site infection.⁶

Statistical analysis

Discrete categorical data were represented as numbers and percentages (N %); normally distributed continuous data were depicted as mean and standard deviation; skewed data in the form of its median and interquartile range. For normally distributed data, means were compared using student's t-test. Proportions were compared using Chi-square or Fisher's exact test, depending on their applicability for two groups. The risk was estimated with a 95% confidence interval. All statistical tests were two-tailed and were performed at a significance level $p \leq 0.05$. The statistical analysis was conducted using IBM statistical package for social sciences (SPSS) statistics version 20.

RESULTS

We enrolled 40 participants, with attrition of 1 case due to cancellation of the planned procedure. 39 patients were randomized into two groups: 20 in the CHO group and 19 in the CO group. The study flow is depicted in the CONSORT diagram. Patient demographics and surgical

characteristics are depicted in Table 1; there was no statistically significant difference between the two groups.

Biochemical parameters

The serum insulin, blood glucose, and insulin resistance values between the two groups are shown in Table 2. The baseline serum insulin, blood glucose, and insulin resistance levels were comparable between the two groups. Serum insulin levels were significantly higher in the CO group (7.5 ± 5.6 IU/ml) when compared to the CHO group (4.5 ± 2.9 IU/ml) two hours before surgery ($t=2.08$; $p=0.04$). There was no significant difference between the two groups in serum insulin levels at other time points or blood glucose levels. Calculated insulin resistance was significantly higher in the CO group (1.9 ± 1.6) when compared to the CHO group (0.9 ± 0.6) two hours before surgery ($t=2.40$; $p=0.02$). Insulin resistance measured at other time points did not show any statistically significant difference.

Clinical parameters

75% of patients in the CHO group achieved bowel sounds within 24 hours of surgery, compared to 73% of patients in the CO group who achieved bowel sounds after 24 hours ($\chi^2=9.24$; $dF=1$; $p=0.02$). 70% of participants in the CHO group achieved tolerance to oral diet in the first 24 hours after surgery, contrary to 84% of participants in the CO group who achieved tolerance after 24 hours ($\chi^2=16.75$; $dF=3$; $p=0.001$). There was no significant difference in postoperative mobilization, indwelling urinary catheter removal, incidence of fever, and incidence of PONV.

In the study population, the mean postoperative day for fitness for discharge was 2.6 ± 0.7 days in the CHO group and 2.7 ± 1.0 days in the CO group, respectively ($p=0.50$). The mean postoperative day for the actual day of discharge was 3.7 ± 1.3 days in the CHO group and 3.6 ± 1.4 days in the CO group, respectively ($p=0.97$). Discharge was delayed in 15 participants owing to the surgeon's discretion. In 3 participants, discharge was delayed due to patient-related factors like non-availability of transport/social and rehabilitation factors, and in 5 patients due to postoperative complications like fever, abdominal distension, and hematuria. No patients in the study population developed surgical site infection when followed up to 30 days after surgery.

Figure 1 illustrates serum insulin levels in IU/ml at four time points: 2 hours before surgery, 1 hour after incision, immediately post-surgery, and 6 hours post-surgery. The blue line shows the cases, who are the CHO group with carbohydrate loading, while the orange line depicts the controls, the CO group with fasting. Insulin in controls was higher at 2 hours before surgery and 6 hours post-surgery, suggesting that individuals in this group had a greater stress response compared to those in the case group.

Figure 2 shows the trend of blood glucose levels, in mg/dl, at four different time points: 2 hours before surgery, 1 hour after incision, immediately after surgery, and 6 hours post-surgery. The cases where CHO was involved with carbohydrate loading were represented by the blue line, while that of the controls were represented by the orange line for the CO group in the fasting state. From this graph, it can be noticed that both levels of blood glucose increased quite similarly in both groups and were only little high at the last time point in cause group.

Figure 3 depicts the trend of insulin resistance, measured using HOMA-IR, at four-time periods: 2 hours before surgery, 1 hour after the incision, immediately post-surgery, and 6 hours post-surgery. The blue line belongs to the cases, which are the CHO group with carbohydrate loading, while the orange line belongs to the controls from the CO group with fasting. This graph shows that, at all times, there is a trend of reduced insulin resistance in cases compared to controls. Specifically, notice the peak increase in insulin resistance at 6 hours post-surgery in the control group.

Table 1: Patient demographics and surgical characteristics in the CHO and CO groups.

Variables	CHO (n=20)	CO (n=19)	P value
Mean age (years)	40.35	46.05	0.159
Preoperative diagnosis			
Ovarian malignancy	11	13	0.623
Fibroid uterus	4	3	
Endometriosis	3	1	
Endometrial malignancy	2	1	
Others	0	1	
Surgery performed			
^a TAH + BSO + omentectomy	8	10	0.212
TAH + BSO	5	6	
^b USO/BSO	4	0	
Myomectomy	1	1	
TAH + BSO + lymphadenectomy	0	1	
Cystectomy	1	0	
USO + cystectomy	1	0	
Others	0	1	
Anesthesia (%)			
^c GA + ^e EA	85	94.7	0.316
^d SA + EA	15	5.3	
Mean duration of surgery (hours)	2.26	2.43	0.389

^aTotal abdominal hysterectomy bilateral salpingo-ophorectomy; ^bunilateral salpingo-ophorectomy; ^cgeneral anesthesia; ^dspinal anesthesia; ^eepidural anesthesia

Table 2: Biochemical parameters in CHO and CO group following preoperative carbohydrate loading.

Parameters and time	CHO (n=20)	CO (n=19)	P value
Serum insulin (IU/ml)			
2 hour prior to surgery	4.52	7.49	0.050
1 hour after incision	4.03	5.59	0.359
Immediately after surgery	8.35	7.68	0.777
6 hours after surgery	8.83	11.61	0.251
Blood glucose (mg/dl)			
2 hour prior to surgery	88.5	85.68	0.639
1 hour after incision	90.95	83.84	0.360
Immediately after surgery	100.20	98.21	0.814
6 hours after surgery	121.10	115.37	0.608
Insulin resistance			
2 hour prior to surgery	0.94	1.88	0.021
1 hour after incision	0.86	1.10	0.501
Immediately after surgery	2.18	2.78	0.815
6 hours after surgery	2.78	3.45	0.495

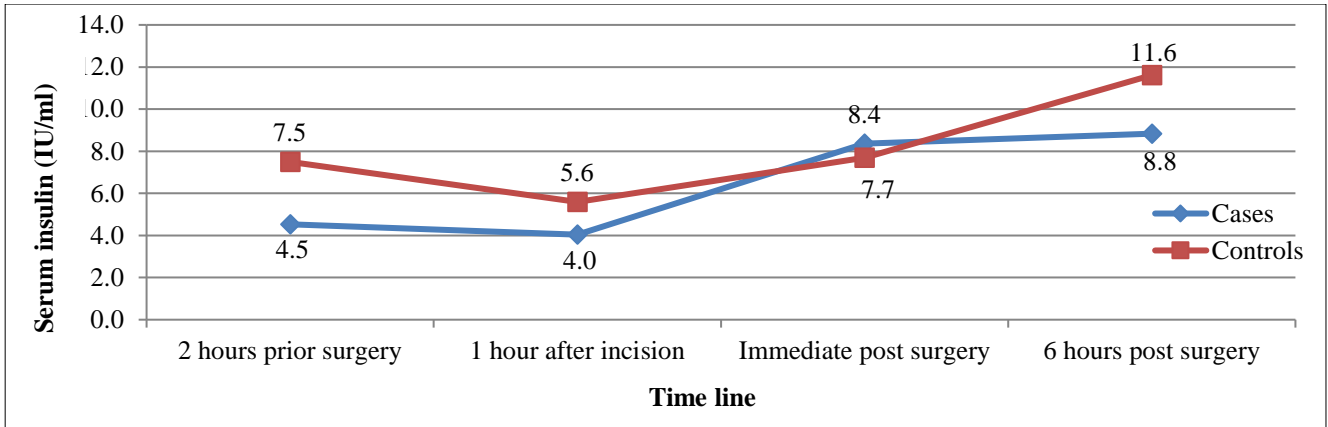


Figure 1: The trend of serum insulin (IU/ml) values in the study population at four different points of time.

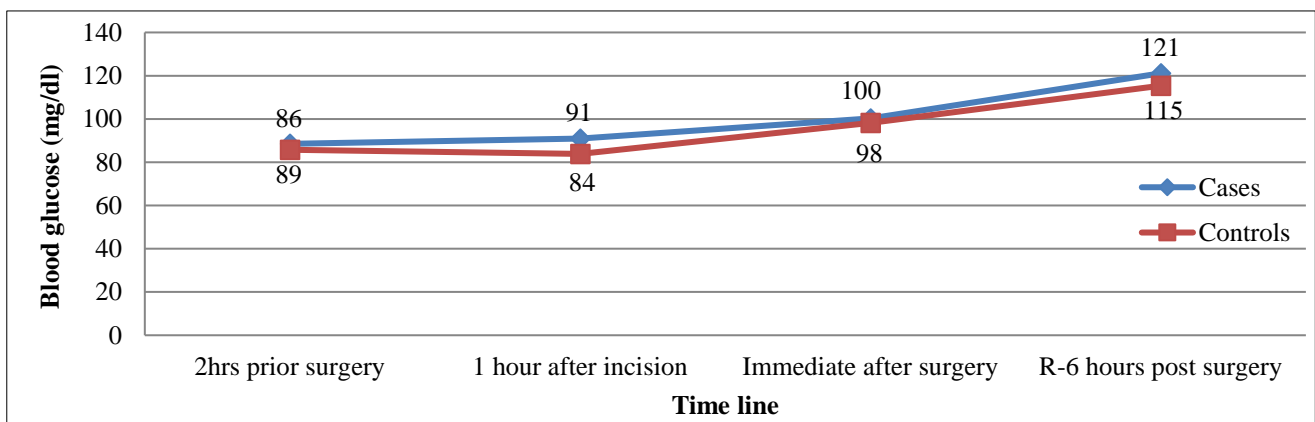


Figure 2: The trend of blood glucose (mg/dl) in the study population at four different points of time.

Table 3: Postoperative clinical outcomes in CHO and CO group following preoperative carbohydrate loading.

Postoperative day and time	CHO (n=20) (%)	CO (n=19) (%)	P value
Onset of bowel sounds			
Day 0	15 (75)	5 (26.3)	0.002
Day 1	5 (25)	14 (73.7)	
Tolerance to oral diet			
Day 0	14 (70)	2 (10.5)	0.001
Day 1	5 (25)	16 (84.2)	
Day 2	1 (5)	0	
Day 3	0	1 (5.3)	
Ambulation			
Day 1	1 (5)	1 (5.3)	0.861
Day 2	17 (85)	15 (78.9)	
Day 3	2 (10)	3 (15.8)	
Removal of urinary/epidural catheter			
Day 1	1 (5)	1 (5.3)	0.581
Day 2	19 (95)	17 (89.5)	
Day 5	0	1 (5.3)	
Length of hospital stay			
Day 2	11 (55)	10 (52.6)	0.487
Day 3	7 (35)	6 (31.6)	
Day 4	2 (10)	1 (5.3)	
Day 5	0	2 (10.5)	
Incidence of ^aPONV	2 (10)	3 (15.8)	0.589

Continued.

Postoperative day and time	CHO (n=20) (%)	C0 (n=19) (%)	P value
Incidence of fever	4 (20)	2 (10.5)	0.412
Surgical site infection			
Day 0 to day 30	0	0	

^aPost-operative nausea and vomiting

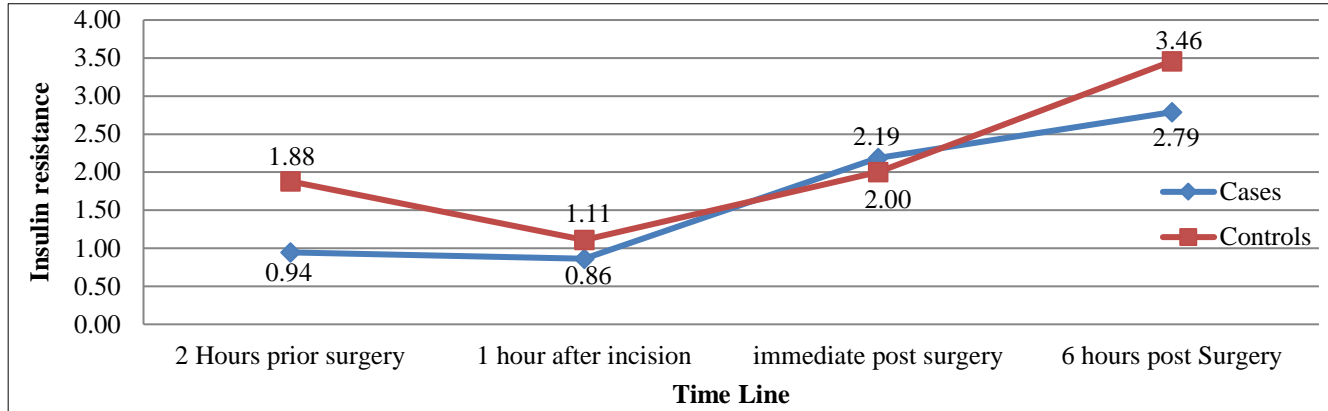


Figure 3: The trend of insulin resistance (HOMA-IR) in the study population at four different points of time.

DISCUSSION

Carbohydrate loading in ERAS has been evaluated in gynecological surgeries and various non-gynecological surgeries like major abdominal surgeries, craniotomy, colorectal, rectal/pelvic surgeries, laparoscopic cholecystectomy, urological surgeries, orthopedic surgeries, and cardiac surgeries.^{4,7-14,17} While most studies have excluded diabetes mellitus, Gustaffson has established the safety of carbohydrate loading in patients with diabetes.^{16,17}

Biochemical parameters

We observed a significant difference between the CHO and CO group in the serum insulin values two hours before surgery, as the carbohydrate loading in the CHO group would attenuate the stress response of the body when compared to overnight fasting in controls. However, there was no statistical difference in the serum insulin level measured at 1 hour after incision, immediate post-surgery, and 6 hours post-surgery. In the study by Zhang et al in gynecological patients, the serum insulin was measured at baseline, immediate post- surgery, and 24 hours after surgery.¹⁸ On comparison between the case and control groups, there were significantly lower insulin levels in the cases group. Likewise, significantly lower fasting insulin levels were demonstrated in patients with preoperative carbohydrate loading by Liu et al in craniotomy surgeries and Faria et al in laparoscopic cholecystectomy surgeries.^{9,19} On the contrary, Mathur et al and Tran et al showed no significant difference between the intervention group and the control group in insulin levels during the postoperative period.^{4,17} The levels of serum insulin in our study were concordant with the results of Onalan et al in which insulin levels were evaluated at 2 hours before surgery, 1 hour after incision, and immediate postoperative

period.²⁰ However, no statistically significant difference was observed between the case and control group.

We observed that the blood glucose levels were slightly higher in the CHO group than controls. However, there was no statistical significance, as also observed by Zhang et al and Mathur et al. Liu et al and Onalan et al found that blood glucose levels were significantly increased in the intervention group due to carbohydrate loading before surgery.^{4,9,18,20}

In our study, insulin resistance at 2 hours before surgery was higher in the control group, owing to the concept of attenuation of the catabolic state by preoperative carbohydrate loading. However, the insulin resistance measured at 1 hour after incision, immediate post- surgery, and 6 hours post-surgery did not show any difference. Zhang et al found a significant difference in the insulin resistance values in both samples taken immediately after surgery and 24 hours after surgery.¹⁸ Probably, the lesser carbohydrate loading in our study (75.6 g in the evening before surgery and 25.2 g 2 hours before surgery) has shown insignificant results when compared to Zhang et al where 100 g of carbohydrate in the evening before surgery and 50 g two hours before surgery was administered.

Conflicting results have been observed in the literature regarding the effect of carbohydrate loading on insulin resistance. Trials conducted by Onalan et al in gynecological surgeries, Mathur et al in major abdominal surgeries, Tran et al in patients undergoing coronary artery bypass/spinal surgery did not find a difference in insulin resistance with preoperative oral carbohydrate loading.^{4,17,20} On the contrary, studies by Okabayashi et al in hepatic resection, Kaska et al in colorectal resection, and Faria et al in laparoscopic cholecystectomy have demonstrated a decrease in insulin resistance after oral

carbohydrate loading.^{19,21,22} Further well-powered studies are needed to strongly correlate the effect of preoperative carbohydrates in this aspect.

Clinical parameters

Despite the development of strategies to prevent PONV, it is still a troublesome consequence in the postoperative period. Two patients (10%) in our study from the CHO group and three patients (15.7%) from the CO group developed PONV in the first 24 hours following surgery. Our results were similar to those observed by Zhang et al and Liu et al where carbohydrate loading did not reduce PONV. Hausel et al advocated that the incidence of PONV decreased significantly in the carbohydrate loading and placebo groups but not in the fasting group.^{9,18} They also found that between 12 and 24 hours after cholecystectomy, many patients in the control group experienced nausea and vomiting compared with the carbohydrate loading group. The effect of high carbohydrate content, its distinct effect on body metabolism, and its probable effect on the hypothalamic serotonin system needs further evaluation. Oral carbohydrate loading may therefore have a role in the multimodal approach to minimize PONV.

Noblet et al observed that the median time after surgery to first flatus was 3 days for both the fasted and water groups compared with 1.5 days in the carbohydrate group.¹⁰ In two trials that reviewed 86 patients, carbohydrate loading was associated with the earlier postoperative return of flatus; however, no difference was found when looking at the actual time of first bowel movement. In our study, the onset of bowel sounds/passage of flatus was achieved in the majority of participants in the CHO group (75%) on day 0 post-surgery, while on day 1 post-surgery in the CO group (73.7%). Thus, carbohydrate loading in elective gynecological surgeries helps in achieving gut function earlier than the routine practice of preoperative fasting. The majority in the CHO group (70%) achieved tolerance to oral diet on day 0, while the participants in the CO group (84%) achieved it on day 1. Oral tolerance to diet was a consequence of earlier return of bowel function in the carbohydrate loading group.

Gynecological surgeries do not involve major bowel handling. Thus, our patients were found to tolerate oral diet faster when compared to the observation by Mathur et al in major abdominal surgeries where the median time to intake of oral diet was 3 (1-33) days in the CHO group and 3 (1-31) days in the placebo group.⁴

Many studies have demonstrated the early discharge of patients receiving oral carbohydrate loading, which could be due to contributory factors like the early return of bowel function, early tolerance to oral diet, decreased postoperative nausea and vomiting, and an overall improvement in the general well-being of the patient like reduced thirst and hunger. In the study by Zhang et al, the hospital LOS was 4.36±0.78 days in the CHO group and 3.82±0.67 days in the CO group, which was statistically

significant.¹⁸ Liu et al demonstrated a significantly reduced postoperative hospital stay in the intervention group (postoperative LOS: 4 days versus 7 days).⁹ Although in the trial by Noblett et al, statistical difference was not observed, a trend towards early fitness to discharge was seen among the patients who received carbohydrate loading compared to those who were fasted.¹⁰ However, in our study population, the mean postoperative period for fitness for discharge did not differ significantly.

Hausel et al found that the mean length of hospital stay was 1.3 days, 1.2 days, and 1.2 days in the fasting, placebo, and carbohydrate groups, respectively.¹² Likewise, the median length of hospital stay was 7 days in the CHO group and 8 days in the placebo group in the study by Mathur et al.⁴

The actual postoperative discharge of patients depends on multiple aspects related to surgeon decision, social and rehabilitation causes, and postoperative complications. The mean time for postoperative discharge in our study was 3.65 days in the CHO and 3.73 days in CO groups, respectively, with no significant statistical difference. In our study, there was no delay in discharge of 28.2% of patients as the fitness for discharge and the actual day of discharge was the same. In 38.5% of participants, the reason for the delay of discharge was based on the surgeon's decision, while 7.7% of participants due to patient-related factors and 5 participants owing to postoperative complications. The reason for the delay of discharge, if addressed vigorously, can lead to early discharge, which is of benefit to the patient and may also help current pressures on the availability of hospital beds. The literature regarding the effect of preoperative carbohydrate loading on the length of hospital stay is conflicting, with some studies demonstrating a reduction and others showing no difference. Reasons for these inconsistencies include smaller sample sizes and heterogeneity of surgical procedures of differing magnitudes. Nevertheless, it may also be difficult to demonstrate absolute benefit from a single intervention within an ERAS protocol where multidisciplinary and multimodal interventions may together improve the postoperative recovery.

In our study, none of the participants in the CHO and CO group developed surgical site infection. Our result has been in concordance with the observation done by Alimena et al, Gionetti et al, Liu et al, and Mathur et al.^{4,9,23,24} Hence, we can substantiate that carbohydrate loading before elective surgeries does not increase the incidence of surgical site infection.

The strengths of our study include the inclusion of gynecologic patients, which have not been addressed in many studies. We also included a follow-up of our patients to address postoperative infections. However, as the study was conducted during the period of the COVID-19 pandemic, the sample size was attenuated. The majority of the participants who were operated on had a diagnosis of

gynecological malignancy, and thus the early discharge in patients might have not been possible. Our population did not include diabetics, and hence the safety and efficacy of carbohydrate loading in them remains unclear and is a scope for future research.

CONCLUSION

Preoperative oral carbohydrate loading in elective gynecological surgeries attenuates insulin resistance and contributes to an earlier return of bowel activity and tolerance to oral diet when compared to traditional preoperative fasting. The administration of an oral carbohydrate drink is safe and does not increase the risk of surgical site infection in the postoperative period.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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