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Original Article

Safety of Early Feeding after Mini-Incision Appendectomy: Randomized Controlled Trial

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Abstract

Introduction: Current evidence seems to suggest that early feeding can improve postoperative recovery after appendectomy. However, the safety of early feeding after mini-incision appendectomy (MOA) is still unclear, especially in complicated appendicitis. The main objective of this study was to assess the safety of early feeding in patients who underwent MOA in both simple and complicated acute appendicitis.

Materials and Methods: This study was an open-label, randomized controlled trial. We randomly allocated patients undergoing MOA to either the early feeding group (EF) or to a standard care group (SC). The primary outcome was postoperative ileus. Subgroup analysis of complicated appendicitis was done in this study.

Results: Patients in the EF group had a significantly shorter duration of postoperative ileus (mean difference 8.65 hours, SD = 3.93, $p = 0.03$) and time taken to tolerate a soft diet (mean difference 9.76 hours, SD = 4.08, $p = 0.02$). There was no significant difference in complications. In the subgroup analysis of complicated appendicitis, there was no significant difference in postoperative outcome between both groups.

Conclusion: Early feeding after MOA reduced postoperative ileus and the time taken to tolerate a soft diet without increased postoperative complications.

Keywords: Appendectomy, Appendicitis, Early feeding, Mini-incision, Postoperative ileus

INTRODUCTION

Appendicitis is one of the most common surgical emergencies, with an incidence of 84.2 cases per 100,000 persons¹. Open appendectomy (OA) and laparoscopic appendectomy (LA) are the standard treatments². Mini-

incision open appendectomy (MOA) is an alternative treatment of appendicitis. MOA is an appendectomy utilizing single small incisions of 2 to 3.5 cm at the right lower quadrant. Some of the advantages of MOA is a lower operation time, lower quantity of analgesics

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used, and decreased length of postoperative hospital stay compared to traditional OA³⁻⁸.

In standard care, patients do not start the diet until the passing of flatus/stool or presentation of bowel sounds. One reason for this is that it is recommended for patients to wait until the resolution of postoperative ileus. Another is the risk that early feeding may increase the potential for anastomotic leakage⁹.

Current evidence indicates that early feeding after appendectomy appears to be safe, and shortens the length of hospital stay (LOS) and time to tolerate solid diet¹⁰. However, most of the studies involving early feeding after an appendectomy were applied in uncomplicated appendicitis with no subgroup analysis of complicated appendicitis. The safety of early feeding after MOA was still unclear, especially in complicated appendicitis¹¹⁻¹⁵.

The main objective of this study was to assess the safety of early feeding in patients who underwent MOA in both simple and complicated acute appendicitis.

MATERIALS AND METHODS

This study was an open-label, randomized controlled trial at the Department of Surgery, Songkhla Hospital. The sample consisted of patients who were of at least 8 years of age, had acute appendicitis, and underwent MOA from October 2018 to October 2019. The exclusion criteria included pregnancy, generalized peritonitis, a normal appendix was seen intraoperatively, and had any additional procedures performed. Informed consent was given before enrollment in this study.

Intravenous antibiotic prophylaxis was given prior to any operation, and the MOA was performed under general anesthesia. One surgeon operated on all patients included in this study. An oblique incision of 2-3.5 cm in length was conducted at McBurney's point. An extended incision would be done if needed. The appendix stump was double ligated using silk 2-0, with irrigation of the subcutaneous layer done with povidone-iodine solution. The subcutaneous thickness was measured before skin closure and the skin was closed using skin staples. The incision length was measured after skin closure.

After surgery, patients were assigned into the early feeding group (EF) and standard care group (SC) by the surgeon by randomization. The random allocation sequence was computer-generated in blocks of four. The randomization sequence was concealed in opaque envelopes. Blinding was not possible due to different

care protocols that patients and physicians could notice. Opioid analgesia was utilized for postoperative pain and postoperative intravenous antibiotics were given to patients with complicated appendicitis. If the patient had no fever for at least 24 hours, their antibiotics were changed to oral form.

Patients in the SC group started a liquid diet after the passing of flatus or presentation of bowel sounds. Physical examinations were conducted twice daily. Once patients could tolerate a liquid diet, the soft diet was started in their next meal. In the EF group, patients began a soft diet as tolerated at 6 hours after appendectomy. Domperidone and Simethicone were given as oral treatments to patients who had abdominal distension, nausea, and vomiting. In patients who had vomiting, intravenous Metoclopramide was injected and their diet was suspended for one meal then started again for their next meal if they no longer experienced nausea and vomiting.

Patients were discharged home when they could tolerate soft diet, presented no fever for at least 24 hours, had no nausea or vomiting, no longer needed intravenous analgesic drugs, and had no complications that needed further hospitalization. Follow ups on patients were conducted one month after operation.

The demographic data collected included age, sex, American Society of Anesthesiologist grade (ASA), body mass index (BMI), white blood cell count (WBC), the onset of symptoms, operative time, subcutaneous thickness, incision length, the severity of appendicitis, and number of patients who failed MOA. The severity of appendicitis was classified into five categories according to the AAST grading system¹⁶. Acute inflamed appendicitis was classified as simple appendicitis. Complicated appendicitis consisted of gangrenous appendicitis, perforated appendicitis, and appendiceal phlegmon/abscess.

The primary outcome was the duration of postoperative ileus. The definition of duration of postoperative ileus is the time interval from surgery until the patient has passed flatus/stool and tolerates an oral diet¹⁷. Secondary outcomes were time until tolerance of a soft diet, time until the passing of flatus, LOS, and complications. The time until tolerance of a soft diet was the interval from surgery until the patient could tolerate a soft diet more than 50% of the time. Complications consisted of abdominal distension, nausea, vomiting, and surgical site infection (SSI).

SSI is defined following the CDC guideline¹⁸ as an

infection at the surgical site that occurs within 30 days of surgery. SSI is classified into three groups: superficial incisional, deep incisional, and organ or space infection.

The local research ethics committee approved this study. This study was registered at www.clinicaltrials.in.th (TCTR20190111004).

Statistical analysis of demographic data, results, and subgroup analysis in complicated appendicitis was performed using IBM SPSS statistics version 19 (IBM Corp., Armonk, NY, USA). Chi-square testing was used to compare categorical data. An independent sample T-test was used to analyze normally distributed data. The significant difference was defined as a *p*-value less than 0.05. Data analysis was done according to the intention-to-treat analysis.

The sample size was calculated according to data from previous studies. At least 12 patients were needed in each group to demonstrate different postoperative ileus at the power of 80% and 5% level of significance.

RESULTS

Seventy-five patients were enrolled from October

2018 to October 2019. Six cases were excluded due to intraoperative findings showing a normal appendix. Two cases were excluded as the patients had an additional procedure performed (such as suture cecum or ileocecectomy). 34 and 33 patients were randomly assigned to the EF group and SC group, respectively. There was no patient loss follow-up in this study (Figure 1).

Based on the demographic data shown in Table 1, there was no significant difference between the EF and SC groups. The mean age of patients was 34.5 years, ranging from 8 to 85 years. The average BMI was 22.1 kg/m², ranging from 12.6 to 35 kg/m². The average operative time was 24.5 minutes, ranging from 8 to 75 minutes. Complicated appendicitis was seen in 36 patients (53.7%), 18 in both groups.

The success rate of MOA was 82%. Three cases of simple appendicitis and nine cases of complicated appendicitis had a failed MOA. The average subcutaneous thickness was 1.97 cm (1.75 and 2.98 cm in successful and failed MOA, respectively). The average incision length after skin closure in successful and failed MOA was 3.12 and 5 cm, respectively. No drain was used in these patients.

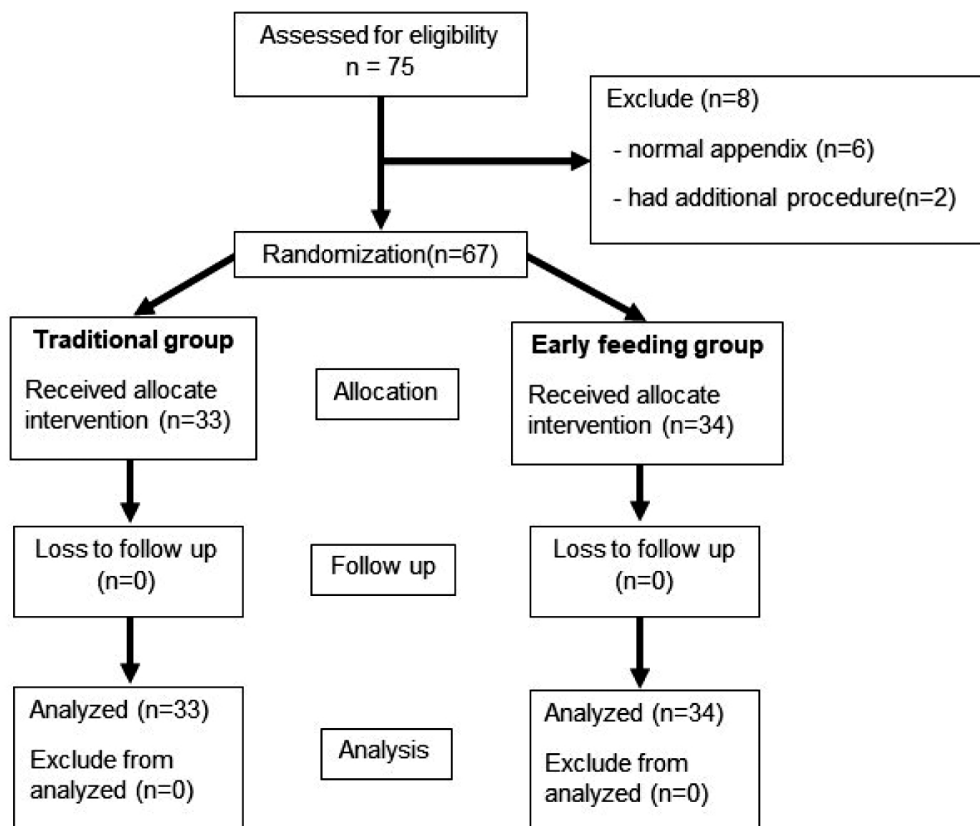


Figure 1 CONSORT flow chart

Table 1 Demographic data

Variable	Early feeding (n=34)	Standard care (n=33)	p-value
Age, year, mean \pm SD	35.88 \pm 20.13	34.91 \pm 17.97	0.84
Sex, n			
Male	17	23	0.10
Female	17	10	
ASA, n			
Class I	28	25	0.50
Class II	6	8	
Body mass index, kg/m ² , mean \pm SD	22.30 \pm 4.71	21.84 \pm 4.60	0.69
White blood cell count, cell/mm ³ , mean \pm SD	14334 \pm 4752	15176 \pm 4358	0.45
Onset, hour, mean \pm SD	16.44 \pm 9.76	23.94 \pm 21.90	0.74
Operative time, minutes, mean \pm SD	24.09 \pm 9.51	24.97 \pm 13.17	0.76
Severity of appendicitis, n			
Inflamed appendicitis	16	15	0.98
Gangrenous appendicitis	11	10	
Perforated appendicitis with localized peritonitis	4	4	
Appendiceal phlegmon/abscess	3	4	
Failed MOA, n	4	8	0.18

ASA, American Society of Anesthesiologist grade; MOA, Mini-incision appendectomy; SD, standard deviation

Table 2 Results

Variable	Early feeding (n=34)	Standard care (n=33)	p-value
Postoperative ileus , hour, mean \pm SD	24.32 \pm 17.64	32.97 \pm 14.31	0.03
Time to tolerate soft diet , hour, mean \pm SD	22.18 \pm 18.47	31.94 \pm 14.79	0.02
Time to flatus, hour, mean \pm SD	14.21 \pm 8.42	15.64 \pm 10.38	0.54
Length of stay, hour, mean \pm SD	47.79 \pm 21.72	58.21 \pm 23.25	0.06
Abdominal distension or nausea, n	6	5	0.78
Vomiting, n	0	2	0.15
Surgical site infection, n	0	2	0.15

SD, standard deviation

Patients in the EF group had a significantly shorter duration of postoperative ileus (mean difference 8.65 hours, SD = 3.93, $p = 0.03$) and time until tolerance of a soft diet (mean difference 9.76 hours, SD = 4.08, $p = 0.02$). The LOS and time to flatus were shorter in the EF group but not to the degree of being considered a significant difference.

There was no significant difference in complications such as SSI, abdominal distension, nausea, or vomiting. SSI was seen in two patients as superficial SSIs and could be treated as OPD cases (one patient had perforated appendicitis with underlying AIDS, and another one had appendiceal phlegmon that needed to extend an incision to 10 cm). Overall, the SSI rate was

2.99% (0% in simple appendicitis and 5.56% in complicated appendicitis). There were no other complications, readmissions, and reoperations in this study. The results are shown in Table 2.

In the subgroup analysis of complicated appendicitis (n = 36), the demographic data had no significant difference between both groups except the number of patients who failed MOA was significantly higher in SC group (8 cases in SC group and 1 case in EF group, $p = 0.007$). The results are shown in Table 3. Postoperative ileus, time until tolerance of a soft diet, time to flatus, LOS and complications were not significant differences in the subgroup analysis of complicated appendicitis. The results are shown in Table 4.

Table 3 Demographic data of subgroup analysis of complicated appendicitis (n = 18 for each group)

Variable	Early feeding (n=18)	Standard care (n=18)	p-value
Age, year, mean ± SD	35.33 ± 20	40 ± 18.24	0.47
Sex, n			
Male	12	13	0.72
Female	6	5	
ASA, n			
Class I	16	12	0.11
Class II	2	6	
Body mass index, kg/m ² , mean ± SD	22.25 ± 5	22.92 ± 4.45	0.67
White blood cell count, cell/mm ³ , mean ± SD	15396 ± 5448	15488 ± 2685	0.95
Onset, hour, mean ± SD	20.28 ± 10.80	35.61 ± 31.06	0.06
Operative time, minutes, mean ± SD	24 ± 9.7	30.33 ± 15.85	0.16
Failed MOA, n	1	8	0.007

ASA, American Society of Anesthesiologist grade; MOA, Mini-incision appendectomy; SD, standard deviation

Table 4 Result of subgroup analysis of complicated appendicitis

Variable	Early feeding (n=18)	Standard care (n=18)	p-value
Postoperative ileus, hour, mean ± SD	26 ± 20.47	35.67 ± 15.38	0.12
Time to tolerate soft diet, hour, mean ± SD	23.28 ± 21.35	34.78 ± 15.52	0.07
Time to flatus, hour, mean ± SD	15.56 ± 10	12.28 ± 9.35	0.32
Length of stay, hour, mean ± SD	52.72 ± 22.01	67.11 ± 25.31	0.08
Abdominal distension or nausea, n	3	4	0.67
Vomiting, n	0	2	0.15
Surgical site infection, n	0	2	0.15

SD, standard deviation

DISCUSSION

In standard care, patients start the soft diet after passing of flatus/stool or presentation of bowel sounds. This is due to concern surrounding postoperative ileus and anastomotic leakage. But current evidence indicates that early feeding was safe and improved postoperative recovery.

In 2008, Kuzma et al. conducted a randomized controlled trial that compared early feeding with opioid-sparing analgesia to traditional care in a patient who underwent OA. In the EF group, the liquid was started at 6 hours after an operation and gradually shifted from a liquid to solid diet. Results have shown that the LOS and time until tolerance of a solid diet were significantly shorter in the EF group (2.44 vs. 4 days, $p < 0.001$) without increased morbidity. Only one case in each group had a surgical site infection. However, 41% of participants

were patients with complicated appendicitis. There was no subgroup analysis of complicated appendicitis¹⁰.

In 2018, Sazhin et al. demonstrated multicenter prospective RCT by comparing standard and fast-track rehabilitation in a patient who underwent LA. In the fast-track protocol group, the liquid diet was started at 6 hours after surgery compared to the traditional care group. LOS was significantly shorter in the fast-track protocol group (LOS 1.45 vs. 3.15 days, $p = 0.002$). However, only ten patients in each group had complicated appendicitis (26.3% in the fast-track protocol group, 20.8% in the control group). There was no subgroup analysis of complicated appendicitis¹¹. Furthermore, this study demonstrated that early feeding is not associated with prolonged postoperative ileus and anastomosis leakage in both simple and complicated appendicitis.

In this study, postoperative ileus was a primary outcome that differs from previous studies that used LOS. There were many confounding factors that caused prolonged LOS but are not associated with early feeding such as postoperative pain and postoperative fever. The time to presentation of bowel sounds was not appropriate for use as a primary outcome because it depended on the frequency of evaluation⁹.

The results in this study seem to convey that early feeding was safe and had resulted in reduced postoperative ileus and time until tolerance of a soft diet. Patients in the EF group had a shorter postoperative ileus because early feeding stimulated gut motility, increased splanchnic flow, and decreased intestinal stasis. This is in contrast to fasting, which contributes to catabolism with loss of weight and skeletal muscle⁹. Other than the benefit of early feeding in metabolic response, the patients could evaluate themselves and start a diet after surgery without waiting for evaluation by a surgeon. Moreover, in patients with a delayed recovery of bowel function, early feeding did not aggravate the symptoms of bowel ileus because patients limited themselves from the diet until postoperative ileus was improved.

NPO after appendectomy had no benefit and may be causing prolonged postoperative ileus compared to early feeding. However, LOS had no significant difference due to confounding factors that caused prolonged LOS, especially in complicated appendicitis.

This study also demonstrated the safety of MOA in both simple and complicated appendicitis. The success rate of MOA was 82%. The rate of SSI was 0% in simple appendicitis and 5.56% in complicated appendicitis. No other complication was seen. The average BMI and subcutaneous thickness in this study were 22.1 kg/m² and 1.97 cm, respectively. Therefore, MOA should be considered within a population with a low BMI and thin subcutaneous tissue.

The limitations of this study were that most patients in this study had low comorbidity and more than half of the patients with complicated appendicitis had gangrenous appendicitis. Gangrenous appendicitis has a better prognosis compared to ruptured appendicitis and appendiceal phlegmon/abscess. Therefore, further studies should be done to support the safety and benefits of early feeding after MOA. The conclusion was that early feeding after MOA reduced postoperative ileus without increased postoperative complications.

CONCLUSION

Early feeding after MOA reduced postoperative ileus and time until tolerance of a soft diet without increased postoperative complications in patients with acute appendicitis undergoing mini-incision appendectomy.

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CONFLICTS OF INTEREST

The author has no conflict of interest.

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บทคัดย่อ ความปลอดภัยของการเริ่มให้ทานอาหารโดยเร็วหลังผ่าตัดไส้ติ่งแบบลงแผลเล็ก: งานวิจัยเชิงทดลองแบบสุ่ม

เมธัส อรัญนารต

กลุ่มงานศัลยกรรม โรงพยาบาลสงขลา

ความเป็นมา: จากงานวิจัยในปัจจุบันพบว่า การให้ทานอาหารโดยเร็วหลังผ่าตัด จะช่วยให้ผู้ป่วยฟื้นตัวหลังผ่าตัดเร็วขึ้น อย่างไรก็ตาม ความปลอดภัยของการเริ่มให้ทานอาหารโดยเร็วหลังผ่าตัดไส้ติ่งแบบลงแผลเล็กยังคงไม่ชัดเจน โดยเฉพาะอย่างยิ่งในผู้ป่วยที่มีภาวะไส้ติ่งอักเสบแบบซับซ้อน วัตถุประสงค์หลักของการศึกษานี้คือ เพื่อศึกษาความปลอดภัยของการเริ่มให้ทานอาหารโดยเร็วหลังผ่าตัดไส้ติ่งแบบลงแผลเล็ก ทั้งในผู้ป่วยที่เป็นไส้ติ่งแบบธรรมดาและแบบซับซ้อน

วัตถุประสงค์และวิธีการ: เป็นงานวิจัยเชิงทดลองแบบสุ่ม โดยแบ่งผู้ป่วยที่ได้รับการผ่าตัดไส้ติ่งแบบแผลเล็กออกเป็นกลุ่มที่ดูแลแบบปกติ กับ กลุ่มที่เริ่มให้ทานอาหารโดยเร็วหลังผ่าตัด ตัววัดผลหลักคือ ระยะเวลาของภาวะลำไส้ไม่ทำงานหลังผ่าตัด มีการนำผู้ป่วยที่มีภาวะไส้ติ่งอักเสบแบบซับซ้อนมาวิเคราะห์แบบกลุ่มย่อย

ผลการศึกษา: ผู้ป่วยในกลุ่มเริ่มให้ทานอาหารโดยเร็วหลังผ่าตัด มีระยะเวลาของภาวะลำไส้ไม่ทำงานหลังผ่าตัดสั้นกว่าอย่างมีนัยสำคัญ (mean difference 8.65 hours, SD=3.93, $p=0.03$) และทนต่อการรับประทานอาหารอ่อนได้ไวกว่าอย่างมีนัยสำคัญ (mean difference 9.76 hours, SD=4.08, $p=0.02$) โดยไม่มีความแตกต่างของภาวะแทรกซ้อนในการวิเคราะห์ผู้ป่วยที่มีภาวะไส้ติ่งอักเสบแบบซับซ้อนในลักษณะกลุ่มย่อย ไม่มีความแตกต่างของผลลัพธ์หลังผ่าตัดอย่างมีนัยสำคัญ

สรุปผลการศึกษา: การเริ่มให้ทานอาหารโดยเร็วหลังผ่าตัดไส้ติ่งแบบลงแผลเล็ก สามารถลดระยะเวลาของภาวะลำไส้ไม่ทำงานหลังผ่าตัด และทนต่อการรับประทานอาหารอ่อนได้ไวกว่า โดยไม่ทำให้เกิดภาวะแทรกซ้อนหลังผ่าตัดเพิ่มขึ้น
