





Flavoured ice popsicle (RESOURCE fruit beverage) for intestinal function recovery after elective laparoscopic colorectal surgery (RePo trial) – A randomized controlled trial

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ABSTRACT

Introduction: Laparoscopic colorectal surgery over the years has become the approach of choice for various pathologies. Despite having a lower complications rate compared to open, studies have shown significant complications rate among laparoscopic patients as well. Our study is to assess the intestinal function recovery (Time to pass flatus) among laparoscopic patients provided with Resource Ice Popsicle and standard clear fluid post operatively.

Materials and Methods: A randomized controlled trial was conducted from August 2022 till November 2023 at 2 centres, namely Hospital Kuala Lumpur and Hospital Canselor Tuanku Muhriz. The time to pass flatus among elective laparoscopic colorectal surgery patients for each group (Popsicle and Clear fluid) as well as time to pass motion, post-operative length of stay and complications of surgery for the two groups were documented.

Results: Total of 62 samples were recruited. It was found that the time to pass flatus, and post-operative length of stay were significantly shorter in the popsicle as compared to clear fluid group. Time to pass motion and complication rates between both groups showed no significant difference.

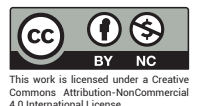
Conclusions: Our study showed no difference in occurrence of anastomotic leak or Resource related mortality. Easy availability and simple preparation with improved outcome, makes this a promising alternative among patients. This can be further extrapolated to other surgical units. A well- designed, large-scale, multi-centered RCT in the future is recommended.

Keywords: Laparoscopic colorectal surgery, popsicles, post-operative recovery



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Introduction

Post-operative recovery in cases with gastrointestinal anastomosis has always been tricky. The need to establish early feeding restoring gut motility versus post operative nausea & vomiting (PONV) as well as anastomotic leak has been a challenging task. ERAS proposes for early feeding (<24 hrs) however with a watchful monitoring of vomiting.

Of recent times, laparoscopic surgery has been the mode of choice in most colorectal cases and from literature reviews, it has been shown anastomotic leaks occur in both approaches. Schiff et al.^[1], 2017, showed that postoperative anastomotic leaks were observed more frequently in patients after open surgery (32 of 56 patients with postoperative leaks, 57.1%) compared to laparoscopic surgery (24 of 56 patients, 42.9%). Meta-analysis by Sciuto et al.^[2], 2018, showed that rate of anastomotic leak was not significantly reduced by the introduction of laparoscopic colorectal resections.

Another important factor to consider in colorectal surgery is the occurrence of Post operative ileus (POI). POI is defined as obstipation and intolerance of oral intake due to non-mechanical factors that disrupt the normal coordinated propulsive motor activity of the gastrointestinal tract following abdominal or non-abdominal surgery.^[3] A systematic review by Vather et al.^[4], 2013, concluded the definitions of POI.^[4] POI is termed as the time from completion of surgery till the opening of bowels and the ability to consume oral diet. Prolonged POI is when “two or more of nausea/vomiting, inability to tolerate oral diet over 24h, absence of flatus over 24h, distension, radiologic confirmation occurring on or after day 4 postoperatively without prior resolution of POI”.

Thus far few studies have been done to improve POI and one of the examples is sham feeding (chewing gum) which has shown to improve ileus. A meta-analysis comprising of 17 RCT and 1845 patients showed that sham feeding significantly reduced time to pass first flatus. It is of importance to note that, in 10/17 studies, time to pass first flatus was recorded to indicate bowel function recovery. Both laparoscopic and open approach had significantly shorter time to pass flatus as evidenced by Shum et al.^[5], and Topcu et al.^[6], respectively.^[3]

No studies thus far have been done to assess the cooling effect that may improve POI. Ice popsicles however have been used in post-operative patients mainly by our anaesthetic counterparts assessing its relation to PONV.^[7-9] Each of this study showed no complications from the use

of ice popsicles post-operatively. The cooling sensation of these popsicles has both physiological and psychological effect on us.^[10,11] Transient Receptor Potential Melastatin 8 (TRPM8) being most sensitive at 25-28 celcius has been found to potentiate the effect of cold sensation. Calcium ion influx via the ion gated channel following the activation of TRPM8 ion channel 7, causes stimulation of the sensory nerve ending leading to firing of action potentials to cause a sensation of cold. This due to negative heat load related to consumption of cold items.

In a similar context, the psychological effect of cooling is associated with a refreshing perception, whereby the word means to “revive” or “restore” or “arouse”.^[10] The physiological aspect of cooling includes thirst-quenching. For a subject who is thirsty, stimulating a cold environment through drinking cold water provides a pleasant signal which helps to restore body water homeostasis. All patients post-operatively would have been fasted and in a thirsty subject, cold water will be a positive stimuli which helps to increase their intake of popsicle.

Materials and Methods

This is a randomized control study done at 2 centers namely Hospital Kuala Lumpur and Hospital Canselor Tuanku Muhriz (HCTM). Both are tertiary referral centers with adequate facilities and sub-speciality surgeons. The study period was from May 2022 till December 2023. The study was approved by the Board of Ethical Committee Members of Universiti Kebangsaan Malaysia (PPI/111/8/JEP-2022-100) and the Malaysia Ministry of Health Medical Research and Ethics Committee (MREC) (NMRR ID-22-00168-TWV) and conducted according to the Declaration of Helsinki. Total of 62 patients were recruited (sample size calculated using comparing two means method). $\alpha=0.01$, 99%CI with a power of 90% was chosen for sample size calculation. Intention-to-treat analysis was used with a drop-out rate of 20% was added to sample size calculation.

Simple randomization method using computer generation was used to recruit the patients.^[12] Patients with colorectal cancer who presented to Colorectal clinic who fits into our inclusion criteria were assigned into two groups: Popsicle and clear fluid groups. The patients in both groups underwent laparoscopic colorectal surgery with or without stoma.

The inclusion criteria were as follows: Age more than 18 years old, underwent elective laparoscopic colorectal surgery and agreed to participate in the study. Patients who are allergic to opioids, intubated post-operative period and converted to open were excluded.

Figure 1 shows the flow of pre-operative assessment, admission and discharge criteria.

Statistical Analysis

Data analysis was performed using Statistical Package for Social Science (SPSS) version 27. Mann Whitney U-test was performed for all variables as the outcome variables

of the study violated the normality assumption test of Shapiro-Wilk.

Results

Based on the final data, out of 62 subjects, mean age of popsicle group 64.97 (SD=9.30) compared to mean age clear fluid 61.55 (SD=13.41). Mean of clear fluid group was

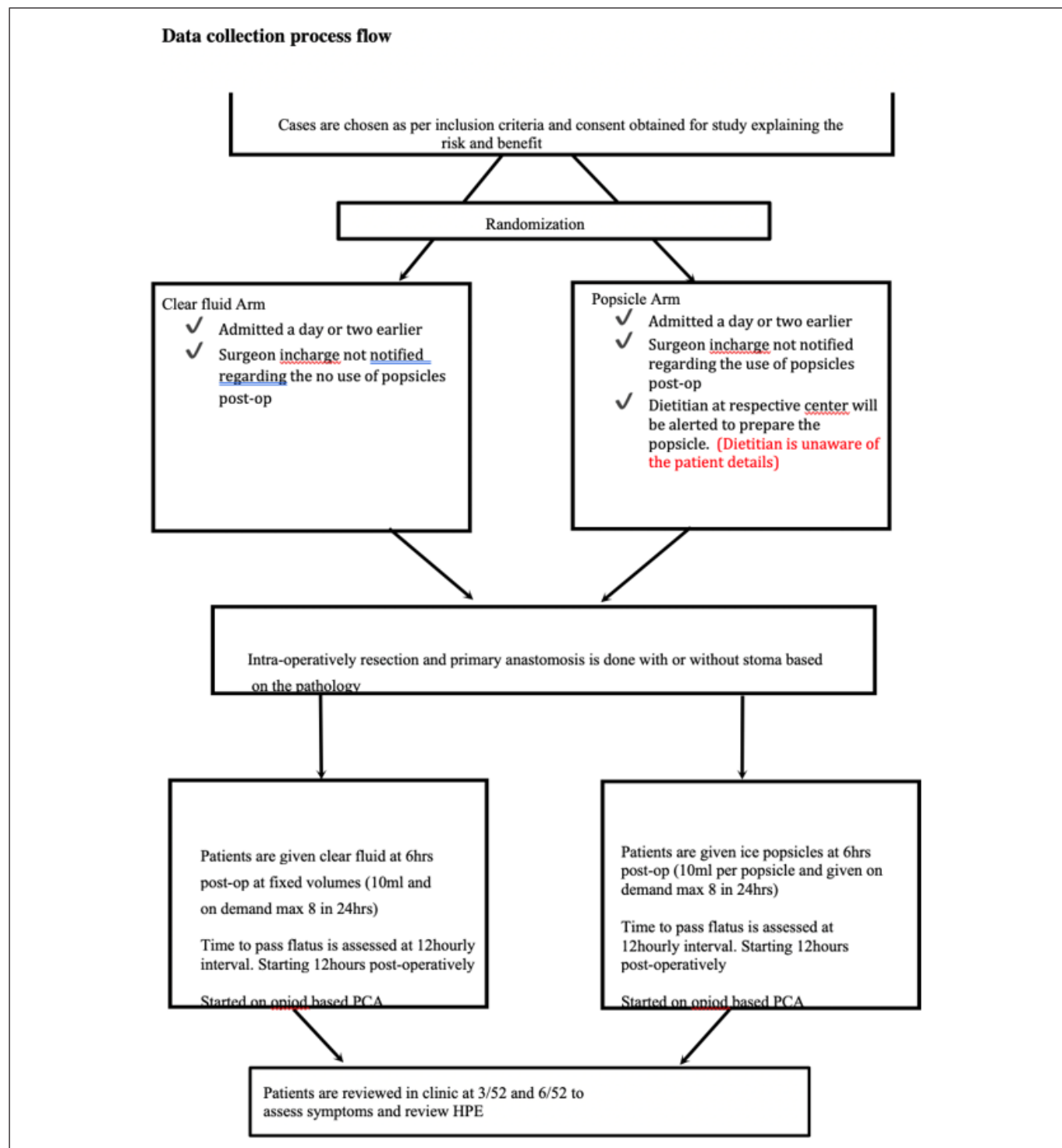


Figure 1. The flow of pre-operative assessment, admission and discharge criteria.

lower for time to pass flatus (PF) 30.19 (SD=12.34), time to pass motion (PM) 45.29 (12.67), and post-operative length of stay (LOS) 6.39 (1.89) respectively. There is a male predominance of subjects 59.7% (n=37). Pre-operative chemoradiotherapy (CCRT) was administered to 40.3% (n=25), and total of 23 subjects underwent previous abdominal surgery 37.1% (n=23). Among our subjects, 3 of them had previous Covid-19 infection 4.8% (n=3). The mean number of consumptions of clear fluid was 4.55 (SD 2.20) in comparison to popsicle 5.42 (SD 2.31). As summarized in Tables 1-3.

Based on normality assumption of Saphiro-Wilk, the assumptions were not met. Hence non parametric (Mann Whitney U) test was considered. Primary outcome of time to pass flatus was documented based on self-report of patients and during 12 hourly assessments.

The test revealed that the time to pass flatus in hours was significantly shorter in the popsicle group (Median=24.00, n=31) as compared to the clear fluid group (Median=24.00, n=31), $U=319.00$, $z=2.50$, $p=0.012$, $r=0.45$ with a medium effect size. It is to be highlighted despite a similar median the p-value is significant. This is due to

Table 1. Summary of demographic data

Variables	Clear fluid		Popsicle	
	Mean (SD)	n (%)	Mean (SD)	n (%)
Age	61.55 (13.41)		64.97 (9.30)	
Passing flatus	30.19 (12.34)		23.61 (11.38)	
Passing motion	45.29 (12.67)		38.71 (15.09)	
Length of stay	6.39 (1.89)		5.53 (1.53)	
Gender				
Male		14 (45.2)		23 (74.2)
Female		17 (54.8)		8 (25.8)
CCRT given				
Yes		15 (48.4)		10 (32.3)
No		16 (51.6)		21 (67.7)
Previous Surgery				
Yes		12 (38.7)		11 (35.5)
No		19 (61.3)		20 (64.5)
Covid				
Yes		1 (3.2)		2 (6.5)
No		30 (96.8)		29 (93.5)
Complication Admission				
CD 1		3 (9.7)		1 (3.2)
CD 2		1 (3.2)		0
CD 3		0		1 (3.2)
CD 4		1 (3.2)		0
CD 5		0		1 (3.2)
ComplicationTCA				
CD 1		3 (9.7)		1 (3.2)
CD 2		0		0
CD 3		1 (3.2)		0
CD 4		0		0
CD 5		0		0

CD: Calvein-Dindo.

Table 2. Demographic comparison between both groups

Features	Total n (%)	Clear fluidn (%)	Popsicle n (%)	X ²	p-value
Gender				5.43	0.037*
Female	25 (40.3)	17 (27.4)	14 (22.6)		
Male	37 (59.7)	8 (12.9)	23 (37.1)		
CCRT given				1.67	0.300
No	37 (59.7)	16 (25.8)	21 (33.9)		
Yes	25 (40.3)	15 (24.2)	10 (16.1)		
Previous Surgery				0.07	0.950
No	39 (62.9)	19 (30.6)	20 (32.3)		
Yes	23 (37.1)	12 (19.4)	11 (17.7)		

X²=Chi Square Test. *p<0.05.

Table 3. Summary of overall complications among both groups

Measure	Number of participants (%)	
	Clear Fluid (n=31)	Popsicle (n=31)
Complications during Admission	5 (16.1)	3 (9.7)
Clavien Dindo 1	3 (9.7)	1 (3.2)
- Ileus	1 (3.2)	1 (3.2)
- Surgical Site Infection	2 (6.5)	
Clavien Dindo 2	1 (3.2)	0
- Lung Atelectasis	1 (3.2)	
Clavien Dindo 3	0	1 (3.2)
- Stoma Related Complication	1 (3.2)	
Clavien Dindo 4	1 (3.2)	0
- Anastomotic Leak	1 (3.2)	
Clavien Dindo 5	0	1 (3.2)
- Cardiac Related Mortality		1 (3.2)
Complications during TCA	4 (12.9)	1 (3.2)
Clavien Dindo 1	3 (9.7)	1 (3.2)
- Adhesion Colic	2 (6.5)	
- High Stoma Output		1 (3.2)
Clavien Dindo 2	0	0
Clavien Dindo 3	1 (3.2)	0
- Anastomotic Leak	1 (3.2)	
Clavien Dindo 4	0	0
Clavien Dindo 5	0	0

Mann Whitney U-test being a test of mean ranks rather than median. Hence despite having a similar median the p-value is significant.

Similarly, significantly shorter LOS with a medium effect size was observed in patients in the popsicle group (Median=5.00, n=31) as compared to the clear fluid group (Medi-

an=6.00, n=31), U=320.00, z=2.16, p=0.031, r=0.39. However, as for time to pass motion, it was found that there was no significant difference between patients in the popsicle group (Median=48.00, n=31) compared to the clear fluid group (Median=48.00, n=31), U=362.50, z=1.72, p=0.086, r=0.31 with a medium effect size. Summarized in Table 4, 5.

Comparing the data among participants that had underwent previous abdominal surgery, it showed no significant difference between both groups for all outcomes. However, among the participants that had underwent previous CCRT, comparing between the two groups showed significant difference in time to pass flatus. Significantly shorter time to pass flatus with a large effect size was observed in patients in the popsicle group (Median=24.00, n=31) as compared to the clear fluid group (Median=36.00, n=31), U=39.50, z=2.06, p=0.048, r=0.65. Summarized in Table 6.

There was a comparable complication rate among both groups. Mainly were Calvein-Dindo 1 complications that

were managed with active observation in patient and medications. We had 2 reported cases of anastomotic leak. The case of anastomotic leak during admission underwent second surgery however the other case was managed conservatively with peritoneal drainage and antibiotics. We had 1 case of mortality in the popsicle arm however it was attributed to sudden cardiac arrest due to poor pre-morbid condition of patient.

Discussion

This randomized controlled trial found that, Resource flavoured ice popsicle improved time to intestinal recovery (time to pass flatus) compared with standard clear fluids in patients undergoing elective colorectal surgery. The effects of the cold flavoured clear fluid onto the receptor TRPM8 potentially reciprocated to the fasten intestinal motility. This is in contrast to the studies conducted thus far comparing temperature and gastric motility. 2 studies

Table 4. Comparing numerical variables between clear fluid and popsicle groups

Variables	Clear fluid (n=31) Median (IQR)	Popsicle (n=31) Median (IQR)	Z statistics	Effect size	p
Passing flatus (Hours)	24.00 (12.00)	24.00 (12.00)	-2.50	0.45	0.012*
Passing motion (Hours)	48.00 (24.00)	48.00 (24.00)	-1.72	0.31	0.086
Length of stay (Days)	6 (2)	5 (1)	-2.16	0.39	0.031*

*p<0.05.

Table 5. Comparing outcome between both groups among subjects that had previous abdominal surgery

Variables	Clear fluid (n=12) Median (IQR)	Popsicle (n=11) Median (IQR)	Z statistics	Effect size	p
Passing flatus (Hours)	30.00 (21.00)	24.00 (18.00)	-1.26	0.38	0.207
Passing motion (Hours)	48.00 (24.00)	48.00 (36.00)	-0.42	0.13	0.677
Length of stay (Days)	6 (3)	5.5 (1)	-1.30	0.39	0.194

Table 6. Comparing outcome between both groups among subjects that had underwent previous CCRT

Variables	Clear fluid (n=15) Median (IQR)	Popsicle (n=10) Median (IQR)	Z statistics	Effect size	p
Passing flatus (Hours)	36.00 (12.00)	24.00 (6.00)	-2.06	0.65	0.048*
Passing motion (Hours)	48.00 (24.00)	48.00 (30.00)	-1.23	0.39	0.218
Length of stay (Days)	6 (2)	5 (2)	-1.67	0.53	0.095

*p<0.05.

published thus far has shown a lower energy consumption of the gastric muscle and a slower emptying time at colder temperatures.^[13,14] However, these 2 studies are low powered studies with less than 10 subjects. Our pilot study focusing on intestinal motility has shown promising results at lower temperatures. Future studies done to assess the intestinal emptying time of fluid at various temperature will be useful.

In addition to that, post-operative length of stay has always been a problem after major colorectal cancer surgeries. This was alleviated to an amount after the assimilation of laparoscopic surgery among colorectal patients. However, complications and mainly post-operative ileus were still seen in the laparoscopic group rendering patients longer in the ward. The introduction of sham feeding (chewing gum) was accepted when it was introduced as passage of flatus and post-operative length of stay was significantly shorter. Our study showed similar results in the popsicle group. This translates to a shorter bed occupancy rate and is more cost effective to the healthcare system in a whole. The likely reason behind this is the lower occurrence of post-operative ileus as well as complications in general.

Based on recent RAPIDO guidelines most of rectal cancer patients undergo neoadjuvant CCRT. Our study has also shown in this subset of patient the time to pass flatus is shorter. Despite the anticipated radiation induced adhesions, the motility of gut has proven to be faster in them. This will serve as a good guide in future during counselling of these patients for surgery. Time to pass motion and post-operative length of stay showed no significance difference and future studies of larger sample size will be beneficial. On the other hand, patients who had previous abdominal surgeries and underwent laparoscopic colorectal surgeries showed no positive effect with popsicle. This is likely due to small subset of patients in our study.

The strength of this study is that it is a pilot RCT study comparing popsicle with clear fluid in patients undergoing elective colorectal surgery. Giving flavoured popsicle after surgery is a novel feature of this work. There are some limitations to the present study. It remains unclear the exact mechanism of action in which popsicle positively affects these patients. Besides the likelihood of patient psychological relieve and comfort due to cold stimuli which in turn leads to an improve in POI, further studies on mechanism would explain this theory further.

Conclusion

Resource has been widely used in hospital setting. Only an alteration in the preparation and serving method should not burden the healthcare system. Safety profile of Resource has been well studied and published and our study showed no difference in occurrence of anastomotic leak or Resource related mortality. Easy availability and simple preparation with proven improved outcome make this as a great alternative among our laparoscopic patients and can be further extrapolated to other surgical units.

Disclosures

Ethics Committee Approval: The study was approved by the Board of Ethical Committee Members of Universiti Kebangsaan Malaysia (PPI/111/8/JEP-2022-100) and the Malaysia Ministry of Health Medical Research and Ethics Committee (MREC) (NMRR ID-22-00168-TWV)

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