‘Cola for oesophageal food bolus impaction’

Cola Trial

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Cola for Oesophageal Food Bolus Impaction (Cola Trial)

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
ASGE	**American Society for Gastrointestinal Endoscopy**
DSMB	**Data Safety Monitoring Board**
ED	**Emergency department**
ESGE	**European Society of Gastrointestinal Endoscopy**
IC	**Informed Consent**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
NFU	**Nederlandse Federatie van Universitair Medische Centra**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Cola as a treatment option for complete oesophageal food bolus obstruction has been promulgated for more than 20 years. Cola has been advocated as safe for patients in whom endoscopic removal of a food bolus is judged to be too risky. However, evidence on safety and efficacy of cola as initial treatment is lacking. The current guidelines recommend an emergent endoscopy for removal of the food bolus. This treatment gives discomfort and risk of aspiration and perforation. If cola were successful in removal of the food bolus, this would greatly improve patient comfort and health care utilisation, since cola is cheap and globally available.

We hypothesize that cola can resolve a substantial percentage of complete oesophageal obstructions.

Objective: To assess the efficacy and safety of cola as the initial treatment of complete oesophageal food bolus impactions.

Study design: a multi-centre randomised clinical trial

Study population: Adult patients with symptomatic complete oesophageal food bolus impaction

Intervention: patients in the cola-arm will drink 25 millilitre sips of Coca-Cola with an interval of 1 minute and a maximum of 8 sips.

Main study parameters/endpoints: the percentage of complete or partial resolution of the oesophageal food bolus obstruction after drinking cola. We also evaluate intervention complications.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Drinking cola during complete oesophageal obstruction can be uncomfortable, however no significant complications have been reported in previous studies on cola use. Patients in the control group will be treated following current guidelines, so for them there will be no burden or extra risk.

1. INTRODUCTION AND RATIONALE

Oesophageal food bolus impaction presentations are commonly seen in the emergency department (ED), with an estimated annual incidence rate of 13 per 100,000 persons.[1] These patients are often acutely uncomfortable, drooling and gagging, and at risk for a variety of complications including oesophageal perforation and aspiration. Males are overly represented. Other risks include: older age, edentulousness, psychiatric disorders and alcohol intoxication.[2,3]

Oesophageal pathology is nearly always present,[4] with strictures and eosinophilic esophagitis being the most common abnormalities.[1,5] Other causes include oesophageal webs, malignancies and motility disorders.[4]

Current guidelines of the American and European Societies for Gastrointestinal Endoscopy (ASGE and ESGE) recommend emergent endoscopy for complete oesophageal food bolus obstructions and timely endoscopy for partial food bolus obstructions.[5,3]

Disadvantages of emergent endoscopic removal include: discomfort for the patient whilst waiting for the procedure; discomfort during endoscopy since adequate sedation is not given per current procedural sedation guidelines to reduce aspiration risk; risk of aspiration due to a non-fasted state; emergent health care utilisation with associated ED and gastroenterologist expenses.

Both guidelines do also allow for pre-endoscopy medical management so long as it does not delay endoscopic removal[3,5]. A variety of non-endoscopic medications and interventions are described in the current medical literature, all with limited or conflicting studies on their use.[4,6] Examples include: butyl scopolamine,[7,8] glucagon,[9,10] benzodiazepines,[11] calcium channel blockers,[12] nitrates,[13,14] meat tenderizers (firmly discredited)[15] and effervescent drinks like cola.

Cola as a treatment option has been promulgated for more than 20 years[16]. In practice, we experience that Cola treatment is used often by general practitioners. Cola has been advocated as safe for patients in whom endoscopic removal of a food bolus is judged to be too risky.[17,18] However, evidence on safety and efficacy is lacking.

The largest two published series to date describe its use in only five patients. [16,17]

One small case series detailed six attempts using cola in five patients and reported a 100% resolution rate within 24 hours[16]. Another more recent case series described cocktails of pancrelipase (Creon 10,000 IU) dissolved in 30 mL of Coca-Cola in five patients and reported either resolution or easier successful post-intervention endoscopy[17].

In our own multicentre retrospective case series (published in the African Journal of Emergency Medicine), cola had a 59% success rate when given in the ED (n=22). No short-term adverse events were recorded for patients who had been successfully treated with cola. During one of the endoscopic removals (4.5%), a small mucosal laceration was noted at the site of meat impaction. This mucosal tear was within the expected range of adverse events following removal of an oesophageal food bolus, but we cannot exclude that cola contributed to this self-limited complication.

2. OBJECTIVES

Primary objective: to assess the efficacy of cola as the initial treatment of complete oesophageal food bolus impactions.
Secondary objective: to evaluate the intervention complications.

3. STUDY DESIGN

This is a multi-centre randomised clinical trial in which treatment with cola while waiting for emergent endoscopic removal will be compared to the standard treatment according to the current ESGE guidelines: no pre-endoscopic treatment while waiting for emergent endoscopic removal. Timing of endoscopy will be minimally affected by this study: for both study arms, endoscopic removal will be planned 30 minutes after being enrolled in the study. In patients who are not included in the study, endoscopy may be planned immediately after seeing the physician. The occurrence of emergent endoscopy may be affected by this study: in the case of successful cola treatment or spontaneous food bolus passage while awaiting endoscopy, the patient no longer requires emergent endoscopic removal. Elective diagnostic endoscopy however will still be required to search for underlying oesophageal diseases (unless this has been done recently), per current ESGE clinical guidelines.[5]

Figure 1 displays the study protocol.

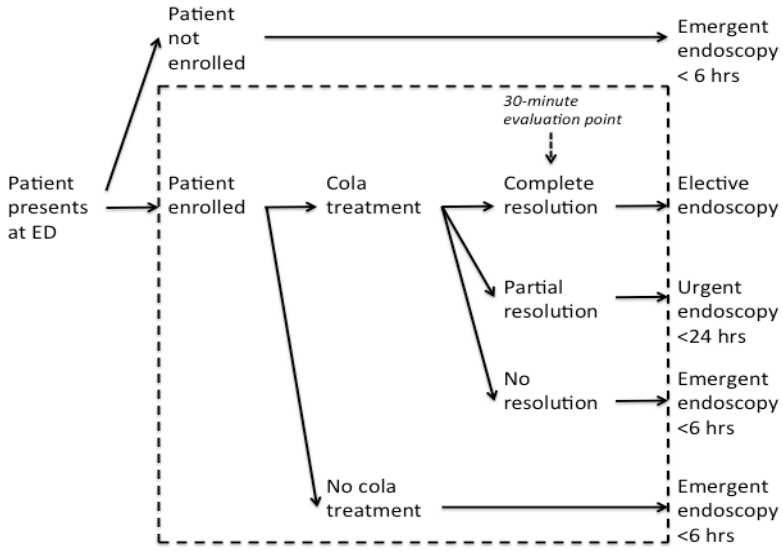

Figure 1. Flow chart for patients who present to the emergency department with a complete oesophageal food bolus obstruction. The dashed box displays the study protocol. Endoscopy criteria are according to the European Society of Gastroenterology guidelines. Emergent endoscopy: within 6 hours. Urgent endoscopy: within 24 hours. Elective endoscopy: no time constraint. ED: emergency department.

4. STUDY POPULATION

4.1 Population (base)

Adult patients with symptomatic complete oesophageal food bolus impaction

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Presence of a complete oesophageal food bolus impaction, as manifested by
  - The sensation of food stuck between the oropharynx and the epigastrium, while attempting to swallow
  - The inability to swallow saliva
- Impaction of soft food (boneless)
- Age >17 years
- Signed written informed consent

4.3 ASA class I, II or IIIExclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- A trial of cola or another carbonated beverage before coming to hospital
- Other pre-endoscopic treatment having been given in-hospital or pre-hospital (such as nifedipine, glucagon, nitrates, butyl scopolamine, benzodiazepines, calcium channel blockers or other)

Impaction of non-food items or food known to contain bones or fish bones

- Visible food bolus upon oral inspection
- Significant aspiration risk: reduced consciousness (GCS<14) or significant aspiration in previous medical history.

4.4 Sample size calculation

Due to a lack of previous data on this subject, we calculated sample size based on our retrospective case series that found a 59% success rate (n=22). We hypothesized that cola will be successful in 50% of patients. Based on judgment alone, we posited a 10% chance of spontaneous passage in those not receiving cola, simply awaiting emergent endoscopy. Assuming a power of 0.8 and a 5% significance level means that a minimal cola intervention group size of 20 is required to make meaningful conclusions on cola's value in treating complete oesophageal food bolus impaction. We increased the group size to 25 to cope with loss to follow-up and to decrease chances of non-normality. We therefore aim to enroll a total of 50 patients.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

In this study Coca-Cola will be used as follows:

Canned Coca-Cola will be kept uncooled in an appropriate place at the Emergency Department. . For every new patient, a new can will be opened.

The patient will be given a bowl or will be placed by the sink because of likely regurgitation and drooling. Access to suctioning will be ensured. The patient will be asked by the treating physician or emergency medicine nurse to swallow a 25ml sip of Coca-Cola from a standard medication measuring cup. The patient will always maintain an upright (sitting or standing) position. They will be asked to wait for 1 minute and if unsuccessful, to continue swallowing 25ml sips at 1-minute intervals. If still unsuccessful after 4 sips, they will 'rest' for 10 minutes in an upright position and then resume 15mins after the initial sip, repeating the same protocol. If unsuccessful after the second series of 4 sips, the protocol will be discontinued. In total, the patient will drink a maximum of 200mls of cola. Dependant of the crowding at the Emergency Department, it is not always possible to let the patient drink cola under the supervision of a nurse or physician. Therefore, in some cases the patient will be asked to keep track of time theirselves.

There are no previous studies that provide protocols for administering cola to patients with a food bolus impaction. In one case report, a patient with food bolus impaction and achalasia drank 50-100mls of Coca-Cola every 12h, in small sips, on the first day, followed by 100mls every 6hrs on the second day.[18] In a recent case series, five patients were given cocktails of pancrelipase (Creon 10.000IU) dissolved in 30mls of Coca-Cola. This was administered via a nasogastric tube.[17] In the other case series, cola was administered to five patients but details on cola use are lacking.[16] The above protocol is therefore based on our own experience with 22 cases of cola use in soft food bolus impactions published in the African Journal of Emergency Medicine.

6. METHODS

6.1 Study parameters/endpoints

6.1.1 Main study parameter/endpoint

Improvement of oesophageal food bolus obstruction, defined as either complete or partial resolution:

- Complete resolution:
  - Complete symptom resolution *and*
  - The ability to swallow saliva.
- Partial resolution:
  - Improvement in symptoms, but not disappearance *and*
  - The ability to swallow saliva.

If patients meet the above criteria, they no longer require emergent endoscopic treatment.

Note:

If the patient feels that their obstruction has resolved completely and the entire food bolus has passed, this is a *complete* resolution of a complete obstruction, for which the ESGE guidelines recommend elective diagnostic endoscopy.

If the patient is able to pass saliva after treatment, but still has the feeling that some food is 'stuck' in their oesophagus, they have *partial* resolution of their complete obstruction. Therefore, they are now considered to have a *partial* food bolus obstruction. According to the ESGE guidelines, there is no need for emergent endoscopic treatment in patients with a partial food bolus obstruction who can pass saliva, but they do require urgent endoscopy within 24hrs.

6.1.2 Secondary study parameters/endpoints

Intervention complications, defined as:

- oesophageal perforation or

- mucosal laceration or
- bleeding or
- aspiration or
- any other complication requiring treatment, leading to a prolonged ED stay or requiring hospitalization.

In the case of treatment success, emergent endoscopy or other diagnostic tests will not be performed to check for the above complications, unless the treating physician decides that this is indicated, i.e. because the patient is symptomatic.

6.2 Randomisation, blinding and treatment allocation

Six centres will participate in the study: AMC, Dijklander Ziekenhuis location Hoorn, Rode Kruis ziekenhuis, OLVG location East and West and Medisch Centrum Leeuwarden. Each centre will have an Emergency Physician as site investigator. Patients who present to the ED with food bolus impaction will be approached for the study. Patients should be diagnosed with complete oesophageal food bolus impaction using the predefined criteria:

- The sensation of food stuck between the oropharynx and the epigastrium, while attempting to swallow
- The inability to swallow saliva

All eligible patients will be given verbal explanation of the study by the treating physician. Each patient will receive a patient information brochure about the study and an informed consent form for participation. Patients will be given sufficient time to read the information and ask questions. Before any study procedures or randomisation is initiated the patient must sign the informed consent form.

When participants are recruited for the study, the time to consider participation in the study is limited because of the urgent nature of their presenting complaint. When the diagnosis of complete oesophageal food bolus obstruction is made by the doctor, the European Society of Gastrointestinal Endoscopy (ESGE) clinical guidelines recommend emergent endoscopic removal, preferably within 2 hours but at the latest within 6 hours (strong recommendation, low quality evidence). The ESGE guidelines allow for medical management of food bolus impactions, as long as this does not delay endoscopy (strong recommendation, low quality evidence).[5] Therefore, the gastroenterology department must be contacted as soon as possible in order to allow for scheduling of the urgent endoscopy. We will give sufficient time for the patient to consider participation, read the patient information letter and ask questions.

If the patient decides not to participate, he or she will undergo regular treatment consisting of keeping nil-per-mouth until endoscopy.

Once the patient has signed the informed consent form, randomisation will be done using Castor and is stratified for each centre, so that the number of patients treated with cola or without cola is similar for each centre. The randomisation for the two treatments will be 1:1.

6.3 Study procedures

In this study, no extra invasive procedures will be performed. Patients in the cola arm of the study will drink Coca-Cola as extra treatment. Patients in both arms of the study will be treated following current guidelines. For all patients, two questionnaires will be filled in. The following will be recorded:

Baseline

At baseline, the following will be recorded for all patients in both study arms:
Gender, age, nature of food bolus, impaction duration, time of presentation to the ED, remedies tried before coming to hospital, whether a GP was contacted and what advise they gave, at how many centimetres below the suprasternal notch the patient indicates the location of the bolus (if able to indicate), previous history of impactions (including number), previous endoscopic procedures and diagnoses.

During treatment

For all patients (both study arms), the following will be recorded:

- When the patient has passed the food bolus:

  Time of bolus passage, whether the bolus passed distally or came out orally, whether the patient thinks there is complete or partial resolution of the bolus, whether the patient aspirated, bled, still experiences pain/discomfort after passage or experiences dyspnoea. Booking of follow-up elective diagnostic endoscopy must be recorded. If this is deemed unnecessary by the gastroenterologist on call, the reason why.

- When the patient has not passed the food bolus 30 minutes after enrolment (i.e. at the end of the study protocol):

  Whether the patient aspirated, bled, still experiences pain/discomfort or feels dyspnoeic and whether the patient is still unable to pass fluids and saliva.

For the patients in the cola arm of the study only, the following will be recorded:
Time of first sip of cola, how many sips in total, total amount drunk in millilitres.

In the endoscopy suite

The following information will be extracted from the endoscopy report by the site investigators: Presence, nature and location of food bolus. Manoeuvres and techniques required to dislodge the bolus. Time of bolus passage. Oral or distal passage. Complications (oesophageal perforation, mucosal laceration, bleeding, aspiration or any other complication) seen before removal and again after removal. Endoscopic diagnosis. Treatment advice, if any.

General follow up

Patients will be contacted by telephone to check for the occurrence of adverse events after discharge from the hospital after one week.

Patients who will have passed their food bolus pre-endoscopically will not need urgent endoscopy. They will however, per current guidelines, need elective diagnostic endoscopy, unless they are known to the department of gastroenterology and the gastroenterologist on call decides that endoscopy is not indicated in the patient. Results of this elective diagnostic endoscopy will be followed up through the endoscopy report.

6.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

6.5 Replacement of individual subjects after withdrawal

Withdrawn subjects will be replaced, in order to include a total of 50 patients.

6.6 Follow-up of subjects withdrawn from treatment

Patients leaving the study will not be followed up, since they will receive the standard treatment following the current guidelines. Follow up will done by the gastro-entologist.

6.7 Premature termination of the study

The investigators, mainly the principal investigator, will monitor efficacy and safety data of the study. The study can be terminated early because of clear harm only. Because the results of our retrospective cola series and other series described above are promising and severe adverse events have not been recorded thus far, it is unlikely that this study will be terminated prematurely.

The stopping regulation will be based on the occurrence of severe complications, SAEs, associated with the treatment. After each inclusion of 20 participants the study investigators will discuss the data and review the stopping regulations.

The incidence of complications during endoscopic removal is normally around 0-5%.[5]

Because larger series on cola treatment are lacking at the moment, the incidence of cola-related SAEs is unknown. If the incidence of SAEs in the cola group exceeds 10%, the study will be terminated prematurely.

SAEs are defined as follows: death, oesophageal perforation, aspiration or bleeding requiring hospitalisation or any other adverse event leading to hospital admission.

7. SAFETY REPORTING

7.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

7.2 AEs, SAEs and SUSARs

7.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to [the investigational product / trial procedure/ the experimental intervention]. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

7.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

All serious adverse events will be reported through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs

that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

7.3 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

8. STATISTICAL ANALYSIS

We aim to perform an intention to treat analysis. After testing for normality using the Kolmogorov-Smirnov test, the two treatment arms will be compared with an unpaired T-test or Mann Whitney U-test. We will then compare primary and secondary categorical outcomes using the Chi-square test or Fisher's exact test.
Randomisation will be done using envelops and is stratified for each participating centre.

9. ETHICAL CONSIDERATIONS

9.1 Regulation statement

This study will be conducted according to the principles of the latest version of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

9.2 Recruitment and consent

Patients will be recruited at the Emergency Department. Patients will get verbal explanation by the treating physician and a patient information letter. The patient should sign the informed consent form. They will be given sufficient time s to consider their decision to participate.

9.3 Benefits and risks assessment, group relatedness

There are some risks with oesophageal food bolus impaction and endoscopic removal of the impacted foods. However, these risks are not increased during participation of this study. Although this is not explicitly mentioned in any guideline, cola is often used already by general practitioners and emergency room physicians. This trial thus basically randomizes between two currently existing practise methods. There is thus no increased risk in participation, as patients can be offered both treatments outside the trial as well.

No complications have been reported in previous studies on cola use. In our own retrospective case series (n=22), no adverse events were reported in patients treated with cola successfully. During one of the endoscopic removals however (4.5%), a small mucosal laceration was noted at the site of meat impaction. The mucosal tear was within the expected range of adverse events following removal of an oesophageal food bolus.

A few more studies have been done on the use of other effervescent agents. In one, a combination of glucagon, water and E-Z gas resulted in 69% clearance in 48 attempts.[19] One complication was detected via a water-soluble oesophagogram: a minor mucosal laceration. In two other studies, a mixture of tartaric acid and sodium bicarbonate was used. The first showed a 100% success rate without adverse events (n=8).[20] The second had a 65% success rate and described one mucosal tear (n=26).[21] A last series with a combination of carbonated soda water and barium sulphate suspension resolved the impaction in 80% (n=20).[22] One complication was noted: a slight laryngeal aspiration of barium suspension in an 89-year old patient with impaction at the level of the cricopharyngeal sphincter.

Following the NFU risk classification chart, we consider the risk of complications of cola treatment low and the degree of damage low/moderate. We classify the study as: negligible risk. The most argument for this is that endoscopic removal and cola treatment are both performed in routine clinical care.

9.4 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO.

The sponsor (also) has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO). This insurance provides cover for damage to research subjects through injury or death caused by the study.
The insurance applies to the damage that becomes apparent during the study or within 4 years after the end of the study.

10. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

10.1 Handling and storage of data and documents

The data of the subjects are coded in order of participation. The site investigators will code the data of the subjects included in their hospital. They will import the data in a database in

Castor. This data will be coded beforehand. Site investigators can only see the data of their own subjects. Only the head investigator and the coordinating investigator have access to the key to the code. Qualified authorities can get insight into code and data, but only when accompanied by the investigators. Data will be stored for 15 years after closure of the trial.

10.2 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

10.3 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

10.4 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.
The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.
In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.
Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

10.5 Public disclosure and publication policy

The trial will be registered in the Netherlands Trial Register. Regardless of the outcome of the study, its results will be offered to a peer reviewed scientific journal and submitted for presentation at a medical conference.

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