ORIGINAL ARTICLE

Effect of Short-term vs Prolonged Nasogastric Decompression on Major Postesophagectomy Complications

A Parallel-Group, Randomized Trial

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Hypothesis: Controversy exists over the need for prolonged nasogastric decompression after esophagectomy. We hypothesized that early removal of the nasogastric tube would not adversely affect major pulmonary complications and anastomotic leak rates.

Design: Single-center, parallel-group, open-label, randomized (1:1) trial.

Setting: A tertiary referral cancer center with high esophagectomy volume.

Patients: One hundred fifty patients undergoing esophagectomy with gastric tube reconstruction.

Interventions: Either conventional nasogastric decompression for 6 to 10 days (75 patients) or early removal (48 hours) of nasogastric tube (75 patients) with stratification for pyloric drainage and anastomotic technique.

Main Outcome Measures: The primary (composite) end point was the occurrence of major pulmonary complications and anastomotic leaks. Secondary end points were the need for nasogastric tube reinsertion and patient discomfort scores. Analysis was performed on an intent-to-treat basis.

Results: No significant differences were seen in the occurrence of the composite primary end point of major pulmonary and anastomotic complications between the delayed (14 of 75 patients [18.7%]) and early (16 of 75 patients [21.3%]) removal groups, respectively ($P=.84$). Nasogastric tube reinsertion was required more often (23 of 75 patients [30.7%] vs 7 of 75 patients [9.3%]) in the early group ($P=.001$). Mean patient discomfort scores were significantly higher in the delayed (+1.3; 95% CI, 0.4-2.2; $P=.006$) than in the early removal group. Significantly more patients in the delayed removal group (26 of 75 patients [34.7%] vs 10 of 75 patients [13.3%] in the early removal group; $P=.002$) identified the nasogastric tube as the tube causing the most discomfort.

Conclusions: Early removal of nasogastric tubes does not increase pulmonary or anastomotic complications after esophagectomy. Patient discomfort can be significantly reduced by early removal of the nasogastric tube.

Trial Registration: Clinical Trials Registry of India Identifier: CTRI/2010/091/003023

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NASOGASTRIC DECOMPRESSION (NGD) after major abdominal surgery is considered standard practice in most centers. The purpose of NGD is to enable gastric decompression, prevent abdominal distension, decrease postoperative nausea and vomiting, reduce the chances of pulmonary aspiration and subsequent pneumonia, and rest the bowel, leading to earlier return of bowel function and consequently earlier discharge from the hospital.[1-3] Several randomized studies and systematic reviews[1-7] have challenged this dogma. Nasogastric decompression is standard practice after esophageal resection in most centers because it is expected to reduce the incidence of esophagogastric anastomotic leakage by preventing overdistension of the gastric conduit. Most esophageal surgeons have been reluctant to move away from this tradition because of the considerable morbidity of anastomotic leaks after esophagectomy. However, a contrarian view is that the use of prolonged NGD may increase the incidence of postoperative pulmonary com-

See Invited Critique at end of article

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plications by promoting aspiration. The discomfort to patients due to prolonged NGD has not been well studied but is expected to be considerable. Several authors have attempted to reduce discomfort to patients by innovative methods of gastric tube decompression, including retrograde jejunogastric,[8] gastrostomy,[9] and pharyngostomy[10,11] tubes. Few studies have evaluated the role of NGD after esophagectomy. Small retrospective[12] and randomized studies[13,14] have shown discordant results.

Our hypothesis was that early removal of the nasogastric tube would not adversely affect pulmonary complications and anastomotic leak rates. Therefore, we performed a randomized study to evaluate whether prolonged NGD was necessary after esophageal resection, the effect of early nasogastric tube (NGT) removal on postoperative pulmonary and anastomotic complications, and discomfort to patients attributable to the NGT.

METHODS

The study was conducted during a 1-year period in a tertiary referral cancer center with a high esophagectomy volume (a mean of 165 operations for esophageal cancer annually). Ethics approval was obtained from the institutional review board before recruitment, and the study was conducted in accordance with the principles of the Declaration of Helsinki. The study was performed as per published guidelines (International Committee of Medical Journal Editors) and is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement. The trial was registered with the Clinical Trials Registry of India (CTRI-2010 003023).

TRIAL DESIGN AND PARTICIPANTS

All patients undergoing total esophagectomy with gastric tube reconstruction through the posterior mediastinal route were considered for the study. Eligible patients had biopsy-proven squamous or adenocarcinomas of the esophagus or gastroesophageal junction without distant metastases and did not have unresectable local disease. Inclusion criteria were patients who were fit for esophageal resection and underwent transthoracic or transhiatal esophagectomy with gastric tube reconstruction. Patients undergoing total laryngopharyngoesophagectomy, partial esophagogastrectomy, or colonic reconstruction and patients not extubated by the second postoperative day were excluded. Written informed consent was obtained from patients preoperatively.

RANDOMIZATION

We randomly assigned these patients (1:1) to either conventional NGT decompression for 6 to 10 days (delayed group) or early removal of the NGT at 2 days (early group). Central telephonic randomization was performed by the Central Research Secretariat of the institute with stratification for pyloric drainage (finger fracture vs no drainage) and anastomotic technique (stapled vs hand-sewn). Sequence generation was performed using a computer-generated sequence of random numbers with permuted blocks. Members of the surgical team telephonically conveyed the details of the patient and the stratification factors to the Central Research Secretariat staff from where the assignment to the 2 groups was made, thereby ensuring allocation concealment. Patients, caregivers, and outcome assessors were not masked to the allocation.

INTERVENTIONS

All operations were performed with the patients under general anesthesia with or without epidural analgesia. The surgery was performed by or under the direct supervision of consultant thoracic surgeons with extensive experience in esophageal surgery. Surgical residents in training were permitted to perform the surgery to keep the trial pragmatic and mimic a real-life situation. Thoracic esophageal mobilization and mediastinal lymphadenectomy were performed by open thoracotomy or video-assisted thoracoscopic surgery. The abdominal part of the surgery was performed by laparotomy, gastric tube reconstruction was performed using linear staplers, and the conduit was brought up to the neck through the posterior mediastinal route. A cervical esophagogastric anastomosis was performed by either hand-sewn or stapled (linear) techniques. A 14F NGT (Romson's Surgicals) was placed across the anastomosis in the stomach tube for decompression. Standard postoperative management protocols were followed in both groups to avoid potential bias. All patients were mobilized early, began early enteral feeding through jejunostomy tubes, and were given aggressive chest physiotherapy. Randomization was performed on the second postoperative day, and the NGT was removed immediately (early removal group) or between the sixth and 10th postoperative days after a contrast esophagogram (late removal group). Contrast esophagography was performed in all patients between the sixth and 10th postoperative days unless leaks had previously manifested clinically. A range between the sixth and 10th postoperative days was specified because logistics did not permit contrast esophagography to be performed on weekends and hospital holidays. A questionnaire regarding tube-related discomfort was administered to patients at the time of NGT removal. This questionnaire had 2 parts: a numerical rating score for discomfort due to the NGT and relative discomfort among the different tubes postoperatively.

OUTCOMES

The primary (composite) end point was the incidence of pulmonary complications and anastomotic leaks. Secondary end points included the need for NGT reinsertion, patient discomfort scores, and perioperative mortality. Pulmonary complications were classified as those managed conservatively, those requiring bronchoscopic toilet, those requiring tracheostomy, or those that were life threatening. Only infectious pulmonary complications were considered; noninfectious complications, such as pulmonary embolism, were not included. All anastomotic leaks diagnosed clinically and radiologically were classified as leaks. Any complication causing delayed discharge from the hospital was classified as a major complication. The prespecified criteria for NGT reinsertion were gastric tube dilatation apparent on chest radiograph, repeated episodes of vomiting, postoperative ileus, or anastomotic leaks. The NGTs were reinserted carefully by surgical residents without specialized radiologic or endoscopic guidance. Patient discomfort scores were marked at the time of NGT removal on a graded numerical rating scale (0 for no discomfort and 10 for worst possible discomfort imaginable). Patients also responded to a simple question at the time of NGT removal: Which of the following tubes caused the maximum discomfort in your postoperative period: intercostal drain, NGT, jejunostomy tube, urinary catheter, and/or epidural catheter? All outcome measures were defined a priori, and no changes occurred during the trial.

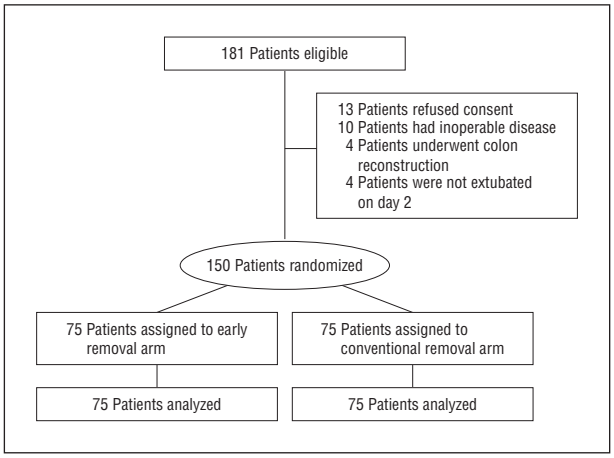

Figure. CONSORT diagram showing participant flow in the trial.

STATISTICAL ANALYSIS

A formal sample size calculation was not performed. No interim analyses were planned or performed during the study. Data were entered into a statistical software package (SPSS statistical software for Windows, version 14; SPSS Inc). We used χ^2 or Fisher exact tests to compare categorical data and the *t* test or the Mann-Whitney test for continuous data. All reported *P* values are 2-sided, and values below .05 were considered statistically significant. No subgroup analyses were planned, and no adjustment was done for multiple comparisons. Analysis was performed on an intent-to-treat basis.

RESULTS

The trial profile is shown in the **Figure**, and the baseline demographic and clinical characteristics of patients are given in **Table 1**. Almost all variables that are known to affect the primary and secondary outcomes of interest were comparable in the 2 groups. All randomized patients were analyzed for all outcomes studied as per the original assignment (intent-to-treat basis). The median day of removal of the NGT was postoperative day 2 (interquartile range [IQR], 2-2 days) in the early group and day 7 (IQR, 6-8.3 days) in the delayed removal arm. The mean (SD) NGT output in the early group (78.0 [10.3] mL) was similar to the delayed group (82.9 [6.3] mL) (*P*=.69). The mean (SD) output on the day of NGT removal was also similar in the 2 groups (77.9 [13.4] mL vs 63.4 [12.1] mL; *P*=.42).

Analysis of the composite primary outcome revealed no difference between the incidence of major pulmonary complications and anastomotic leaks in the 2 groups (**Table 2**). When the composite end point was split into its components, no differences were found in the incidence of any pulmonary complication, major pulmonary complications, or anastomotic leaks between the 2 groups. The need for reintubation and ventilation was similar in the early (5 of 75 patients [6.7%]) and the delayed (6 of 75 patients [8.0%]) groups (*P*=.77).

Analysis of the secondary outcomes revealed that 23 of 75 patients (30.7%) in the early removal arm required reinsertion of the NGT compared with 7 of 75 (9.3%) in the conventional removal arm (*P*=.001). Reasons for NGT reinsertion included gastric tube dilatation and repeated episodes of vomiting (**Table 3**). Within the early removal group, the mean (SD) NGT output on the day of removal was similar in patients who required reinsertion (80.6 [19.1] mL) and those who did not (76.6 [17.5] mL) (*P*=.89). No failures or complications related to reinsertion of the NGT occurred. The mean patient discomfort score was higher in the delayed removal group than the early removal group (+1.3, 95% CI, 0.4-2.2; *P*=.006). Significantly more patients in the delayed removal arm (26 patients [34.7%]) identified the NGT as the tube causing the most discomfort compared with the early removal arm (10 patients [13.3%]) (*P*=.002). Perioperative mortality was similar in the 2 arms (6 patients [8.0%] in both groups) (*P*>.99). Hospital stay was similar in the early (median, 12 days; IQR, 9-17 days) and delayed (median, 12 days; IQR, 10-17 days) groups (*P*=.18).

Table 1. Baseline Demographic and Clinical Characteristics of Randomized Patients[a]

Characteristic	Early Removal Arm (n = 75)	Delayed Removal Arm (n = 75)
Age, mean (range), y	53.4 (25-79)	56.7 (34-80)
Sex		
Male	51 (68.0)	51 (68.0)
Female	24 (32.0)	24 (32.0)
Tumor location		
Upper	1 (1.3)	0
Middle	29 (38.7)	27 (36.0)
Lower third	45 (60.0)	48 (64.0)
Neoadjuvant treatment		
None	39 (52.0)	37 (49.3)
Chemotherapy	35 (46.7)	37 (49.3)
Chemoradiation therapy	1 (1.3)	1 (1.3)
Pulmonary comorbidity		
None	31 (41.3)	30 (40.0)
Mild	37 (49.3)	39 (52.0)
Moderate	7 (9.0)	6 (8.0)
ASA status		
1	58 (77.3)	56 (74.7)
2	17 (22.7)	19 (25.3)
Surgical approach		
Transthoracic	57 (76.0)	60 (80.0)
Transhiatal	18 (24.0)	15 (20.0)
Transthoracic approach		
Open	35 (46.7)	34 (45.3)
VATS	21 (28.0)	23 (30.7)
VATS converted	1 (1.3)	3 (4.0)
Lymphadenectomy		
3-Field	16 (21.3)	19 (25.3)
2-Field	41 (54.7)	41 (54.7)
Abdominal	18 (24.0)	15 (20.0)
Pyloric drainage		
None	40 (53.3)	35 (46.7)
Pyloric finger fracture	35 (46.7)	40 (53.3)
Anastomotic technique		
Stapled	73 (97.3)	73 (97.3)
Hand sewn	2 (2.7)	2 (2.7)

Abbreviations: ASA, American Society of Anesthesiologists; VATS, video-assisted thoracoscopic surgery.
[a] Data are presented as number (percentage) of patients unless otherwise indicated.

Table 2. Primary Outcomes of the Study Patients

Outcome	No. (%) of Patients: Early Removal Arm (n = 75)	No. (%) of Patients: Delayed Removal Arm (n = 75)	*P* Value
Composite end point (major pulmonary complications and anastomotic leaks)	16 (21.3)	14 (18.7)	.84
Any pulmonary complication	18 (24.0)	16 (21.3)	.85
Major pulmonary complication	10 (13.3)	9 (12.0)	>.99
Anastomotic leaks	8 (10.6)	6 (8.0)	.78

Table 3. Indications for Nasogastric Tube Reinsertion

Indication	No. (%) of Patients: Early Removal Arm (n = 75)	No. (%) of Patients: Delayed Removal Arm (n = 75)
Gastric tube dilatation	9 (12.0)	3 (4.0)
Repeated vomiting	8 (10.7)	3 (4.0)
Anastomotic leaks	4 (5.3)	0
Postoperative ileus	2 (2.7)	1 (1.3)

COMMENT

Major postoperative complications after esophagectomy were similar in patients whose NGT was removed early compared with conventional delayed removal. We chose these primary outcomes because these are the most common complications after esophageal resection and are ones that could be influenced by early removal of the NGT. These reasons are also why most esophageal surgeons are reluctant to shorten the duration of NGD. Equivalence in these outcomes would be of clinical importance and would also be the major factors that affect immediate postoperative outcomes. Alternative outcomes, such as passage of flatus and recovery of bowel function, are more subjective and prone to bias. Some surgeons have attempted to achieve gastric decompression without NGTs by introducing pharyngostomy tubes and retrograde jejunogastric tubes for decompression.[8-11] However, these procedures add to the complexity of an already complex surgical procedure. To our knowlegde, our study with 150 patients is by far the largest randomized study to date and adds considerable support to the hypothesis that early removal of the NGT is safe and does not adversely affect the postoperative outcome.

Previous studies[1-7] on the need for NGD after abdominal surgery have found that routine postoperative NGD may not be necessary. There is also some evidence[1,2] to suggest that prolonged postoperative NGD may actually increase the incidence of pulmonary aspiration and consequent infection. Moreover, NGTs are known to cause considerable discomfort to patients. These potential benefits of shortening the duration of NGD may be offset if other complications increase after esophageal resection. Gastroparesis is not uncommon after esophagectomy and could cause distension of the gastric conduit, which in turn could increase the chances of pulmonary aspiration and anastomotic leaks. Major pulmonary complications and anastomotic leaks are the most common and most dreaded complications after esophagectomy and are directly related to postoperative mortality. Esophageal surgeons would need strong evidence that these complications are not increased by shortening the duration of NGD.

A previous retrospective study[12] found that NGD could be omitted without an adverse effect on postoperative outcomes. However, this study was small (only 26 patients had no NGD) and the evidence was retrospective. Two small randomized studies have attempted to address this question. In one of these studies,[13] 34 patients were randomized to 3 arms: the first with free nasogastric drainage, the second with sump-type drainage, and the third with no NGD. The no-NGD arm had significantly higher tracheal acid aspiration and increased respiratory complications. In the other study,[14] 40 patients were randomized to NGD or no NGD with time to return of normal bowel activity as the primary end point. No differences were found in the incidence of nausea, vomiting, abdominal distension, pulmonary complications, and perioperative mortality, but an unexplainable increased incidence of anastomotic leaks in the NGD arm was found.

Before starting our trial, we debated whether to compare routine NGD with no NGD or shortened NGD. We decided on the latter because most esophageal surgeons would find it unacceptable to completely eliminate NGD from their perioperative protocols. We considered the modality and timing of assessing patient discomfort due to the NGT. In the absence of a formal, validated questionnaire or score, we settled on a simple patient-reported score similar to the visual analog score for pain assessment. Recording patient response in both groups on the same day (sixth to 10th postoperative days) would have biased the scores because the early group would have given lower scores because the NGT was removed several days earlier. Hence, we decided to record the scores on the day the tube was removed to ensure optimum recall of the discomfort due to the tube.

Although some surgeons might believe that the NGT reinsertion rate of 30.7% in the early removal group was high, the corollary is that more than two-thirds of patients were relieved of the discomfort of the NGT by the second postoperative day. Moreover, conventional delayed removal of the NGT did not guarantee that patients would not require reinsertion because 9.3% of patients in this group also required NGT reinsertion. Our personal experience with NGT reinsertion has been that it is safe and easy with the active cooperation of a fully conscious patient. It would be a value judgment of the surgeon to decide between early and delayed removal of the NGT based on these data. We have followed a protocol of early removal of the NGT subsequent to our trial in our unit with similar indications for reinsertion. We have had no complications directly related to NGT reinsertion even outside the trial.

Our study has some limitations. The lack of a formal sample size calculation and the limited number of patients in the study are obvious drawbacks. We decided

on an arbitrary sample size to make the accrual realistic and to enable the study to be completed within a reasonable period. The only 2 other randomized studies[13,14] evaluating the same issue had 40 or fewer patients. Patient discomfort due to NGT reinsertion and the vomiting and gastric distension in patients who required NGT reinsertion were not recorded. However, the lack of objective measures to evaluate these outcomes made this assessment difficult. The design of the study precluded masking either the caregiver or the patient. Potential assessor bias in interpretations of pulmonary complications cannot be ruled out. However, our primary end points were classified based on the intervention performed to treat the complication, thereby minimizing this bias. Using a composite end point as the primary outcome has its limitations, especially if the components of the composite end point are disparate or have discordant results. However, the most important complications after esophagectomy are pulmonary and anastomotic, with both affecting postoperative outcomes. In our study, the results of the composite end point and the individual components produced similar results.

Our results are generalizable across all patients undergoing esophagectomy because the eligibility criteria were liberal. All operations were performed by experienced surgeons and residents in training, mimicking a real-life situation. We had no complications directly related to reinsertion of the NGT in patients who had early removal. Fear of possible disruption of the anastomosis due to this intervention is one of the reasons why esophageal surgeons play it safe and retain the NGT for a relatively longer period. Our study adds to the overall experience that NGT reinsertion in the early postoperative period is safe and requires no special expertise. Our current protocol is early removal of the NGT unless there is evidence of aspiration or gastric tube dilatation clinically or on the routine plain chest radiograph. With these criteria, our current rate of NGT reinsertion has reduced further (data not shown).

In summary, our study found that early removal of the NGT after esophagectomy is safe and does not adversely influence the postoperative outcome. Patient discomfort can be significantly reduced by early removal of the NGT.

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REFERENCES

1. Nelson R, Tse B, Edwards S. Systematic review of prophylactic nasogastric decompression after abdominal operations. *Br J Surg*. 2005;92(6):673-680.
2. Nelson R, Edwards S, Tse B. Prophylactic nasogastric decompression after abdominal surgery. *Cochrane Database Syst Rev*. 2007;(3):CD004929. doi:10.1002/14651858.CD004929.pub3.
3. Pessaux P, Regimbeau J-M, Dondéro F, Plasse M, Mantz J, Belghiti J. Randomized clinical trial evaluating the need for routine nasogastric decompression after elective hepatic resection. *Br J Surg*. 2007;94(3):297-303.
4. Cheatham ML, Chapman WC, Key SP, Sawyers JL. A meta-analysis of selective versus routine nasogastric decompression after elective laparotomy. *Ann Surg*. 1995;221(5):469-478.
5. Vermeulen H, Storm-Versloot MN, Busch ORC, Ubbink DT. Nasogastric intubation after abdominal surgery: a meta-analysis of recent literature. *Arch Surg*. 2006;141(3):307-314.
6. Petrelli NJ, Stulc JP, Rodriguez-Bigas M, Blumenson L. Nasogastric decompression following elective colorectal surgery: a prospective randomized study. *Am Surg*. 1993;59(10):632-635.
7. Nathan BN, Pain JA. Nasogastric suction after elective abdominal surgery: a randomised study. *Ann R Coll Surg Engl*. 1991;73(5):291-294.
8. Puri V, Hu Y, Guthrie T, et al. Retrograde jejunogastric decompression after esophagectomy is superior to nasogastric drainage. *Ann Thorac Surg*. 2011;92(2):499-503.
9. Sato T, Takayama T, So K, Murayama I. Is retention of a nasogastric tube after esophagectomy a risk factor for postoperative respiratory tract infection? *J Infect Chemother*. 2007;13(2):109-113.
10. Katsoulis IE, Livingstone JI, Sagor GR. Tube pharyngostomy: a simple method for prolonged intubation of the foregut following oesophagogastric surgery. *Dig Surg*. 2006;23(5-6):292-295.
11. Rueth NM, Lee N, Groth SS, et al. Pharyngostomy tubes for gastric conduit decompression. *J Thorac Cardiovasc Surg*. 2010;140(2):373-376.
12. Nguyen NT, Slone J, Wooldridge J, Smith BR, Reavis KM, Hoyt D. Minimally invasive esophagectomy without the use of postoperative nasogastric tube decompression. *Am Surg*. 2009;75(10):929-931.
13. Shackcloth MJ, McCarron E, Kendall J, et al. Randomized clinical trial to determine the effect of nasogastric drainage on tracheal acid aspiration following oesophagectomy. *Br J Surg*. 2006;93(5):547-552.
14. Daryaei P, Vaghef Davari F, Mir M, Harirchi I, Salmasian H. Omission of nasogastric tube application in postoperative care of esophagectomy. *World J Surg*. 2009;33(4):773-777.