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Efficacy of cola ingestion for oesophageal food bolus impaction: open label, multicentre, randomised controlled trial

E G Tiebie,^{1,2} E P Baerends,³ T Boeije,⁴ P G Frankenmolen,⁵ H Lameijer,⁶ W van den Berg,⁷ K J van Stralen,⁸ M L Ridderikhof,⁹ A J Bredenoord¹

For numbered affiliations see end of the article

Correspondence to: E G Tiebie e.g.tiebie@amsterdamumc.nl (ORCID 0009-0003-7869-9181)

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ABSTRACT

OBJECTIVE

To determine the efficacy and safety of cola in resolving complete oesophageal food bolus impaction.

DESIGN

Open label, multicentre, randomised controlled trial.

SETTING

Emergency departments of five Dutch hospitals at the secondary and tertiary level, between 22 December 2019 and 16 June 2022.

PARTICIPANTS

51 adults presenting with complete oesophageal food bolus impaction, defined as a sudden inability to pass saliva after consumption of foods. Patients who ingested meat that contained bones, and patients with an American Society of Anesthesiologists (ASA) physical status classification of IV or higher were excluded.

INTERVENTIONS

28 patients in the intervention group were instructed to consume 25 mL cups of cola at intervals up to a maximum total volume of 200 mL. 23 patients in the control group awaited spontaneous passage. In either group, if complete resolution of symptoms did not occur, endoscopic removal was performed following current guidelines: within 6 hours for patients with complete obstruction, and within 24 hours for partial obstruction. In case of complete resolution of symptoms, elective diagnostic endoscopy was required.

MAIN OUTCOME MEASURES

Improvement of oesophageal food bolus obstruction as reported by patients (ie, aggregate of complete and partial passage), and evaluation of complete passage. The secondary outcome was any intervention related adverse event.

RESULTS

Cola did not have a meaningful effect on the improvement of food bolus obstruction (17/28 (61%) intervention v 14/23 (61%) control; odds ratio 1.00, 95% confidence interval 0.33 to 3.1; relative risk reduction 0.0, 95% confidence interval -0.55 to 0.36; P>0.99). Complete passage was reported more often in the intervention group but this difference was not significant (12/28 (43%) intervention v 8/23 (35%) control; odds ratio 1.4 (0.45 to 4.4); relative risk reduction -0.23 (-1.5 to 0.39); P=0.58). No severe adverse events occurred. However, six (21%) patients in the intervention group experienced temporary discomfort after drinking cola.

CONCLUSIONS

In this study, cola consumption did not lead to a higher rate of improvement of complete oesophageal food bolus impaction. Given the lack of adverse events in the treatment group and some events of resolution after treatment, cola might be considered as a first line treatment, but should not delay any planning of endoscopic management.

TRIAL REGISTRATION

Netherlands Trial Register (currently International Clinical Trial Registry Platform) NL8312.

Introduction

Oesophageal food bolus impaction is a common medical emergency. During the holidays, healthcare personnel are faced with an increased number of patients presenting with food bolus impactions from copious meals and tachyphagia, resulting in an added workload burden on emergency and endoscopy staff.¹ Food bolus impaction is not only uncomfortable but can also lead to risk of a variety of complications, including oesophageal perforation and aspiration. Underlying oesophageal pathology is nearly always present, with structural abnormalities and eosinophilic oesophagitis being the most common diagnoses. Impacted food boluses most often consist of meat.²⁻⁴

The American and European societies for gastrointestinal endoscopy (ASGE and ESGE) currently recommend emergent endoscopy (within 6 hours) for complete oesophageal food bolus obstructions and urgent endoscopy (within 24 hours) for partial food bolus obstructions. Both guidelines allow medical management before endoscopy without delaying endoscopic removal.⁵⁻⁶ Various drug treatments have been evaluated previously, such as glucagon,⁷⁻⁸ nitrates,⁹ and butyl scopolamine,¹⁰⁻¹¹ but with limited or conflicting studies on their use. Previous small studies have reported success rates of cola ingestion

WHAT IS ALREADY KNOWN ON THIS TOPIC

Emergent endoscopy, which is invasive and expensive, is the current preferred treatment for complete oesophageal food bolus impaction

Guidelines allow pre-endoscopic medical treatment if it does not delay endoscopy

Previous cohort studies and case series have reported the use of cola to resolve oesophageal food bolus impactions in 59-100% of patients

WHAT THIS STUDY ADDS

In this randomised controlled trial, findings suggest that cola does not have a meaningful effect on complete oesophageal food bolus impaction

The results could support a pre-endoscopic trial of cola, given the lack of adverse events in the intervention group and some events of resolution after cola ingestion

ranging from 59% to 100%, with no reported short term adverse events.¹²⁻¹⁵ Carbon dioxide is thought to be responsible for the mechanism of clearing impaction, or disimpaction, by effervescent agents. However, the exact mechanism is unclear. A study using cola in healthy volunteers without food bolus impaction found a decrease in lower oesophageal sphincter pressure. This decreased pressure could facilitate food bolus passage.¹⁶

Our objective was to compare the efficacy of cola consumption as pre-endoscopic treatment for patients presenting to the emergency department with complete oesophageal food bolus impactions, with the current standard of care according to ESGE guidelines (ie, no pre-endoscopic treatment while waiting for emergent endoscopic removal). Cola is cheap and globally available. If proven efficacious, cola treatment could prevent emergency department visits and emergent endoscopies because patients can drink it at home or at the primary healthcare level. To our knowledge, this randomised controlled trial is the first conducted on this topic.

Methods

Study design and setting

This open label, multicentre, randomised controlled trial was conducted at five Dutch hospitals: one tertiary and four secondary level facilities. The study was approved by the Amsterdam University Medical Centre medical ethics committee (METC 2019_035) and registered in the Netherlands Trial Register (currently International Clinical Trial Registry Platform; ID NL8312) before recruitment of the first participant. We conducted the study in accordance with the principles of the Declaration of Helsinki, the Dutch Medical Research Involving Human Subjects Act, and good clinical practice guidelines.

Participants

Participants aged 18 years or older who presented to the emergency department with a complete food bolus impaction were eligible for inclusion in the study. We diagnosed complete food bolus impaction using predefined criteria, including the sensation of food being lodged between the oropharynx and epigastrium during

attempted swallowing, and a complete and sudden inability to pass saliva. Only patients with a soft food bolus obstruction (ie, without bones) and an American Society of Anesthesiologists (ASA) physical status classification of I, II, or III were included in the study.

Exclusion criteria included use of conservative treatments before presentation, such as glucagon, nitrates, nifedipine, or carbonated beverages. We also excluded individuals with a visible food bolus on oral inspection or at a severe risk of aspiration (Glasgow Coma Scale <14 or previous relevant aspiration).

Randomisation

Emergency physicians and registrars were responsible for enrolling patients in the emergency department after providing verbal explanation and obtaining written informed consent. We performed randomisation using an electronic data capture system (Castor Electronic Data Capture) that complied with good clinical practice. Patients were stratified by centre with a 1:1 allocation ratio.

Interventions

Participants in the intervention group were instructed to consume regular Coca-Cola (Coca-Cola company, Atlanta, GA) in an upright or sitting position. We poured cola from uncooled cans into standard measuring cups to ensure that each sip contained 25 mL. Patients ingested cola at one minute intervals in the presence of a nurse or doctor up to a maximum of 200 mL (eight sips). If four sips proved ineffective, a 10 minute pause followed before continuing the one minute interval protocol for an additional four sips. The patients were positioned near a sink in case of regurgitation or drooling. They were allowed to discontinue the intervention at any time. Patients in the control group did not receive any pre-endoscopic treatment.

Endoscopy

Timing of the endoscopic procedure was based on the passage of the food bolus, in accordance with the ESGE guideline.⁴ If we observed complete passage, elective diagnostic endoscopy was recommended to detect underlying pathology. Endoscopic removal took place within 24 hours for partial passage, and within 6 hours

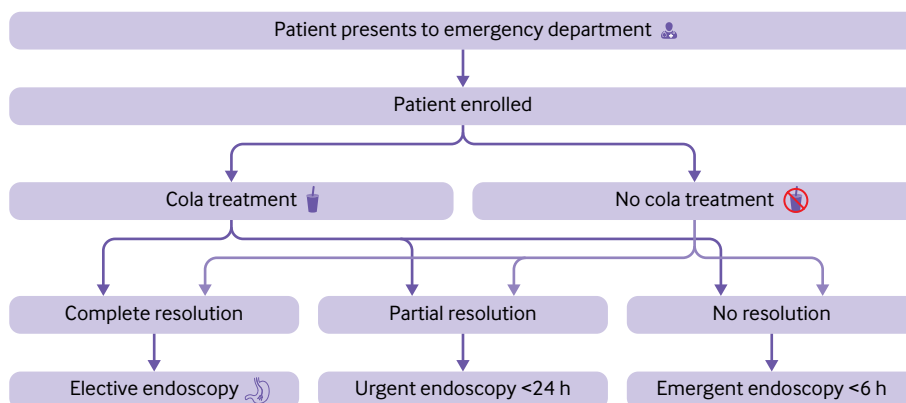


Fig 1 | Study protocol

for the absence of passage (fig 1). During endoscopic removal, underlying pathology was also examined and biopsies were obtained when indicated.

Outcomes

The primary outcome of the study was the improvement of oesophageal food bolus obstruction, which was the aggregate of complete and partial passage. We evaluated complete passage separately because of the clinical significance: this group does not need emergent or urgent endoscopy. Complete passage was characterised by complete symptom resolution and the ability to pass saliva. Partial passage was defined as an improvement in symptoms, including the passage of saliva, but not reaching complete symptom resolution. No passage meant no symptom improvement and an ongoing inability to pass saliva. This outcome was evaluated in the emergency department before patients were either moved to the endoscopy unit or discharged home.

The secondary outcome was any intervention related adverse event, such as oesophageal perforation, mucosal laceration, bleeding, aspiration, or any other adverse event requiring treatment or resulting in a prolonged stay in hospital.

Methods of measurements

We collected sociodemographic and health status data in the emergency department using questionnaires. All relevant data pertaining to oesophageal food bolus obstructions were recorded, such as the nature of the food, duration of the impaction, any previous food bolus obstructions, and known oesophageal pathology.

In the intervention group, we registered the exact amount of cola consumed. In both the intervention and control groups, symptom resolution and adverse events were registered. We retrieved endoscopic data after the procedure and assessed the occurrence of early postprocedural adverse events. These events were graded according to the Adverse Events Gastrointestinal Endoscopy (AGREE) classification.¹⁷ One week after discharge from the emergency department, we contacted all patients via telephone to evaluate any late adverse events.

Statistical methods

We hypothesised that cola would be successful in 50% of patients, based on previous non-randomised studies on cola treatment reporting food bolus passage in 59-100% of instances.¹²⁻¹⁵ We estimated a 10% chance of spontaneous passage in the control group, simply awaiting emergent endoscopy. Assuming a power of 0.8 and a 5% significance level, a sample size of 40 patients was required. We increased the sample size to 50 to cope with loss to follow-up and reduce chances of non-normality. We created a database in Castor EDC (Castor Electronic Data Capture, Amsterdam, 2019, <http://www.castoredc.com>). Statistical analyses were performed using IBM SPSS statistics version 28.

Analyses were based on intention to treat, which was equal to as-treated analyses because every patient received the treatment to which they were randomly assigned. We used Fisher’s exact test (two sided) to compare the efficacy between the groups and considered P values <0.05 to be significant. We

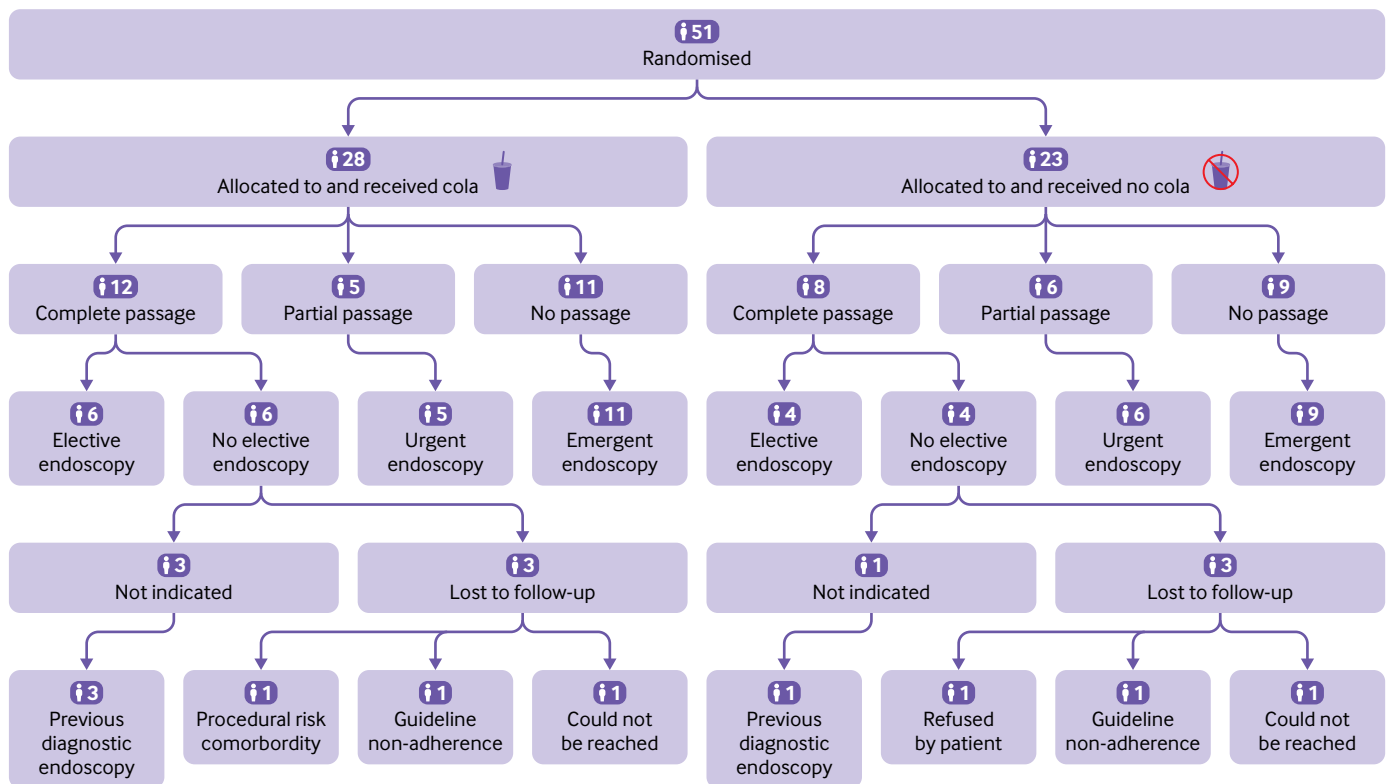


Fig 2 | CONSORT participant flow diagram

Characteristic	Intervention group (n=28)	Control group (n=23)
Patient characteristics		
Age (years)		
Median	58	54
Range	23-86	22-82
Sex		
Male	19 (68)	16 (70)
Female	9 (32)	7 (30)
Previous food bolus impaction	22 (79)	15 (65)
Known oesophageal disorder	11 (39)	6 (26)
Eosinophilic oesophagitis	2	1
Malignancy	2	0
Reflux oesophagitis/Barrett's oesophagus	2	2
Schatzki's ring	2	2
Impaction characteristics		
Nature of food bolus		
Meat	22 (79)	19 (83)
Other	6 (21)	4 (17)
Patient interventions before admission to hospital		
Drinking water	18 (78)	17 (77)
Trying to vomit	9 (39)	7 (32)
Eating other food	6 (26)	4 (18)
Other	4 (23)	3 (14)
Impaction duration before presentation at emergency department (h:min)		
Mean	5:2	5:14
Range	0:15-20:30	0:25-20:15

calculated odds ratios with 95% confidence intervals via SPSS and risk reduction rates with 95% confidence intervals via <http://www2.ccrb.cuhk.edu.hk/web>.

Patient and public involvement

Patients or the public were not involved in the design, conduct, or reporting plans of our research. Patient involvement is not common in this type of research. Food impaction typically occurs unexpectedly in a heterogeneous group of patients, and there is no patient advocacy group representing these patients. Individual results of the intervention were discussed with participants in the emergency department or after endoscopy.

Results

Patient baseline characteristics

Between 22 December 2019 and 16 June 2022, we included 51 patients (28 in the intervention group; 23 patients in the control group). Figure 2 shows the participant flow diagram of this study. At baseline, the

patient characteristics were comparable in both groups (table 1). Median age was 58 years in the intervention group and 54 years in the control group. Both groups had a predominance of male patients. Most food bolus impactions were caused by meat. Other food items that caused impaction included bread, fries, or sauerkraut.

Primary outcome

Improvement of food bolus impaction was observed in 61% in both study groups (odds ratio 1.00 (95% confidence interval 0.33 to 3.1); risk reduction rate 0.0 (95% confidence interval -0.55 to 0.36); $P>0.99$; table 2). Complete food bolus passage occurred in 43% (n=12) of patients in the intervention group versus 35% (n=8) in the control group (1.4 (0.45 to 4.4); -0.23 (-1.5 to 0.39); $P=0.58$; table 2). Partial passage of the food bolus was reported in 18% (n=5) of patients in the intervention group and in 26% (n=6) in the control group. In both the intervention and control group, two patients reported partial resolution of symptoms in the emergency department, but

Table 2 | Primary study outcome—patient reported improvement of food bolus impaction. Data are presented as number (%) of participants unless stated otherwise

Primary outcome	Intervention group (n=28)	Control group (n=23)	Odds ratio (95% CI)	RRR (95% CI)	Fisher exact P value
Complete or partial passage v no passage					
Complete or partial passage of food bolus as reported by patient	17 (61)	14 (61)	1.0 (0.33 to 3.1)	0.00 (-0.55 to 0.36)	>0.99
No passage of food bolus as reported by patient	11 (39)	9 (39)	1 (reference)	1 (reference)	—
Complete passage v partial or no passage					
Complete passage of food bolus as reported by patient	12 (43)	8 (35)	1.4 (0.45 to 4.4)	-0.23 (-1.5 to 0.39)	0.58
Partial or no passage of food bolus as reported by patient	16 (57)	15 (65)	—	—	—

CI=confidence interval.

Table 3 | Endoscopic findings and proportion of complete passage per finding. Data are number of participants

Endoscopic finding	Intervention group (n=22)	Complete food bolus passage/total	Control group (n=19)	Complete food bolus passage/total
Benign stricture	2	1/2	1	1/1
Ear, nose, and throat area	1	1/1	0	—
Eosinophilic oesophagitis	6	1/6	4	1/4
Malignancy	1	0/1	0	—
Schatzki's ring	6	2/6	5	2/5
Diaphragmatic hernia	4	—	2	—
Reflux oesophagitis	2	—	3	—
Normal endoscopy	4	0/4	5	0/5

subsequent endoscopy found complete passage of the food bolus. In all patients reporting ongoing complete obstruction, a food bolus was found during emergent endoscopy.

In the control group, patients who reported complete passage in the emergency department all did so within 40 minutes of randomisation; those patients in the cola group completed passage within 45 minutes. Endoscopic removal of the food bolus was performed within the recommended timeframe in accordance with the ASGE and ESGE guidelines in all patients with partial or no passage.

Secondary outcomes

Adverse events in the emergency department

We did not observe any severe adverse events in either the intervention or the control group. However, as an adverse event, we found that six patients (21%) in the intervention group experienced increased discomfort or pain after consuming cola, without the need for intervention or prolonged stay in the emergency department. One of these patients passed the food bolus subsequently. The amount of cola that was consumed in this group varied between 25 mL and 125 mL. The average total amount consumed in this group was 50 mL (2 sips), compared with 118 mL (4.7 sips) sipped by patients who did not experience any pain or discomfort (n=21).

Complications detected during endoscopy

According to the AGREE classification, no adverse events occurred in patients receiving emergent or urgent endoscopic procedures. Two patients in the intervention group had a mucosal lesion. In the control group, four patients had mucosal lesions, one vomited during endoscopy, and one had minimal bleeding. We cannot assess with certainty whether mucosal lacerations or bleeding were caused by the food bolus impaction, by cola treatment, or by the endoscopic procedure. None of these findings led to an intervention or prolonged hospital stay.

Subgroups

Nature of food bolus

Of 41 patients with meat impaction, the rate of complete food bolus passage reported by the patient in the emergency department was 41% (9/22) in the intervention group and 37% (7/19) in the control group (P>0.99). Of 10 participants who ingested other food, complete food bolus passage was seen in 50%

(3/6) of patients in the intervention group and 25% (1/4) of patients in the control group (P=0.57).

Duration of impaction before presentation to the emergency department

Mean duration of impaction before presentation to the emergency department was similar in both groups with a wide range in time. Twelve patients had impaction for less than 1 hour, eight in the intervention group and four in the control group. Within this subgroup with a short duration of impaction, we found complete resolution in five (63%) patients in the intervention group versus one (25%) in the control group (odds ratio 5.0; 95% confidence interval 0.34 to 72.8; P=0.55). Of ten patients who had an impaction for more than 10 hours (five in each study group), only one patient in the control group experienced complete resolution before endoscopy (0.27; 0.01 to 8.5; P>0.99).

Endoscopic findings

In the intervention group, 22 (79%) of 28 patients received emergent, urgent, or elective endoscopy versus 19 (83%) of 23 patients in the control group (fig 2). In 32 (78%) of 41 patients, endoscopy revealed oesophageal pathology (table 3), showing multiple abnormalities in some instances. Not all findings were related to the food impaction. The most common diagnosis was a Schatzki's ring (27%), followed by eosinophilic oesophagitis (24%). In total, nine (22%) of 41 patients did not have any oesophageal pathology.

Ten of 20 patients who reported complete resolution of their symptoms never underwent diagnostic endoscopy. For four patients, this diagnostic endoscopy was not indicated because they were known to have oesophageal pathology. The other six patients were lost to follow-up for different reasons (fig 2). Of the patients in whom endoscopy revealed no pathology, none passed their food bolus in the emergency department. We did not detect any differences in findings between the intervention and control groups, or when comparing the subgroup of patients who experienced passage of the bolus with the subgroup that did not.

Volume of cola consumption

In the intervention group, the quantity of cola ingested varied from 25 mL to 200 mL. Patients who did not pass the food bolus ingested an average of 117.5 mL (4.7 sips), with four patients in this group ingesting the maximum amount of 200 mL specified by our protocol. Patients with partial passage ingested an average of

135 mL (5.4 sips), and those who successfully passed the food bolus ingested an average of 80 mL (3.2 sips). Most patients in this last group who successfully passed the food bolus (n=5) ingested only 50 mL (2 sips).

Discussion

Principal findings

To our knowledge, this randomised controlled trial is the first studying the efficacy and safety of cola as treatment for food bolus impaction. It showed that in both the intervention and control groups, 61% of patients with complete oesophageal food bolus impaction improved partially or completely in the emergency department. Cola consumption did not lead to a higher rate of improvement. Complete passage was more frequently reported in the cola group than in the control group, but the difference was not significant. No adverse events related to cola use were reported, apart from discomfort.

The high rate of symptom resolution in the control group, and the fact that all control patients who reported complete passage did so within 40 minutes of randomisation, were unexpected outcomes. We do not think it is likely that the lack of effect from cola was dose related. Several patients in the intervention group who were unable to pass their food bolus did consume the maximum amount of cola specified by our protocol.

Comparison with other studies

Previous studies sparked our curiosity for this festive holiday drink owing to impressive disimpaction rates of 59-100%.¹²⁻¹⁵ Our trial reported a lower disimpaction rate, which suggests that those higher success rates were, at least in part, due to inherent bias associated with retrospective cohort studies.

Strengths and limitations

Our trial had several strengths. Randomisation successfully achieved balanced baseline characteristics among participants, while the multi-hospital setting contributed to increased generalisability. We had no missing data for the primary outcome measure or deviations from the study protocol. The trial did have some limitations. The design was not blinded and the sample size was relatively small, which limited the statistical power to explore subgroups and precluded us from drawing definitive conclusions on the safety of cola treatment.

Furthermore, six (12%) patients with complete passage of the food bolus in the emergency department did not receive the recommended elective diagnostic endoscopy. Some patients refused, some were lost to follow-up, and one 76-year-old patient's endoscopy was not arranged owing to perceived lack of benefit. These deviations from protocol had no impact on our primary outcome, but prevented us from detecting any underlying causes.

Implications for healthcare

We do not recommend implementing cola as standard treatment for complete oesophageal food bolus

obstruction in guidelines. However, without delaying endoscopic management, healthcare providers could discuss a trial of cola treatment with patients because of the non-significant but positive result when regarding complete passage only. Furthermore, we found no notable adverse events in our trial, but our study was underpowered to detect safety signals. Current guidelines recommend follow-up in all instances of food bolus impaction, as well as those with spontaneous passage. Our study supports the need for follow-up, since we found pathology in 78% of patients during endoscopic follow-up.

Future research

The benefit of cola could be investigated further in early or partial oesophageal food bolus impactions, also considering data collection at primary healthcare level. In our study, patients with a short duration of impaction before presentation at the emergency department had a higher likelihood of successfully passing the food bolus with cola treatment. However, the size of this subgroup was insufficient to draw a reliable conclusion. We would like to caution the public around the holidays that as yet, no quick and pleasant treatment has been proven to resolve food bolus impactions after copious meals.

AUTHOR AFFILIATIONS

¹Department of Gastroenterology and Hepatology, Amsterdam Gastroenterology and Metabolism, Amsterdam University Medical Centres, PO Box 22660, 1100 DD Amsterdam, Netherlands

²Department of Emergency Medicine, Spaarne Gasthuis, Haarlem, Netherlands

³Department of Emergency Medicine, Victoria Hospital, Wynberg, Cape Town, South Africa

⁴Department of Emergency Medicine, Dijklander Hospital, Hoorn, Netherlands

⁵Department of Emergency Medicine, OLVG hospital, Amsterdam, Netherlands

⁶Department of Emergency Medicine, Medisch Centrum Leeuwarden, Leeuwarden, Netherlands

⁷Department of Emergency Medicine, Rode Kruis hospital, Beverwijk, Netherlands

⁸Spaarne Gasthuis Academy, Spaarne Gasthuis, Haarlem, Netherlands

⁹Department of Emergency Medicine, Amsterdam University Medical Centres, Amsterdam, Netherlands

Contributors: EPB and TB conceptualised the intervention. EPB, TB, EGT, and AJB designed the trial. EGT was responsible for the day-to-day running of the trial, data collection, and project administration. AJB supervised the project. EGT, TB, MLR, HL, PGF, and WvdB assisted recruitment and data collection. EGT and PGF undertook trial follow-up. EGT and KJvS performed data and statistical analysis. EGT and TB prepared the figures and tables. EGT and EPB drafted the manuscript with input from all authors. All authors approved the final manuscript. EGT is the guarantor and accepts full responsibility for the work and the conduct of the study, had access to the data, and controlled the decision to publish. The corresponding author (EGT) attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The study was approved by the Amsterdam University Medical Centre Medical Ethics Committee (METC 2019_035) and prospectively registered in the Netherlands Trial Register (currently International Clinical Trial Registry Platform) ID NL8312.

Data sharing: De-identified patient data and the full dataset with low risk of identification are available on reasonable request from the corresponding author (eg, tiebie@amsterdamumc.nl).

The lead author (EGT) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: There are no plans to communicate the trial results to the study participants, but individual results of cola were discussed with patients after endoscopy. The results will be disseminated through an open access publication at *The BMJ*, via <https://colatrial.nl> and conference presentation.

Provenance and peer review: not commissioned; externally peer reviewed.

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