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"COMPARISON OF THE EFFECT OF CHEWING GUM AND HONEY ON POSTOPERATIVE RECOVERY AND COMPLICATIONS IN ILEOSTOMY REVERSAL"

BY

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INTRODUCTION

Ileostomy reversal is associated with postoperative morbidities, such as postoperative intestinal obstruction, wound infection, anastomotic leakage (AL), intestinal perforation and peritonitis. Another common clinical manifestation is postoperative functional ileus causing delayed gastrointestinal function recovery GIFR (1,2). Delayed GIFR raises the risk of intestinal blockage and dysregulation of the gastrointestinal flora and can cause gas and effusion to build up in the lumen of the gastrointestinal tract. Delay in flatus or defecation, abdominal pain, distension, nausea, vomiting, and postoperative intestinal blockage, which often requires nasogastric tube intubation, are the primary clinical manifestations of delayed GIFR (3).

Postoperative care has always been oriented around adequate nutrition (4). The Enhanced Recovery After Surgery (ERAS) program recommends shorter periods of starvation in adults both before and after surgery (5,6). By using this method, anastomotic leaks are avoided, and the bowel anastomosis is allowed to heal. Early postoperative enteral feeding not only lowers postoperative morbidity and mortality, but may also shorten the duration of postoperative ileus and length of stay after surgery (2,7). The surgical technique utilized, the use of analgesics, the existence of an underlying condition, and the type of postoperative care given are factors connected to postoperative ileus following colon resection (8).

Sham feeding is the practice of stimulating gastrointestinal peristalsis without actually ingesting any food into the digestive system (9). Chewing gum is used in postoperative sham feeding to encourage the return of gastrointestinal peristalsis. The physiologic theory that underlies chewing gum with regards to promoting peristalsis and shortening the time to postoperative intestinal recovery includes the idea that oral and masticatory stimulation provided by gum chewing sufficiently simulates food ingestion to stimulate a neurohumoral reflex that increases gastrointestinal fluid secretion. In addition, the vagus nerve, which is involved in promoting peristalsis, may be stimulated by oral stimulation and chewing (10). According to studies, chewing gum reduces the risk of postoperative ileus and shortens the time it takes for the first postoperative flatus and defecation (9–14). By contrast, some studies of patients undergoing surgery have indicated that chewing gum has not been found to significantly reduce average hospital stay days, shorten the onset of the first postoperative flatus and feces, or prevent postoperative nausea, vomiting, or bloating in studies of patients undergoing surgery (10).

Numerous studies have proven that honey has protective properties for the gastrointestinal system. The gut microbiota after honey ingestion showed changes in lactic acid bacteria, which may suggest that honey has a role in regulating gut microbiota (15–17). Honey taken orally guards against gastrointestinal infections such as gastritis, duodenitis, and gastric ulceration brought on by bacteria and rotavirus (18). Oral honey and water administration can reduce the incidence and severity of postoperative nausea and vomiting (19,20). Preoperative intake of honey drink results in significantly less wound infections (21). Literature search could not find any previous study about the postoperative use of honey in stoma reversal or intestinal anastomosis patients. However, studies done in rats showed a statistically significant increase in tensile strength of colon anastomosis, decrease in peritoneal adhesion and improved wound

healing (22–25). Human clinical trials need to be performed to better understand the effect of honey intake following intestinal surgery.

The current practice in stoma reversal and intestinal anastomosis patients in the surgical department of Mayo Hospital Lahore is to allow early water sips, chewing gum and honey intake from the 1st or 2nd postoperative day onwards and to allow full soft oral feeds after the passage of flatus or stool and bowel sounds on auscultation, usually on the 3rd or 4th postoperative day. This practice has yielded apparent improvements in postoperative outcomes, but no research or clinical trials have been performed yet to prove significant differences in results.

Previous literature is deficient in directly comparing chewing gum and honey as effective and cost-effective methods to alleviate or prevent postoperative complications following ileostomy reversal and to improve patient recovery. To fully understand their role in the restoration of intestinal function following surgery, more RCTs are necessary (11).

RATIONALE

The rationale of this study is to investigate and identify interventions that can positively impact the postoperative outcomes of patients undergoing ileostomy reversal. After ileostomy reversal, patients may experience complications such as postoperative ileus, delayed bowel function, or anastomotic leakage. Exploring interventions such as chewing gum and honey could help find simple and cost-effective methods to mitigate these postoperative complications. Previous studies have hinted at the potential benefits of interventions like chewing gum or honey in improving postoperative recovery in various surgical procedures (7,10,29,30,11,14–16,20,26–28).

Previous literature is deficient in exploring the role of honey intake in gastrointestinal surgery and specifically ileostomy reversal, so honey is being investigated in our study to bring novelty and uniqueness to the topic. Although it is a common practice to start early oral intake of honey before starting full feeds in our clinical setup, there is deficiency of literature to prove its efficacy in improving postoperative recovery and reducing complications. This study aims to specifically evaluate the efficacy of honey and chewing gum in the context of ileostomy reversal. Identifying interventions to shorten hospital stays, lower the frequency of complications, or enhance patient recovery may have an impact to maximize the effectiveness and economy of healthcare resources.

OBJECTIVE

To compare the effect of chewing gum and honey on postoperative recovery and complications in ileostomy reversal (as mentioned below).

OPERATIONAL DEFINITIONS

1. **Early enteral nutrition:** Defined as oral intake started on the first postoperative day. In contrast, the traditional way of normal enteral nutrition is nothing by mouth until the resolution of ileus, then a fluid diet, followed by a regular diet (27).

2. **Ileostomy reversal:** When the ileum previously used to form the stoma i.e. Loop Ileostomy, Double Barrel Ileostomy, Ileocolostomy or End Ileostomy is reconnected to the remainder of the bowel internally (31).

3. **Postoperative recovery and complications:**
    - **Time to bowel sounds:** Defined as the time, in hours, between the completion of surgical closure and the first audible auscultation of non-continuous, high-pitched bowel sounds originating from the reconnected intestine, documented by a trained healthcare professional using a stethoscope placed over the lower quadrants of the abdomen (32,33).
    - **Time to pass flatus:** Defined as the time, in hours, between the completion of surgery and the documented passage of the first objectively confirmed flatus by auscultation or direct observation (33).
    - **Time to pass feces:** Defined as the time, in hours, between the completion of surgery and the documented first independent bowel movement, excluding any stool manually evacuated or stimulated by laxatives (33).
    - **Time to full feeds:** Defined as the time, in hours, between the surgery and the first point at which the patient tolerates and consumes a regular, unrestricted diet without experiencing any significant postoperative gastrointestinal complications (e.g., nausea, vomiting, abdominal pain, ileus) for a predetermined timeframe (i.e., 24 hours) (7,26)
    - **Postoperative pain:** Postoperative pain in stoma reversal surgery was defined as the subjective pain intensity experienced by the patient at rest or during movement, assessed using the Visual Analog Scale (VAS). The VAS consists of a 10 cm horizontal line anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 10), with patients marking the point on the line that best represented their pain intensity (4).
    - **Postoperative ileus:** Postoperative ileus is an abnormal pattern of slow or absent gastrointestinal motility in response to surgical procedures. It is measured as the absence of flatus/stool and inability to tolerate an oral diet within 3 days after surgery (34) (35).
    - **Postoperative nausea and vomiting (PONV):** PONV is defined as documented postoperative nausea/emesis or administration of a rescue antiemetic (36).
    - **Length of postoperative stay:** Defined as the time, in hours, from completion of reversal surgery to the time of discharge from the hospital (14).

HYPOTHESIS

There is a significant difference in the effect of chewing gum and honey on postoperative recovery and complications in ileostomy reversal.

MATERIALS AND METHODS

METHODS

Trial Design: Prospective single-blinded randomized controlled trial. Parallel design with allocation ratio 1:1 will be used. This manuscript is a protocol for the pilot RCT.

Participants: Patients presenting to the outdoor and ward of West Surgical Department with an Ileostomy and undergoing Ileostomy reversal surgery in the operation theatre.

Study Setting and Location: Male and Female Ward, West Surgical Department, Mayo Hospital, Lahore

Sample Size:

Due to deficiency of literature about the use of honey in gastrointestinal surgery and specifically intestinal anastomosis, it was decided that pretesting with a pilot study would be conducted to calculate the sample size. The overall sample size of 30 participants for the pilot trial was selected according to the Rule of Thumb for pilot trial sample size calculation. 15 participants in each group, i.e. Group A for chewing gum and Group B for honey, were allocated randomly using the lottery method. The primary outcome variable was time to pass flatus. The results of the pilot trial for the primary outcome variable showed that the mean time to pass flatus in Group A was 67.73 ± 8.481 hours and Group B was 75.73 ± 9.968 hours.

Outcome Variable	Group A		Group B		Population SD (σ)	Sample Size (n)
	Mean	SD	Mean	SD		
Bowel sounds	51.20	9.937	59.20	8.970	9.466	31
Time to pass flatus	67.73	8.481	75.73	9.968	9.254	29
Time to pass stools	100.80	11.632	119.47	12.994	12.332	10
Time for full feeds	79.47	10.239	93.33	11.178	10.719	13

The means and standard deviations of the pilot trial data was used to calculate the sample size using WHO Sample Size Calculator using the formula for hypothesis tests for two population means (one-sided test) as follows:

$$n = \frac{2\sigma^2 (z_{1-\alpha} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Where,
n = Sample size = 60
σ = Population standard deviation = 9.2245
σ^2 = Variance = 85.0914

$Z_{1-\alpha}$ = Confidence level 95% = 1.96
$Z_{1-\beta}$ = Power of test = 95%
μ_1 = Population mean Group A = 67.73
μ_2 = Population mean Group B = 75.73

A total sample size of 60 patients (30 patients in each group) is estimated by using 5% level of significance and 95% power of test with expected mean value time to pass flatus in Group A (Chewing Gum) as was 67.73 ± 8.481 hours and Group B (Honey) as 75.73 ± 9.968 hours in the pilot study.

Sampling Technique: Non-probability purposive sampling. Patients admitted to the hospital for stoma reversal procedure will be assigned into Group A or B using a lottery method, ensuring that the sample population is divided into the two groups equally and randomly regardless of their characteristics (33).

Sample Selection:

Inclusion Criteria:

- All patients of age more than 18 years with an Ileostomy
- Undergoing surgery involving reversal of an Ileostomy i.e., Loop Ileostomy, Double Barrel Ileostomy, Ileocolostomy or End Ileostomy
- Time from fashioning of ileostomy to its reversal is of a duration greater than 1 month

Exclusion Criteria:

- Patients with existing complications as mentioned above in the operative definition of postoperative complications
- Patients with malignancy
- Patients with inflammatory bowel disease
- Patients who cannot communicate well
- Patients who have difficulty chewing or swallowing
- Patients who are prohibited from oral intake by the surgeon
- Patients having undergone Ileostomy reversal more than 1 day before being included in the study

Outcome Measures:

- Primary Outcome
    - Time to pass flatus
- Co-primary Outcomes
    - Time to bowel sounds
    - Time to pass feces
- Secondary Outcomes

- Time to full feeds
- Postoperative pain
- Postoperative nausea and vomiting
- Length of postoperative stay /Time to discharge

Data Collection Procedure:

After the approval to carry out this study from the Research Evaluation Unit (REU) College of Physicians and Surgeons Pakistan and the Institutional Review Board (IRB) King Edward Medical University, subjects meeting the operational definitions and the inclusion & exclusion criteria will be enrolled in the study after informed consent.

Randomization:

Allocation: Patients will be randomly allocated in group A or B: A for the Oral Chewing Gum group and B for the Oral Honey group using the lottery method by the principal investigator.

Sequence Generation: The lottery method is a simple form of simple randomization used to assign participants into the two groups in a way that ensures unbiased allocation. Each participant will be assigned a case number from 1 onwards based on their induction into the study by the principal investigator. 30 identical paper slips will be made and Group A will be written in 15 slips and Group B will be written on the other 15 slips. The slips will be folded to conceal the written text. The slips will be mixed thoroughly and drawn randomly, and the participants will be assigned to a group based on the identifier on the slip, i.e. either Group A (chewing gum) or Group B (honey).

Concealment: The identifier "Group A" or "Group B" will be written on identical slips of paper and the slips will be folded to conceal the written text, ensuring blinding by making them indistinguishable.

Implementation:

The random allocation will be done by the principal investigator. The participants presenting to the out-patient clinic for ileostomy reversal will be admitted to the ward and enrolled into the study after fulfilling the inclusion criteria and passing the exclusion criteria by the principal investigator.

After a period of 24 hours from the ileostomy reversal surgery, the patients will be asked to start early water sips intake according to the ERAS protocol (6). Group A patients will be asked to chew gum for 5 minutes every 4 hours. Group B patients will be asked to eat one half tablespoon of natural honey every 4 hours. The outcome parameters will be assessed and

documented every 8 hours in the case report form by the doctor on duty in the ward. As the data collection schedule will be 8 hourly, the doctor on duty in the ward for each day will be responsible for data collection. The doctors on duty in the ward will be trained by the principal investigator about the data collection procedure. The bowel sounds will be auscultated using a stethoscope placed on the right iliac fossa of the patient's abdomen. The patients will be questioned about whether they have passed flatus and feces and at what time they did so. The patients will be questioned about their last time taking full feeds, nausea, vomiting episodes. A visual analog scale for pain will be used to assess the pain score from 0 to 10 i.e. from no pain to the worst possible pain, subjective to each patient. The postoperative antibiotic, IV fluid, analgesic and PPI regimen will be standardized across the study participants. Relevant investigations to confirm the presence of complications will be carried out. All this information will be recorded in the case report form (attached).

Blinding: Selection bias will be addressed by randomly assigning the participants to the groups. Performance bias could not be eliminated due to different surgeons performing the ileostomy reversal surgery. Detection bias will be addressed by keeping the participants unaware of what group they are assigned to and because of the objective nature of the outcome variables. There will still be some detection bias in some respects involving the subjective opinion of the participants e.g. pain score. Intention-to-treat analysis will be done to address attrition bias.

Follow-up: The primary and secondary outcomes will be assessed at 8 hourly intervals after starting either oral chewing gum or honey 24 hours postoperatively and the data will be written manually in the case report form. The final assessment point will be till the time of discharge or a maximum of 5 days/144 hours postoperatively. Data collection will be concluded when the patients will be discharged by the consultant orders in the ward round. Oral chewing gum or honey intake will be stopped on discharge and the patients will be recommended to continue taking oral meals at home. Further follow-up will be not done after the patients are discharged from the hospital.

Data Analysis Procedure:

Statistical analysis of the data will be carried out using IBM SPSS Statistics V26.0 for the Window program (IBM, Armonk, New York, USA). Qualitative variables such as gender, presence or absence of postoperative complications will be analyzed using frequencies and percentages. Quantitative variables such as age, length of postoperative stay, time to full feeds, time to bowel sounds, time to pass flatus and time to pass feces will be analyzed by calculating their mean and standard deviation. The data collected will be analyzed using descriptive statistics, such as frequencies, percentages, and means. Chi-Square test and logistic regression will be used to analyze the categorical variables whereas continuous variables will be analyzed using student t-test. Outcome data of the three groups will be compared to see the statistically significant difference, p-value of < 0.05 will be considered statistically significant. Outcome data will be stratified for age, gender, operative surgery, postoperative complications and post stratification chi square test will be applied. All qualitative data will be evaluated using

frequency tables. Any changes in the pre-operative and post-operative values will be calculated in absolute as well as percentages. The data will be explored using descriptive studies.

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Consent Form

"COMPARISON OF THE EFFECT OF CHEWING GUM AND HONEY ON POSTOPERATIVE RECOVERY AND COMPLICATIONS IN ILEOSTOMY REVERSAL"

You are asked to participate in a research study conducted by Dr. Shahroze Wajid under supervision of Dr. Bahzad Akram Khan (Assistant Professor, West Surgical Ward, Mayo Hospital, Lahore), from the West Surgical Ward at Mayo Hospital affiliated with King Edward Medical University (KEMU). The Institutional Review Board (IRB) of KEMU has reviewed this project. IRB is an independent hospital committee that safeguards the welfare and rights of human research participants. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

You are being asked to take part in this study because you had undergone an ileostomy formation surgery and have now presented to the hospital to undergo stoma reversal surgery. The purpose of this study is to compare the effect of chewing gum and honey on postoperative recovery and complications in ileostomy reversal. About 100 people will take part in this study. You will be randomly allocated to a group upon consent to this study and will be asked to start oral intake either chewing gum or honey 1 day after your stoma reversal procedure. Starting from 1 day after the surgery, depending on your allocated group, you will be either be asked to chew gum for 5 minutes every 4 hours or to eat one half tablespoon of natural honey every 4 hours. Your postoperative recovery and complication parameters will be assessed and documented every 8 hours. Relevant questions and investigations including history taking, clinical examination and blood sampling to confirm the presence of complications will be carried out accordingly. The total length of time for your participation in the study will be up to a maximum of 5 days or earlier if you are discharged from the ward upon consultant orders.

Any foreseeable risks or discomforts from undergoing the surgery could include postoperative bloating, pain, nausea, vomiting, change in bowel habits, delayed recovery after surgery or reoperation (in case of intraabdominal infection or anastomotic leakage). These risks or discomforts may or may not be related to or caused by the use of chewing gum or honey and may entirely be due to postsurgical complications. The potential benefits of the study intervention can be improved postoperative recovery after surgery, decreased likelihood of postoperative complications, early return of bowel function and early discharge. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of restricting your data to only the relevant medical professionals involved in this study. The case report forms containing your data will be safely kept in the research record in the custody of the principal investigator and will not be shared to any irrelevant person without your informed consent. You will not receive any payment to participate in this study.

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. The investigator may withdraw you from this research if circumstances arise which warrant doing so. If you have any questions or concerns about this research, please contact the principal investigator, Dr. Shahroze Wajid, Email: shahrozewajid@gmail.com, Contact Number: +923054480616. The Institutional Review Board of KEMU has reviewed this project. If you have any concerns or questions about your rights in this study as a research subject, you should contact the Secretary, Institutional Review Board, KEMU.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Name of the participant: _____ Patient I.D: _____

Name of the witness: _____ Witness I.D: _____

Signature of the participant: _____ Signature of the witness:_____

Name and signature of the person obtaining consent: _____