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Original Article / Özgün Makale

What is the optimal postoperative oral feeding timing protocol for thoracotomy patients? Prospective randomized clinical trial on postoperative complications

Torakotomi hastaları için en ideal ameliyat sonrası oral beslenme zamanlaması protokolü nedir? Ameliyat sonrası görülen komplikasyonlar hakkında ileriye dönük randomize klinik çalışma

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ABSTRACT

Background: This study aims to determine the optimal postoperative oral feeding initiating time with the lowest postoperative pulmonary complication rate in thoracotomy patients and compare cardiac and psychiatric complication rates caused by different feeding schemes.

Methods: The study included 107 consecutive patients (84 males, 23 females; mean age 53.9 years; range 17 to 81 years) planned to undergo lung resection via elective thoracotomy for both benign and malignant pathologies in a single institution during a time period of two years. Patients were prospectively randomized into three groups according to postoperative oral intake initiation time: oral intake was initiated on the postoperative sixth hour in group 1, 24th hour in group 2, and when bowel functions resumed in group 3. Groups were then compared in terms of postoperative complication rates.

Results: Groups were homogenous according to demographic properties. Twenty patients (18.7%) developed postoperative pulmonary complications: four (11.1%) in group 1, eight (22.2%) in each of groups 2 and 3. Median oral intake initiation time for group 3 was 47 hours (range 27 to 82 hours). There was no significant difference between the groups in terms of postoperative pulmonary and cardiac complications (p=0.358 and p=0.175, respectively). While postoperative incidence of delirium was significantly increased in group 3 (n=5, 14.3%, p=0.032), it was not observed in group 1 and it was observed in two patients (5.6%) in group 2. This complication was directly correlated with development of postoperative pulmonary complications (odds ratio=14.2; p=0.002).

Conclusion: Early (sixth hour) initiation of postoperative oral feeding is not related with increased pulmonary complications. On the contrary, early initiation may enable rapid recovery of postoperative mental and physical conditions, prevent psychiatric disorders, and reduce pulmonary complication rates. Thus this scheme can be administrated safely in all thoracotomy patients without potential risk for preoperative aspiration.

Keywords: Aspiration; complications; dietary management; pulmonary; thoracotomy.

ÖZ

Amaç: Bu çalışmada, torakotomi hastalarında en düşük ameliyat sonrası pulmoner komplikasyon oranı ile en ideal ameliyat sonrası oral beslenmeye başlangıç zamanı belirlenmeye çalışıldı ve farklı beslenme planlarının yol açtığı kardiyak ve psikiyatrik komplikasyon oranları karşılaştırıldı.

Çalışma planı: Çalışmaya iki yıllık bir süre boyunca tek bir kurumda hem benign hem malign patolojiler nedeni ile elektif torakotomi yolu ile akciğer rezeksiyonu yapılan 107 ardışık hasta (84 erkek, 23 kadın; ort. yaş 53.9 yıl; dağılım 17-81 yıl) dahil edildi. Hastalar ameliyat sonrası oral alım başlangıç zamanlarına göre üç gruba prospektif olarak randomize edildi: Oral alım grup 1'de ameliyat sonrası altıncı saatte, grup 2'de 24. saatte ve grup 3'te bağırsak fonksiyonları yeniden başladığında başlatıldı. Gruplar daha sonra ameliyat sonrası komplikasyon oranları açısından karşılaştırıldı.

Bulgular: Demografik özellikler bakımından gruplar homojen idi. Yirmi hastada (%18.7) pulmoner komplikasyonlar gelişti: Grup 1'de dört (%11.1), grup 2 ve 3'te sekizer (%22.2) hasta. Grup 3 için oral alım başlangıç zamanı ortancası 47 saat (dağılım 27-82 saat) idi. Ameliyat sonrası akciğere ait ve kardiyak komplikasyonlar açısından gruplar arasında anlamlı farklılık yoktu (sırasıyla, p=0.358 ve p=0.175). Grup 3'te ameliyat sonrası deliryum insidansı anlamlı şekilde artar iken (n=5, %14.3, p=0.032) grup 1'de hiç görülmedi ve grup 2'de iki hastada (%5.6) görüldü. Bu komplikasyon ameliyat sonrası pulmoner komplikasyon gelişimi ile doğrudan ilişkili idi (göreceli risk oranı=14.2; p=0.002).

Sonuç: Ameliyat sonrası ağızdan beslenmeye erken (altıncı saat) başlanması pulmoner komplikasyon artışı ile ilişkili değildir. Tam tersi, erken başlangıç ameliyat sonrası mental ve fiziksel durumların daha hızlı iyileşmesini sağlayabilir, psikiyatrik bozuklukları önleyebilir ve pulmoner komplikasyon oranlarını azaltabilir. Dolayısıyla, ameliyat öncesinde olası aspirasyon riski olmayan tüm torakotomi hastalarında bu plan güvenle uygulanabilir.

Anahtar sözcükler: Aspirasyon; komplikasyonlar; beslenme yönetimi; pulmoner; torakotomi.

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Postoperative pulmonary aspiration of gastric content is an increasingly renowned complication after thoracotomy for lung resection.[1]

The rationale of nil by mouth is to prevent postoperative nausea and vomiting, thus a possible aspiration.[2] There are controversies on the oral intake starting time after a general anesthesia operation. It has been shown that gag reflex is regained on second to sixth hour after extubation.[3] Other researchers have shown that after a long duration of anesthesia, tracheal aspiration risk is relatively higher, and they advocate that normal feeding must be started on postoperative day one to avoid aspiration and pulmonary complications.[4,5] In this study, we aimed to determine the optimal postoperative oral feeding initiating time with the lowest postoperative pulmonary complication (PPC) rate in thoracotomy patients and compare cardiac and psychiatric complication rates caused by different feeding schemes.

PATIENTS AND METHODS

The study was conducted with 108 consecutive patients (85 males, 23 females; mean age 53.9 years; range 17 to 81 years) planned to undergo lung resection via elective thoracotomy for both benign and malignant pathologies in Marmara University Medical Faculty Hospital, between June 2008 and May 2010. Based on their admission order, patients were prospectively randomized into three groups according to postoperative oral intake initiation time: oral intake was initiated on the postoperative sixth hour in group 1 (n=36), 24th hour in group 2 (n=36), and when bowel functions resumed in group 3 (n=36). One patient in group 3 did not want to continue fasting on his 28th hour and was excluded accordingly due to research committee's decision on consent withdrawal. Thus, the study was completed with 107 patients (84 males, 23 females; mean age 53.9 years; range 17 to 81 years) (Figure 1). The study protocol was approved by the Marmara University Medical Faculty Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient allocation was done by a single surgeon. Preoperative assessment included medical history (demographics, symptoms, and their duration), presence of comorbidities (pulmonary, cardiac, and metabolic), tobacco or alcohol habits, recent chest X-ray, electrocardiogram (ECG), spirometry, blood count, biochemistry and arterial blood gas analysis, with predictive perfusion scintigraphy and an echocardiogram, where indicated. All patients were operated via standard serratus-sparing posterolateral thoracotomy, by three consultant surgeons, whom were also blinded to the group allocation. Clinical data, as well as presence of postoperative complications, were recorded prospectively postoperatively.

Postoperative complications were defined as pulmonary (pneumonia, atelectasis requiring bronchoscopy, or acute respiratory failure), cardiac (arrhythmias or myocardial infarction, documented by ECG and/or necessary laboratory tests, and confirmed by a cardiologist), and psychiatric problems (anxiety, organic brain syndrome - cognitive disorder, or delirium). Psychiatric complications were assessed and diagnosed by an expert psychiatrist, called for a consultation over an atypical witnessed behavior or an illusion/hallucination of the patient. Diagnosis was made after confirmation of normal blood electrolyte levels and with the mini-mental state examination, the patient was revisited daily by the consultant, and was called for a minimum of six-months for clinical follow-up after discharge. Postoperative pneumonia was defined as *(i)* onset of new radiographic parenchymal infiltrates on routine postoperative daily X-rays, determined by the operating consultant surgeon, *(ii)* fever over 38 °C, and *(iii)* one of the following: increased C-reactive protein or leukocyte count within 24 hours (>10x10^9/L), purulent sputum, and positive blood or sputum culture (>10^7 cfu/mL).

Standard "nil-by-mouth from midnight" fasting policy was applied preoperatively. Patients were randomized into three groups with different timings of postoperative oral feeding initiation. Term "feeding" included administration of water and other liquids of unlimited volume, directly advanced to semi-solid foods subsequent to comfortable liquid intake without any delay, followed by a normal (solid) diet given for the next meal, under the supervision of a nurse or a resident. In case of excessive nausea or vomiting, intake would be postponed. Feeding was started on the postoperative sixth hour in group 1, on the 24th hour in group 2, and when the bowel sounds or flatus was present in group 3. All patients were given oral analgesics after postoperative day three.

Exclusion criteria included: *(i)* patients with any type of antibiotic usage one week preoperatively for any reason, or *(ii)* pre-existing pulmonary infection, documented clinically (purulent sputum or fever >38 °C) or radiologically; *(iii)* any patient in whom the routine cefazolin antibiotic prophylaxis was not possible due to drug allergy, or *(iv)* had a history of any previous gastric operation; *(v)* patients on neoadjuvant

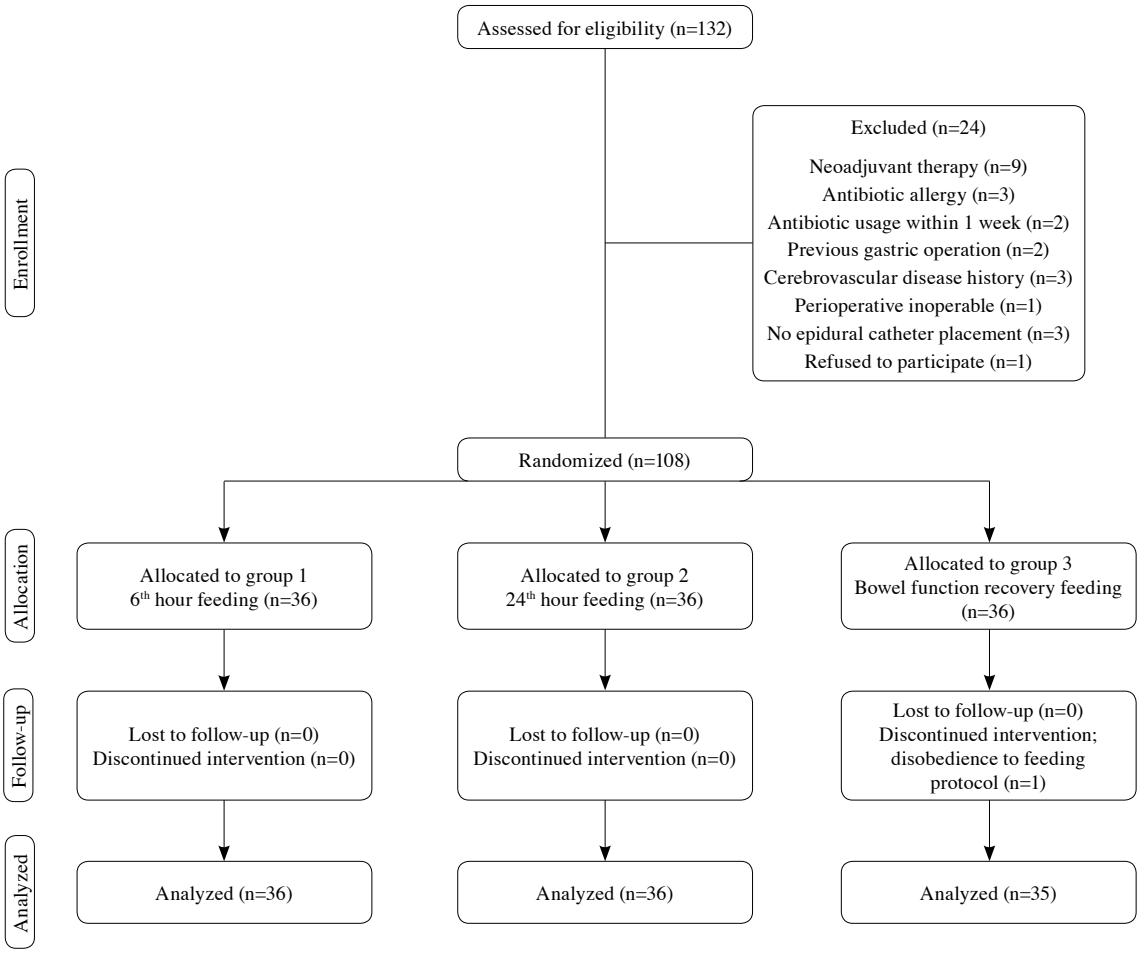

Figure 1. Consolidated standards of reporting trials flow diagram.

chemo/radiotherapy, *(vi)* under any medication possible to alter esophageal motility, or with a history of cerebrovascular disease or stroke because of increased aspiration risk; *(vii)* patients in whom preoperative thoracic epidural catheter placement was not achieved were not eligible for the study since they received different postoperative analgesics regimen which may influence the gastrointestinal motility; *(viii)* patients in whom the planned lung resection was cancelled due a to perioperative inoperability criterion, *(ix)* not strictly conforming the feeding timetable protocol, or *(x)* not willing to attend at all.

Table 1. Comparison of continuous variables among study groups

Variables	Group 1 (n=36)	Group 2 (n=36)	Group 3 (n=35)	
	Mean±SD	Mean±SD	Mean±SD	*p*
Age (years)	51.4±17.5	54.5±17.4	54.8±14.9	0.511
Smoking (pack years)	37.7±37.0	22.2±27.2	33.1±27.4	0.340
Forced expiratory volume in first second (L)	2.6±0.9	2.6±0.9	2.5±0.5	0.686
Forced expiratory volume in first second (%)	81.2±21.4	86.5±24.3	81.1±17.8	0.478
Forced vital capacity (L)	3.3±1.2	3.2±1.2	3.2±0.8	0.892
Forced vital capacity (%)	83.8±21.9	88.5±25.0	83.9±20.0	0.757
Anesthesia time (hours)	3.8±1.0	4.2±1.4	4.3±1.5	0.146
Intensive care unit stay (days)	2.0±4.8	3.1±5.5	1.9±1.6	0.535
Hospital stay (days)	7.5±4.99	8.9±6.5	10.8±15.8	0.511

SD: Standard deviation.

Statistical analysis

Normally distributed parametrical scale variables were reported as mean and standard deviation within 95% confidence interval and were compared using Student's t-test or analysis of variance. Mann-Whitney U test was used for non-parametrical variables. Categorical variables were presented as percentages with ranges and were assessed using Fisher's exact test or Pearson's chi-square. Odds ratio (OR) was used to quantify the risk of postoperative complication rates according to known patient variables. In this study, the maximum type I error was 0.05, and the level of significance was accepted as $p<0.05$. All analyses were performed using a registered MedCalc Statistical Software Package (MedCalc Software bvba, Belgium).

RESULTS

Of a total of 107 patients, 22 had benign pathology, while 85 underwent resection for malignant lesions. By means of continuous (Table 1) and categorical variables (Table 2), there were no statistically significant differences between groups. No significant nausea or vomiting leading to a patient not being able to start the diet at the assigned time point was seen. The median duration of nil-by-mouth for group 3 was 47 hours (range 27-82 hours).

Table 2. Comparison of categorical variables among study groups

Variables	Group 1		Group 2		Group 3		
	n	%	n	%	n	%	*p*
Gender							0.391
Male	27	75.0	31	86.1	26	74.3	
Female	9	25.0	5	13.9	9	25.7	
Smoking							0.394
Yes	6	16.7	8	22.2	3	8.6	
No	10	27.8	13	36.1	10	28.6	
Quitted	20	55.6	15	41.7	22	62.8	
Alcohol abuse							0.512
Yes	3	8.3	4	11.1	6	17.1	
No	33	91.7	32	88.9	29	82.9	
Hypertension							0.521
Yes	7	19.4	9	25.0	5	14.3	
No	29	80.6	27	75.0	30	85.7	
Diabetes							0.213
Yes	7	19.4	6	16.7	2	5.7	
No	29	80.6	30	83.3	33	94.3	
Cardiac disease							0.986
Yes	4	11.1	4	11.1	4	11.4	
No	32	88.9	32	88.9	31	88.6	
COPD							0.874
Yes	2	5.6	3	8.3	2	5.7	
No	34	94.4	33	91.7	33	94.3	
Operation type							0.469
Lobectomy/Bilobectomy	18	50.0	15	41.7	15	42.9	
Pneumonectomy	3	8.3	5	13.9	4	11.4	
Wedge or segmentectomy	12	33.3	11	30.6	7	20.0	
Extended resection	3	8.3	5	13.9	9	25.7	
Postoperative analgesia							0.277
Epidural	32	88.9	32	88.9	27	77.1	
Intravenous	4	11.1	4	11.1	8	22.9	
Pathology							0.132
Benign	11	30.6	7	19.4	4	11.4	
Malignant	25	69.4	29	80.6	31	88.6	

COPD: Chronic obstructive pulmonary disease.

Twenty patients (18.7%) developed PPCs: four (11.1%) in group 1, eight (22.2%) in group 2, and eight (22.9%) in group 3. Eleven patients with postoperative atelectasis resolved after flexible bronchoscopy and did not require additional invention, where six patients developed pneumonia and treated with susceptible antibiotics. One patient from each group (2.8%) progressed to respiratory insufficiency and required mechanical ventilation. Two of them died of septic shock on postoperative day 11 and 13, and the other was discharged on day 21. Although there was a lower complication proportion seen in group 1, the difference did not reach significance level (p=0.358).

Cardiac complications were observed in three (8.3%), four (11.1%), and eight (22.9%) patients within the groups, respectively (p=0.175). One patient in group 3 died of anterior myocardial infarction on postoperative day six.

The only significant difference between the groups was seen in the incidence of psychiatric complications: none in group 1, two (5.6%) in group 2, and five (14.3%) in group 3 (p=0.032). Prior to the study, none of these patients had medical history of any known psychiatric disorder or drug usage. The complication distribution is listed in Table 3.

In 16 patients (15.0%), epidural catheters were taken out and admission of intravenous (IV) analgesics was initiated earlier than the routine 48-hour duration on the early postoperative period, due to ineffectiveness. No significant difference between the PPC rates of the epidural group and the IV analgesics group was detected (17.6% vs 25.0%; p=0.48).

Variables significantly associated with PPCs were the coexistence of a psychiatric complication, the history of chronic obstructive pulmonary disease (COPD), and male gender. Five of seven (71.4%) patients with psychiatric complications developed PPC, while 15 of 100 (15.0%) patients without psychiatric complications had PPC (OR=14.2; p=0.002). These ratios were 14.7% vs. 2.7% in patients with or without history of COPD, respectively (OR=6.1; p=0.032). Postoperative pulmonary complication was present in 19 of 84 (22.6%) male patients, in contrast to one of 23 (4.3%) female patients (OR=6.4; p=0.036). Coexistence of diabetes or a cardiac disease history, operation duration, pathology of lesion, resection type, smoking history, or perioperative blood transfusion was not correlated with PPC occurrence. The examined variables possibly associated with pulmonary complications and their ORs are listed in Table 4.

DISCUSSION

Pulmonary complications are the most frequent complications seen after the operations performed under general anesthesia, caused by numerous factors summarized in Table 5, with an incidence of up to 50%;[3-8] majorly dependent to the impeded swallowing, traumatic discordance in pharyngeal structures, and alterations on the physiology of the gastrointestinal tract,[9-14] of which may last up to the postoperative 18th hour.[15,16] Postoperative pulmonary complication incidence of our study was 18.7%, which revealed that male gender, smoking history, coexistence of COPD, and psychiatric complication occurrence were the factors associated with higher risk for post-thoracotomy

Table 3. Comparison of complication rates among study groups

Postoperative complications	Group 1		Group 2		Group 3		
	n	%	n	%	n	%	*p*
Pulmonary*							0.358
No	32	88.9	28	77.8	27	77.1	
Yes	4	11.1	8	22.2	8	22.9	
Cardiac							0.175
No	33	91.7	32	88.9	27	77.1	
Yes	3	8.3	4	11.1	8	22.9	
Others**							0.025
No	31	86.1	26	72.2	20	57.1	
Yes	5	13.9	10	27.8	15	42.9	
Psychiatric***							0.032
No	36	100.0	34	94.4	30	85.7	
Yes	0	0	2	5.6	5	14.3	

* Pulmonary complications: Pneumonia, atelectasis or acute respiratory insufficiency; ** Other complications: Ileus, neurogenic bladder, ophthalmological, renal failure, and wound dehiscence; *** Psychiatric complications: Mood or anxiety disorders, delirium, non-affective psychoses.

Table 4. Odds ratios for presence of certain variables for postoperative pulmonary complications

Risk factors	Odds Ratio	95% CI	95% CI	
	Lower	Upper		*p*
Psychiatric complications	14.17	2.51	79.85	0.002
Chronic obstructive pulmonary disease history	7.00	1.43	34.31	0.022
Smoking history	6.46	1.10	37.92	0.037
Gender				
Male	6.43	0.81	50.87	0.036
Alcohol abuse	1.36	0.34	5.47	0.706
Blood transfusion	0.94	0.35	2.54	1
Cardiac disease	0.86	0.17	4.25	1
Diabetes	0.63	0.13	3.06	0.732
Hypertension	0.40	0.08	1.87	0.351

CI: Confidence interval.

pulmonary complication incidence; all in accordance with the current literature.

Numerous clinical trials have been conducted for building a feeding protocol for patients having surgical interventions under general anesthesia. Recently, there are some guidelines for preoperative fasting for patients of various clinical subtypes, different age groups, and operation types.[17,19] As "fast-track" operative managements and discharges are gaining popularity lately, researchers are concentrating more on shortening the postoperative fasting period, some even advocating that immediate oral intake increases postoperative comfort, without causing extra nausea or vomiting.[20-22] Latest meta-analyses give grade A recommendation for similar early postoperative resuming of drinking, both for adults and children with evidence level of 1++.[23,24]

In regard of these findings, we attempted to create a routine postoperative schedule for thoracotomy patients. Our data showed that fasting until recovery of bowel functions does not have beneficial outcomes on PPCs over early (sixth hour) oral feeding. On the contrary, it is significantly associated with increased resolution of postoperative psychiatric complications, possibly by causing electrolyte imbalance, which is found to be an important and significantly associated factor with PPC occurrence as well.[25]

Our study has some limitations. Randomizing patients according to their admittance order may have introduced a bias. Regardless of the numerical variance, the difference between PPC rates among our groups did not reach the significance level. In addition, despite the homogenous distribution (Table 2), enrolling patients with both malignant and benign pathologies may also be accounted as a limitation, because of potential systemic effects of malignancies on the esophageal motility. Moreover, lack of preoperative psychiatric assessment of each patient caused our correlation to lose power.

In conclusion, all patients without high potential risk for preoperative aspiration, such as due to gastric motility alteration by a preoperatively used drug, illness, or a previous operation, should be allowed to resume oral intake on the sixth hour, since it

Table 5. Risk factor classification of postoperative pulmonary complications[3,8,11,12]

Patient-based	Procedure-based
• General health condition (ASA score >2)	• General anesthesia
• Nutrition status	• Operation duration (>3 hours)
• Fluid balance	• Emergency operations
• Presence of COPD	• Thoracic or upper abdominal operations
• Smoking history (within last 8 weeks)	• Operation technique (endoscopic vs. open)
• Age	• Postoperative pain
• Obesity (BMI >27.5 kgm^{-2})	• Mucociliary activity interruption
	• Orogastric aspiration

ASA: American Society of Anesthesiologists; BMI: Body-mass index; COPD: Chronic obstructive pulmonary disease.

was not associated with postoperative pulmonary complications. It should also be kept in mind that patients developing postoperative psychiatric disorders need rigorous attention, as they are most likely to develop postoperative pulmonary complication as well.

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