Buscopan (Hyoscine Butylbromide) In The Management Of Food Bolus Obstruction In Oesophagus: Randomised Controlled Trial

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Citation

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Abstract

Objectives: To assess the efficacy of buscopan (Hyoscine Butylbromide) in the management of food bolus obstruction of the oesophagus.

Setting: Two district general hospitals in UK.

Study Design: Single blinded randomised controlled study.

Participants: All patients who presented with acute dysphagia secondary to food bolus obstruction (without bone) were involved in the study.

Outcome measures: Dislodgement of food bolus obstruction allowing them to eat and drink normally.

Results: Food bolus was dislodged without surgical intervention in 52 % and 58% in buscopan and placebo groups respectively.

Conclusions: The efficacy of buscopan in aiding dislodgement of an obstructing food bolus from the oesophagus was no better than a placebo.

INTRODUCTION

Food bolus impaction of the oesophagus is a common Ear Nose Throat (ENT) emergency [1, 2]. The exact incidence of oesophageal obstruction in United Kingdom (UK) is unknown as there is no published data. The management of this acute condition varies between different countries and in some instances between hospitals [3, 4]. There is neither agreed consensus nor well documented guidelines for the management of this acute condition in UK. American Society of Gastrointestinal Endoscopy (ASGE) guideline [4], for management of ingested foreign bodies, suggests immediate surgical intervention for patients who are in severe distress or unable to swallow oral secretions. If the patient is not uncomfortable, then conservative management for 24 hours is suggested before performing any invasive procedures.

Various pharmacological or non-pharmacological agents have been used as conservative management, to dislodge the impacted food bolus with varying success [5-13]. Proteolytic enzymes have unacceptable risk of serious complications [5]. Carbonated beverages may be useful for food bolus impaction in the lower end of the oesophagus [6, 7]. Although exact cause for oesophageal food impaction is not known, muscle spasm has been proposed as a causative factor [14]. Based on this theory, various spasmolytic drugs have been tried [3, 7-13]. The reported success of glucagon in dislodging a food bolus obstruction varies between 33% and 69% [7-9]. However, one randomised controlled trial showed no significant difference between glucagon and placebo [10] in dislodging impacted coin in children. Other muscle relaxants used are diazepam [3, 9] and nefidipine [11].

The most commonly used pharmacological agent in the UK for this indication is buscopan (hyoscine butylbromide) [3].

Buscopan is a spasmolytic, regularly used in radiological and endoscopic procedures to temporarily abolish bowel peristalsis. There are randomised controlled trials and prospective case series showing their efficacy in relaxing the smooth muscles of the intestines [15-17]. It is believed that the antispasmodic activity of buscopan relaxes the oesophageal musculature facilitating dislodgement of an obstructed bolus. However, the majority of musculature in the oesophagus is skeletal muscle, except the distal third which has smooth muscle. Hence its mechanism of action, in dislodgement of a food bolus, is not clear. Two retrospective studies, comparing the dislodgement of food bolus between buscopan and no treatment or use of other agents, showed no difference [12. 13].

METHOD

Patient blinded randomised placebo controlled trial was conducted over two years in two district general hospitals. All patients who were admitted through the Accident and Emergency (A&E) department with difficulty swallowing due to food bolus obstruction were invited to participate in the study. Patients with history of bone in the food bolus, those with any previous diagnosis of oesophageal disorder, those allergic to buscopan and children under 16 years of age were excluded from the study. Patients were also excluded if they had received buscopan or diazepam before allocation. Patients with history of previous food bolus obstruction, but with no oesophageal problems noted on either barium swallow or oesophagogastroduodenoscopy (OGD) were included in the study. Once the diagnosis was confirmed with history (sudden onset of complete dysphagia while eating food) and examination (inability to swallow any liquids), the patients were explained about the study. Patients willing to take part were given the information sheet and informed consent was obtained, before randomisation. Ethical approval was obtained from Aryshire & Arran and Cheshire ethical committees.

Simple randomisation from computer generated random numbers was used. The attending physician was aware of which group the patients were in, but the patients were blinded.

Participants in the study and control groups were given single intravenous dose of buscopan 20mg (Boehringer Ingelheim, Bracknell, UK) and placebo (same volume of normal saline – 1 ml) respectively. All patients were admitted and were advised to inform the staff, the time of dislodgement i.e. when they felt the obstruction was relieved and were able to swallow their own saliva or drink water. The available ENT doctor / staff confirmed that they could swallow liquid without any problems and documented the time. Those patients who continued to have symptoms of obstruction for more than 24 hours were taken to emergency theatre at the earliest available opportunity. All patients were discharged from the ward once they were able to eat and drink without any difficulty. The data that was collected included age and sex of patients, type of food bolus, duration of the obstruction (from onset of symptoms to time when buscopan or placebo was injected), site of obstruction according to patient, history of previous food bolus obstruction, barium swallow or OGD done in the past, time to dislodgement (from medication being given to the time when spontaneous dislodgement occurred), and any adverse effects to medication.

The sample size calculations using 80% power and of 0.05 obtained 20 patients in each arm to prove that buscopan is at least 20% better than the placebo which was based on the retrospective study done by Basavaraj et al [12]. In this study food bolus was dislodged in 68.5% and 62.5% in the buscopan and no treatment groups respectively. So we felt that buscopan had to be at least 20% better than placebo to be clinically effective. Analyses were done with SPSS 11.0 and we used chi-square test to analyse the results.

RESULTS

A total of 42 patients were included in the study out of 46 patients who presented to the hospital with food bolus obstruction symptoms. Four patients were excluded from the study because three received buscopan before they were randomised and the other was 15 years old. Out of 42 patients randomised 23 received buscopan and 19 received placebo (Fig 1). Table 1 shows the baseline characteristics of the participants. The median age was 49 and 68 years in the buscopan and control groups respectively. The male to female ratio was 3.6:1 in buscopan group and 1.7:1 in placebo group. The duration of obstruction, from onset of symptoms to time when they received buscopan or placebo, varied from 2 to 48 hours, the median being 5 hours in the buscopan group and 7 hours in the placebo group. The majority of obstruction (around 90%) was secondary to meat (chicken, lamb, beef or sausage) in both groups. One patient from each group had obstruction due to cucumber; the others had broccoli (buscopan) and onion (placebo). Seven patients (30.4%) in the buscopan group had similar complaints in the past compared to 1 (5.3%) in placebo group. Five of these

had barium swallow and three had both barium swallow and OGD which showed no oesophageal abnormalities.

Table 1

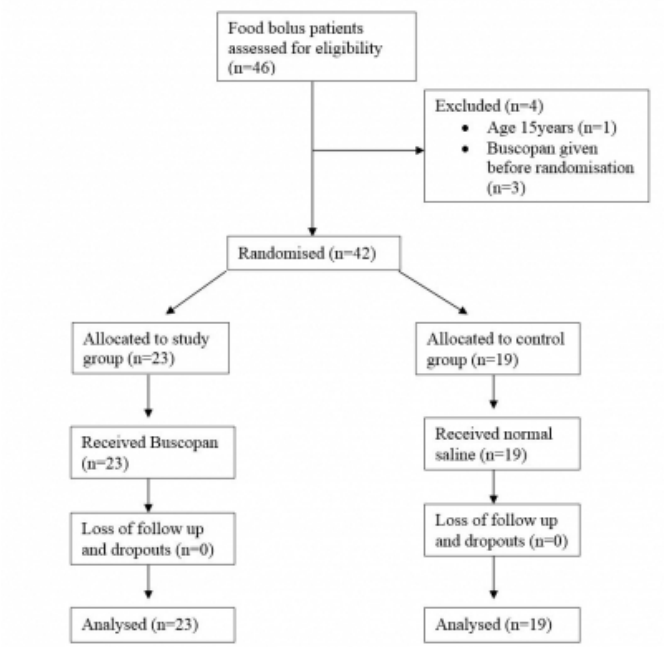
Participant baseline characteristics

Variable	Buscopan (n=23)	Placebo (n=19)
Age (years)	49 (30-65)	68 (38-76)
Sex (M:F)	18:5	12:7
Duration of obstruction(hours)	5 (3-8)	7 (5-9)
H/O previous obstruction	7 (30.4%)	1 (5.3%)
Food bolus – Meat	21 (91.3%)	17 (89.5%)

Data are ratio or median (Interquartile Range) or number (%)

Figure 1

Flow of participants through stages of RCT.



Dislodgement occurred in 52.2% (12/23) of patients receiving buscopan and 57.9% (11/19) of patients who received the placebo. There was no statistical difference between the two groups (P=0.477). The time for this to happen varied between 1 and 23 hours, the median (Interquartile Range [IQR]) being 5 (2-6) hours in the buscopan group and 5 (3-6) hours in the placebo group. Majority of spontaneous dislodgement occurred within 7 hours in 83.3% (10/12) and 100% (11/11) in buscopan and placebo groups respectively. Two other patients in the buscopan group had symptom resolution in 12 and 23 hours. There was no complication from either treatment and there were no withdrawals or dropouts.

DISCUSSION

Food bolus obstruction in the oesophagus can be very distressing to the patients, especially if the obstruction is in the upper part of oesophagus. The ASGE guidelines suggest immediate removal, either with OGD or rigid oesophagoscopy, after initial failure with pharmacological agents. Though, there are no published reports of aspiration or complications from delayed removal of obstructing food bolus, there is a theoretical risk of aspiration in high obstruction. Any intervention with pharmacological agents should be based on evidence based practice.

This is the first randomised controlled study to assess the efficacy of buscopan in dislodgement of food bolus obstruction in the oesophagus. None of the participants received any other forms of treatments in addition to buscopan or placebo. There were no dropouts or withdrawals and hence no missing data. This study was conducted in two Hospitals in different parts of UK making it more generalised. Simple randomisation was used and has resulted in unequal group sizes. There was imbalance in the baseline characteristics especially previous episodes of similar oesophageal food bolus obstruction which had dislodged spontaneously. There were more patients with this problem in the buscopan group (30.4%) than placebo group (5.3%) which could have had an effect on the result of the study (could have led to buscopan being less effective). But, none had any underlying oesophageal problems. The median age was higher in the placebo group and male to female ratio was higher in the buscopan group. We do not consider age and sex to affect the outcome of this study. Although randomised trials are supposed to provide similar groups in all respects except for the drug in question, imbalance in baseline characteristics can occur by chance. Randomisation was done appropriately, but proper allocation concealment was difficult in our study as too many patients were missed because of two reasons. One, too many medical staff were involved in recruiting these patients and second, the odd time of presentation of these patients to the hospital. As too many doctors recruited these patients (none of authors involved) and as this is an acute condition we believe selection bias due to lack of allocation concealment to be negligible. Lack of financial resources prevented us from achieving double blinding as we could not get buscopan and normal saline dispensed in similar containers. Ideally we should have used null hypothesis and power of 90% in sample size calculations but this would have needed a sample size of around 1000.

Our study showed no statistically significant difference between buscopan and placebo in dislodging the oesophageal food bolus. Placebo (57.9%) was more successful than buscopan (52.2%). Dislodgement of the food bolus occurred within 7 hours in 95% of the patients. There are couple of retrospective studies which have showed similar results [ref]. With some drawbacks with our study, it may be appropriate to say we need a larger multicentre study to prove that there is no difference between buscopan and placebo.

CONCLUSION

Buscopan is no better than placebo in dislodging a food bolus impacted in the oesophagus and it is worth waiting for at least 7 hours, before considering surgical intervention, as spontaneous dislodgement may occur.

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