

## Randomized Clinical Trial on the Effect of Coffee on Postoperative Ileus Following elective Colectomy

### BACKGROUND:

- Postoperative ileus is common after abdominal surgery especially after procedures involving the colon. Post operative ileus contributes to longer hospital stay and has a major economic impact on healthcare services. Owing to the significant implications of ileus after colectomy and the lack of effective therapies, surgeons have devised various preventive strategies. The intake of coffee might offer a simple approach to alleviate or prevent ileus after elective colectomy.

### OBJECTIVE

- To assess whether coffee consumption accelerates the recovery of bowel function after elective colectomy.

### METHODS

- **Design:** Multiple site, randomized controlled parallel study
- **Inclusion criteria:** 18 years old or older and scheduled for elective open or laparoscopic colonic resection for malignant or benign diseases
- **Exclusion criteria:** if rectal resection was intended, a stoma was required or multivisceral resection was planned, known hypersensitivity or distaste for coffee, expected lack of compliance, impaired mental state, and if the intended colonic surgery was not performed.
- **Primary Outcome:** time to first postoperative bowel movement.
- **Secondary Outcomes:** time to tolerance of solid food (no vomiting), time to first flatus, need for additional laxatives, safety, and length of hospital stay.
- 80 patients randomized:
  - 40 patients received placebo (warm water) and were not allowed to drink coffee until after the first bowel movement
  - 40 patients received 100 mL of coffee daily at 8:00, 12:00, and 4:00 beginning on the morning after surgery
- Power 80% with an alpha level of 0.05 to detect a 24 hour difference in time to first bowel movement between 2 groups, assuming a SD of 24 to 36 hours. This was calculated to be sufficient for 36 patients in each study arm.
- Data handling method was intent-to-treat and per protocol analysis

### RESULTS

- 35 out of 40 patients completed the study in the coffee group and 36 of 40 patients completed the study in the water group.
- The intent to treat analysis analyzed 39 patients in the coffee group and 40 patients in the water group. The per protocol analysis analyzed 35 patients in the coffee group and 36 patients in the water group.
- **Primary outcome measures:**
  - Intent to treat analysis: There was a significant difference in time to first bowel movement between groups: 74 hours in the water group vs 60.4 hours in the coffee group,  $p=0.006$ .
  - Per protocol analysis: There was a significant difference in time to first bowel movement between groups: 73.7 hours in the water group vs 62.1 hours in the coffee group,  $p=0.028$ .
- **Secondary outcome measures**
  - Intent to treat analysis: There was no significant difference between groups for time to solid food: 55.8 hours in the water group vs 49.2 hours in the coffee group,  $p=0.276$ .

There was no significant difference between groups for time to flatus: 46.4 hours for the water group vs 40.6 hours for the coffee group,  $p=0.214$ . There was no significant difference between groups for percentage of laxatives used: 21% in the water group vs 13% in the coffee group,  $p=0.055$ . Lastly, there was no significant difference between length of hospital stay between groups: 11 days in the water group vs 8 days in the coffee group,  $p=0.394$ .

- Per protocol analysis: There was a significant difference between groups for time to solid food: 57.3 hours in the water group vs 45.1 hours in the coffee group,  $p=0.038$ . There was no significant difference between groups in time to flatus, percentage of laxative use, and length of hospital stay.
- **Author's conclusion:** The time to first bowel movement was significantly shorter after regular coffee consumption during postoperative period after elective colectomy. Therefore, the use of coffee is a cheap and safe way to activate bowel motility.

#### STRENGTHS

- Controlled randomized parallel study design
- No conflicts of interest existed within the study
- Inclusion and exclusion criteria were appropriate and representative for the population of interest
- Adverse effects were appropriately analyzed

#### LIMITATIONS

- Unblinded, open label study
- Heterogeneity of the patient population
- The study did not indicate the amount of water/liquid consumed in the placebo group
- Other home medications taken by the patients prior to surgery and after surgery were not reported
- Compliance was an issue with patients in the water group
- The study calculated an 80% power based on a 24-hour effect size which was not achieved and therefore the power of the study was lowered increasing the risk for Type II error
- Amount of coffee ingestion prior to the study was not assessed

#### CONCLUSION

The study showed that coffee decreases the time to bowel movement compared to the placebo and the use of coffee does appear to be a safe and cheap way to increase bowel motility. However, the 14-hour difference between groups may not be clinically significant in actual practice. Also, there were several limitations to the study which concludes the need for further research.

- Future research:
  - Additional studies should be done that properly measure the amount of liquid consumed by the treatment and placebo group as well as find a way to control compliance of patients. The power of the study should be calculated with a lower effect size to reduce the chance for Type II error.

**Reference:** Miller SA, Rahbari NN, Schneider F, et al. (2012) Randomized Clinical Trial on the Effect of Coffee on Postoperative Ileus Following Elective Colectomy. *British Journal of Surgery* 2012; 99:1530-1538.