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# THE EFFECT OF PREOPERATIVE ORAL CARBOHYDRATE SOLUTION INTAKE ON PATIENT COMFORT: A RANDOMIZED CONTROL STUDY

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**ABSTRACT** Surgical patients are required to fast before anaesthesia and surgery with the goal of reducing the gastric volume and acidity, so as to reduce the risk of regurgitation and aspiration of gastric contents during the procedure. American Society of Anaesthesiologists (ASA) developed guidelines that support a more liberal preoperative fasting protocol to ensure perioperative safety from the classically dreaded Mendelson syndrome8. The traditional long duration fasting periods are being reviewed and researched presently as it has become evident that prolonged periods of fasting may cause complications such as distress, confusion, hypoglycaemia, headache, dehydration, electrolyte imbalance, postoperative nausea and vomiting (PONV), and increased insulin resistance. Various studies have shown that if the 6 hour fasting state is changed into a carbohydrate fed state before the onset of the surgery, several further benefits may be achieved. The most widely known clinical metabolic disturbance is elevated blood sugar which occurs during anaesthesia. A clear carbohydrate (CHO) drink intake instead of a fasting period is expected to decrease insulin resistance and reduce postoperative hyperglycemia. In today's era of evidence-based medicine, there are no scientific reasons to keep a patient in prolonged preoperative fasting.

**KEYWORDS :** Preoperative fasting, Insulin resistance, Gastric volume, Patient comfort, Blood sugar

## BACKGROUND

The pioneers of anaesthesia realized that there was a risk of vomiting and aspiration if the stomach was full at the time of anaesthesia.[1] More extended periods of overnight fasting before surgery have been reported to cause stress, dehydration, anxiety, uneasiness, hunger, thirst, dry mouth, fatigue and headache in the patients[2,3,4] Guidelines related to fasting periods have recently been changed and it is now recommended that patients can drink clear fluids up until 2-3 hours before surgery and anaesthesia.[5] The driving force behind this study is that drinking reduces the discomfort of thirst during preoperative hours. Fasting for a long time before surgery can cause adverse effects such as a sense of thirst, dry mouth, hunger and tiredness. Under normal unstressed conditions, a carbohydrate load causes a prompt release of insulin which in turn activates a series of metabolic reactions like reduction in endogenous glucose release, activation of glucose release, activation of glucose transport systems in insulin-sensitive tissues and activation of enzymes allowing storing excess glucose as glycogen. If, however, the same load of carbohydrates is given once a stress reaction is ongoing, the metabolic effect of insulin is all hampered by the influence of catecholamines, glucocorticoids, glucagon and growth hormone, all of these oppose the action of insulin. This forms the basis of stress-induced insulin resistance.[6] Postoperative hyperglycemia is a risk factor for many postoperative complications and a longer period of preoperative fasting further aggravates the complications. A clear carbohydrate (CHO) drink intake instead of a prolonged fasting period is expected to decrease insulin resistance and reduce postoperative hyperglycemia. Preoperative carbohydrate loading causes secretion of insulin, which will result in high levels of free insulin-like growth factor 1.[7] This help to explain why metabolism is much less catabolic in the postoperative period in patients given preoperative carbohydrates instead of undergoing an overnight period of fasting[5]. The reason for preoperative midnight fasting (at least 6 hours fasting) is to reduce the volume and acidity of stomach contents, thus decreasing the risk of aspiration.[8] In today's era of evidence-based medicine, there are no scientific reasons to keep a patient in prolonged preoperative fasting.[5,8] There is less evidence to suggest a shortened fluid fasting results in an increased risk of aspiration. However, it is important to clarify that fasting for solids 6-8 hours before an elective operation is mandatory.

Though clear fluids are being recommended but choice of fluid is still in question. Simplest, safest and most used is water but whether it's benefits are equivalent to carbohydrate rich fluid or not is still being researched. Also side effects profile and evidence based objective (USG guided) assessment of gastric volume post administration of both these fluids are still in question. We initiated this study of viewing the effect of the oral carbohydrate loading on the patients comfort with the view of getting close to answering these questions with regard to choice of fluid to be given in the stipulated conventional "fasting period" as well as its relation to gastric volume.

## MATERIALS AND METHODS

After receiving the approval of the research and ethics committee and written informed consent obtained from the patients, the proposed study was carried out in a controlled prospective randomized manner in laparoscopic cholecystectomy cases at IGMC, Shimla (CTRI/ 2020/ 09/ 036398). The patients were assigned to their respective groups using random allocation software. ASA 1 patients of either gender between the age group 18-60 years and with BMI 18.5-24.9 were taken in the study. Only surgeries lasting less than 60 minutes were taken into consideration. Pregnant patients and patients with a history of delayed gastric emptying, gastrointestinal obstruction, liver cirrhosis, diabetic mellitus, hypertension, severe hepatic or renal failure, thyroid disorders, Cushing's or adrenal insufficiencies were excluded from the study. Written informed consent was obtained from all eligible patients before recording data.

### Sample Size

Based on a prior similar study[9], a sample size of 69 was calculated on the assumption of power as 80% and alpha error as 0.01. So, a sample size of 90 patients was decided and divided into 3 groups of 30 patients each.

**Product:** Clear Apple juice (containing 15gm carbohydrate and 100 calories per 100ml).
**Blood Sugar Measurements:** Blood sugar was measured by an automatic blood glucose meter (ACCUCHEK).
**Gastric Volume Measurements:** Gastric volume (GV) was assessed using Sonosite Fujifilm ultrasound and calculation was made by using the formula, GV (ml)=27+14.6 X right-lateral CSA-1.28 X age where CSA is cross-sectional area
**Anaesthetic Protocol:** The patients posted for laparoscopic cholecystectomy were randomly allocated into three groups as follows:
Group 1- Patients fasted as per the department protocol of atleast 6 hours of fasting. No intervention was undertaken.
Group 2- (water). These patients received 200ml of water approximately 3 hours before surgery.
Group 3- (a carbohydrate-rich drink). These patients received an oral carbohydrate solution (clear apple juice - 100kcal per 100ml) 200 ml approximately 2 hours before surgery.

### Departmental Protocol

All the patients underwent routine pre-anaesthetic check-ups. During this, a thorough history and general physical examination of the patient was carried out. Routine investigations were done and informed consent was taken from the patient after a detailed explanation of the study. Patients were given premedication with etizolam 0.5 mg at night. All patients were instructed for a fasting period of atleast 6 hours as per departmental protocol. Patients falling under group 2 or 3 received randomly allocated drinks 2 hours before surgery. All the patients participating in the study received anaesthesia and perioperative care. Gastric volume was measured just before general anaesthesia. General anaesthesia was given as per the departmental protocol and according to the anaesthetist in charge of the operation theatre. Care was taken to avoid any drug which can affect blood sugar levels such as ketamine and dextrose. During surgery, Ringer Lactate was given to all the patients until adequate oral intake was achieved by the patients. Study interventions were undertaken according to the randomized group.

### Data Collection

Patients were asked on the morning of planned surgery to rate the following parameters pre-intervention and 5 minutes before induction: 1. hunger, 2. thirst, 3. mouth dryness, 4. weakness, and headache.

All these parameters were rated on a 3-point scale (EDESP Perioperative discomfort scale) of: not bothered (0), slightly bothered (1) and very bothered (2).

Gastric volume was measured preoperatively before induction.

Blood Glucose was checked 5 minutes before induction, 15 minutes after induction, 2 hours after induction.

Need to initiate dextrose solution: if blood sugar level was found to be less than 80 mg/dl, dextrose was initiated and these patients will be excluded from the study. Patients were monitored for any complications. The data of the study was recorded in the record chart and the results were evaluated using appropriate statistical tests as applicable.

## RESULTS

On comparing our results among the three groups, we found that there was significant difference in the blood sugar on comparing overnight fasting group and the carbohydrate solution group and also among water group and carbohydrate solution group. No significant difference was seen between overnight fasting group and water group. On comparing patients comfort between the three groups, we found that hunger, thirst, dry mouth, headache and weakness was mostly complained by over night fasting group and least by oral carbohydrate solution group. On comparing gastric volume between the three group, significant difference was seen between over night fasting group and least by oral carbohydrate solution group.

**Table 1:-comparison Of Blood Sugar (mg/dl) Between Group 1, 2 And 3.**

| | Group 1 (n=30) | Group 2 (n=30) | Group 3 (n=30) | Total | P value |
|---|---|---|---|---|---|
| Pre-operative | | | | | |
| Mean ± SD | 100 ± 9.58 | 105.4 ± 8.94 | 103.2 ± 9.21 | 102.9 ± 9.1 | 0.06‡ 1 vs 2:0.065 1 vs 3:0.054 2 vs 3:0.085 |
| Median (25th-75th percentile) | 101.5 (94.25-105.5) | 105 (98.25-111.75) | 105 (100-109) | 104.5 (99.25-111.75) | |
| Range | 84-118 | 89-119 | 85-122 | 84-122 | |
| 5 minutes after induction | | | | | |
| Mean ± SD | 121.83 ± 8.41 | 123.63 ± 7.58 | 121.33 ± 6.09 | 122.27 ± 7.4 | 0.454‡ 1 vs 2:0.35 1 vs 3:0.795 2 vs 3:0.233 |
| Median (25th-75th percentile) | 121.5 (116.25-127) | 125 (119-128.75) | 121 (118-126.75) | 121.5 (118-128) | |
| Range | 104-142 | 104-140 | 108-131 | 104-142 | |
| 2 hours after induction | | | | | |
| Mean ± SD | 135.03 ± 7.57 | 135.3 ± 7.13 | 128.43 ± 6.63 | 132.92 ± 7.73 | 0.0003‡ 1 vs 2:0.885 1 vs 3:0.0005 2 vs 3:0.0003 |
| Median (25th-75th percentile) | 134.5 (129-140.5) | 137 (129-139) | 128 (125.25-131.75) | 131.5 (127.25-138.75) | |
| Range | 123-148 | 121-149 | 115-139 | 115-149 | |

‡ ANOVA

**Table 2:-comparison Of Pre-intervention Patient's Comfort Between Group 1, 2 And 3.**

| Pre-intervention patient's comfort | Group 1 (n=30) | Group 2 (n=30) | Group 3 (n=30) | Total | P value |
|---|---|---|---|---|---|
| Hunger | 10 (33.33%) | 6 (20%) | 10 (33.33%) | 33 (36.67%) | 1 vs 2:0.243† 1 vs 3:1† 2 vs 3:0.243† |
| Thirst | 19 (63.33%) | 19 (63.33%) | 15 (50%) | 56 (62.22%) | 1 vs 2:1† 1 vs 3:0.297† 2 vs 3:0.297† |
| Headache | 14 (46.67%) | 12 (40%) | 9 (30%) | 35 (38.89%) | 1 vs 2:0.602† 1 vs 3:0.184† 2 vs 3:0.417† |
| Dry mouth | 13 (43.33%) | 11 (36.67%) | 11 (36.67%) | 35 (38.89%) | 1 vs 2:0.598† 1 vs 3:0.598† 2 vs 3:1† |
| Weakness | 4 (13.33%) | 6 (20%) | 4 (13.33%) | 23 (25.56%) | 1 vs 2:0.731† 1 vs 3:1* 2 vs 3:0.731* |

* Fisher's exact test, † Chi square test

**Table 3:-comparison Of Post-intervention Patient's Comfort Between Group 1, 2 And 3.**

| Post-intervention patient's comfort | Group 1 (n=30) | Group 2 (n=30) | Group 3 (n=30) | Total | P value |
|---|---|---|---|---|---|
| Hunger | 10 (33.33%) | 5 (16.67%) | 3 (10%) | 25 (27.78%) | <.0001† 1 vs 2:0.001† 1 vs 3:0.0003* 2 vs 3:0.706* |
| Thirst | 19 (63.33%) | 2 (6.67%) | 2 (6.67%) | 26 (28.89%) | <.0001† 1 vs 2:<.0001* 1 vs 3:<.0001* 2 vs 3:1* |
| Headache | 14 (46.67%) | 4 (13.33%) | 3 (10%) | 21 (23.33%) | 0.001† 1 vs 2:0.01* 1 vs 3:0.003* 2 vs 3:1* |
| Dry mouth | 13 (43.33%) | 1 (3.33%) | 0 (0%) | 14 (15.56%) | <.0001* 1 vs 2:0.0004* 1 vs 3:<.0001* 2 vs 3:1* |
| Weakness | 4 (13.33%) | 2 (6.67%) | 0 (0%) | 15 (16.67%) | <.0001† 1 vs 2:0.002* 1 vs 3:<.0001* 2 vs 3:0.492* |

* Fisher's exact test, † Chi square test

**Table 4:-comparison Of Gastric Volume (ml) Between Group 1, 2 And 3.**

| Gastric volume (mL) | Group 1 (n=30) | Group 2 (n=30) | Group 3 (n=30) | Total | P value |
|---|---|---|---|---|---|
| Mean ± SD | 19.39 ± 5.74 | 17.25 ± 5.58 | 15.21 ± 5.15 | 17.28 ± 5.7 | 0.016‡ 1 vs 2:0.134 1 vs 3:0.004 2 vs 3:0.154 |
| Median (25th-75th percentile) | 19.4 (16-24.55) | 16.1 (13.05-20.05) | 14.75 (11.725-17.95) | 16.3 (12.825-21.425) | |
| Range | 8-28 | 10-29 | 6-27.6 | 6-29 | |

‡ anova

## DISCUSSION

According to the American Society of Anaesthesiologists (ASA) preoperative fasting is a prescribed period of time before any surgical procedure when patients are not allowed the oral intake of liquids or solids. American Society of Anaesthesiologists (ASA) developed guidelines that support more liberal preoperative fasting protocol. Prolonged periods of fasting may cause complications such as distress, confusion, hypoglycaemia, headache, dehydration, electrolyte imbalance, postoperative nausea and vomiting (PONV), and increased insulin resistance.[10] The stress response to surgery is characterized by increased secretion of pituitary hormones and activation of the sympathetic nervous system.[11] The ultimate effect of these various endocrine changes is increased catabolic activity by increased secretion of catabolic hormones like cortisol and glucagon. The effect of these endocrine and metabolic changes ultimately leads to increased gluconeogenesis and hyperglycaemia. So this stress response may be quantified by the incidence of hyperglycemia.[12]

In our study, pre-intervention blood sugar was comparable in all three groups, and non-significant variation ( p value> 0.05) was noted. Even at 5 minutes after induction, blood sugar levels were comparable with non-significant variation (p-value >0.05). However, after 2 hours of induction, significant variation was noted in blood sugar in comparison among group one and group three and also group two and group three. Although group one and group two showed no significant variation in blood sugar levels. A similar study by Emine et al.[13] concluded that preoperative carbohydrate therapy might reduce endogenous glucose release during the post-operative period. In our study, although a significant rise in the blood sugar was noted in all the three groups in the perioperative period, this rise was less in the clear oral carbohydrate solution group when compared to the fasting group and water group, indicating better sugar control probably because of better insulin sensitivity and glucose metabolism. Widnyana et al[14], in their study found that the mean blood sugar level was higher in the over night fasting group than in the sugar solution group and the mineral water group, and the mean sugar level between the sugar solution group and the mineral water group was not statistically significant. All these results are similar to what we have found in our study.

In our study, in the pre-intervention phase in all the three groups, the comparison of parameters of patients comfort was not statistically significant (p-value >0.05). Post-intervention statistically significant difference was seen between group 1 vs group 2 and group 1 vs group 3 in hunger, and no significant difference in hunger was seen between group 2 vs 3. On comparing thirst, a statistically significant difference was seen between group 1 vs two and group 1 vs 3, but no difference was seen between 2 vs 3. On comparing headaches, a significant difference was seen between group 1 vs two and group 1 vs 3, but no difference was seen between groups 2 and 3. On comparing dry mouth, a statistically significant difference was seen between group 1 vs 2 and group 1 vs 3 but no difference between group 2 vs 3. Similarly, on comparing weakness, a statistically significant difference was seen between group 1vs 2 and group 1 vs 3 but no difference between group 2 vs 3. This implies that post-intervention, both group 2 and group 3 patients had better comfort than group 1 patients. Also, group 2 and group 3, were not have statistically significant differences in terms of comfort. This suggests clear fluid (water or oral carbohydrate solution) provides better patient comfort when given 2 hours before surgery. Similarly Zhong et al.[15] in their study used VAS (visual analog scale) to evaluate the subjective discomfort. As measured by VAS at baseline, subjective feelings of thirst, hunger, anxiety, and fatigue were similar between carbohydrate solution and water groups. One hour after intake, levels of thirst and hunger had significantly decreased in both groups. A similar effect was seen in our study, where in both groups' thirst significantly decreased. Hunger was decreased in both groups, but the p-value was not significant. However, in their study, carbohydrate-rich liquid or water ingestion did not affect anxiety or fatigue. In our study, weakness and headache were reduced in both groups, but a significant reduction in headache was seen only in the water group. In the study by Allan et al.[13] patients were randomly divided into an oral carbohydrate solution (OCS) group and overnight fasting group. Patient well-being, hunger, thirst, pain, and anxiety were assessed using VAS (Visual Analog Scales) scores. The carbohydrate preparation led to significant reductions in hunger, thirst, anxiety, and pain. So the significant differences in the patient comfort (hunger,

thirst, anxiety and pain) between the two groups were similar to the results of our study. In contrast to our finding, in the study by Reddy et al.[17], the well-being of patients in the pre and post-operative period was assessed using visual analogue scores (VAS) for pain, thirst and hunger. They found a significant decrease in the VAS scores of hunger, thirst and pain in the study group. Whereas in our study, no significant difference was seen between the water group and clear carbohydrate solution group, the difference might be different objective parameters used in studies (VAS vs EDESP discomfort scale).
In our study, mean gastric volume in group 1(fasting), group 2 (water) and group 3 (oral carbohydrate) were measured and lower values of mean gastric volume were found in group 2 and group 3, but statistically, a significant difference was found only between group 1 and group 3. Similar effects were seen in the study by Zhong et al.[15]. Their findings suggest that in the carbohydrate beverage group and pure water group, none of the patients had GV (gastric volume) >1.5 mL/kg before induction of anaesthesia, which is considered to predict a high risk for aspiration. This was similar to our finding, none of our patients had gastric volume more than 1.5ml/kg. Also, patients given the carbohydrate beverage had a similar rate of gastric emptying to those given pure water, with no instance of regurgitation or aspiration in either group. These findings suggested that oral intake of 200 mL carbohydrate beverage 2 hr before ambulatory surgery is safe. Interestingly, in some patients, cross-sectional area (CSA) was much lower at T3 (2 hours after intake) than it was at T0 (baseline before intake). This is because clear fluid may accelerate gastric emptying and reduce CSA.

In the study by Yagci et al.[19],the volume and pH of preoperative residual gastric contents were measured and no statistical difference between the carbohydrate group and fasting group with respect to gastric residue contents or gastric fluid pH. The preoperative intake of carbohydrate-rich fluids did not appear to alter the amount of pH of gastric contents, and they suggested that this is a safe procedure in terms of aspiration risk. In contrast, there is a statistically significant difference between the fasting group and oral carbohydrate solution group in our study, but mean gastric volume was found to be lower in group 3, suggesting its use safely in terms of aspiration risk.

This study shows that giving clear carbohydrate solution 2 hours before surgery, rather than keeping patients fasting for 6 hours, provides better patient comfort and reduces gastric volume, probably by accelerating gastric emptying. When we compared clear oral carbohydrate solutions with water, we found that although there was no significant difference among the two concerning hunger, thirst, weakness, dry mouth and headache, all the parameters were better in the clear oral carbohydrate solution group. Also, clear oral carbohydrate solutions provide better sugar control. Our findings are in accordance with European guidelines, which have shifted from "allow" to "encourage" fluids till 2 hours prior to surgery. In ERAS protocols, only 2 hours fasting prior to surgery protocols are implemented due to better patient satisfaction and better glucose control.[20] All this is in line with our finding of improved patient well-being if the fasting period is reduced to 2 hours. In our study, either water or sugar 2 hours prior to surgery had significantly improved the patient's perioperative experience compared to prolonged fasting. Moreover, this happens without any other significant side effects. Literature does not demarcate the best between sugar and water, and we also found them almost the same. Further research with a larger database is needed to evaluate this confounding result.

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