A comparison of two feeding methods in the alleviation of diarrhoea in older tube-fed patients: a randomised controlled trial

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Abstract

Objective: to compare the effect of two feeding methods on older tube-fed patients suffering from diarrhoea.

Design: randomised controlled study.

Setting: geriatric wards in a regional hospital.

Subjects: 105 patients over the age of 60 who developed diarrhoea while on intermittent bolus tube feeding.

Methods: subjects were randomised either to switch to continuous tube feeding or to continue with intermittent bolus tube feeding for 3 days, with some extended to 5 days. Incontinence pads were inspected 6 times per day by independent observers. Each motion was evaluated using a validated score according to its volume and consistency. Stools were sent for pathogen culture and Clostridium difficile cytotoxin assay. Those with positive assays were excluded from analysis. Gastric aspirations were performed at regular intervals and significant residual volumes recorded.

Results: 86 patients completed the study. Twelve patients (14%) were excluded due to positive CD stool assays. Seventy-four patients were entered into analysis. The median diarrhoea scores of the continuous infusion group and the intermittent bolus group were: day 0 (12 versus 10, \( P = 0.18 \)), day 3 (4 versus 6, \( P = 0.23 \)) and day 5 (5 versus 4, \( P = 0.83 \)) respectively. There was no statistical difference between the two groups. Two patients in the continuous infusion group (n=37) and 4 patients in the intermittent bolus group (n=37) had significant gastric residual volumes. The incidence did not differ significantly.

Conclusion: contrary to common belief and recommendation, we could not find a significant difference between the continuous feeding method and the intermittent feeding method in the alleviation of diarrhoea in tube-fed patients. We do not recommend routine switch to continuous pump feeding in the management of tube-fed patients suffering from diarrhoea.

Keywords: older adults, tube feeding, diarrhoea, randomised

Introduction

Diarrhoea is one of the commonest gastrointestinal problems seen in tube-fed patients. In studies, the incidence of diarrhoea in tube-fed patients varies from 2 to 68% [1, 2]. This wide discrepancy arises from the fact that there is no standardised definition of diarrhoea; some define it by stool weight, others by frequency of bowel openings, and still others by the consistency of the stool [3].

A large number of factors have been studied in the past for an association with diarrhoea in tube-fed patients. Established culprits include infective causes such as Clostridium difficile (CD) cytotoxin [4, 5], recent or concurrent antibiotic usage [1, 4], syrup medication constituents, namely sorbitol [5], and of course spurious diarrhoea secondary to faecal impaction, another common gastrointestinal problem in tube-fed patients. So far there are no conclusive results regarding factors such as fibre content [6–10], osmolality of the feeding formula [11], or the method of feeding, i.e. intermittent bolus or continuous infusion [12, 13], though general recommendations were to start continuous infusion if tube-fed patients experience diarrhoea.

There has been a paucity of studies of older tube-fed patients despite the large number of older adults put on
tube feeding for various reasons, especially neuro-dysphagia after stroke or in late stage dementia. Most clinical trials in tube-feeding have involved patients in an intensive care unit (ICU) setting and frequently in post-operative conditions.

There have been two randomised trials which compared intermittent and continuous tube feeding in terms of the incidence of complications including diarrhoea, aspiration pneumonia, clogged tubes, and the time to achieve the required caloric goal. Hiebert et al. [12] studied 76 adult burn patients in a burn centre and randomised them to receive either mode of feeding. Among the 62 patients (age 12–81 years) who completed the study period of 1 week, those fed continuously had significantly less frequent stools than intermittently fed patients. The volume and consistency of stools were not studied.

In the randomised trial done by Kocan and Hickisch [13], 34 adult patients in a neurological intensive care unit were randomised to receive either mode of tube feeding. The number and consistency of stools per day, the incidence of aspiration as evidenced by presence of blue dye indicator in pulmonary secretions, the amount of residual gastric contents, the amount of nursing time required, and the time required to meet caloric goals were compared. Only 17 patients completed the entire study period of 10 days, the mean study period being 7.6 days in both groups. No significant differences were found in the number or consistency of stools per day, incidence of aspiration, or caloric intake as a percentage of the nutritional goal.

There is only one randomised prospective trial that has studied the effect of the mode of feeding on the incidence of diarrhoea exclusively in older patients [14]. This study, which involved 30 elderly patients in each group, continuous feeding was associated with a 30% reduction in the incidence of diarrhoea (96% versus 66%, \( P < 0.008 \)). This study randomised patients with no diarrhoea to begin with and looked for the incidence of diarrhoea after receiving different methods of feeding. No study has ever been performed to study the effect of switching to continuous pump feeding when patients developed diarrhoea. Our study aims to see whether changing to the continuous infusion mode of feeding would be useful in the management of diarrhoea.

**Patients and methods**

One hundred and five patients receiving intermittent bolus feeding and suffering from diarrhoea were recruited. Forty-two patients suffered from advanced dementia; 33 patients had cerebrovascular disease; 25 patients were tube-fed for nutritional support in acute illness; and 1 patient had oral malignancy. Diarrhoea was defined as three or more bowel opennings in one day. All subjects were 60 years or older. Patients with laxative use in the previous 72 hours were excluded, as were those with spurious diarrhoea or with a history of frequent self-extubation. The study was approved by the ethics committee of the hospital and subjects or their next of kin gave informed consent.

Subjects were randomised into two groups. Block randomisation in groups of 6 (3 for intermittent bolus feeding and 3 for continuous infusion feeding) was used to avoid high discrepancy between the subject number in each group. The first subject was assigned by drawing a sealed envelope out of six. The second subject was assigned by drawing a second envelope out of the remaining five, and so on. When all the six envelopes had been drawn the cycle was repeated again.

In the intermittent bolus group (I) the patients continued to receive the same mode of feeding. In the continuous infusion group (C) the patients were switched to continuous infusion of the same daily volume of feeding over the next 3 days, with some extended to 5 days. Continuous infusion was delivered via a pump set at a rate of 1–2 ml per minute for 16 hours per day. Intermittent bolus feeding was delivered via a hanging feeding funnel at a rate of 10 ml per minute, 250 ml per bolus, with 4–6 bolus per day depending on the prescribed caloric intake. Incontinence pads were inspected every 4 hours by staff nurses who were independent observers. The frequency of bowel openings, volume and consistency of stool were recorded daily. The volume of stool was graded as small, moderate and large, and the consistency of stool was graded as watery, loose and soft, according to standard nursing practice in our hospital. Interrater reliability of observations by nurses had been established in a previous study [15]. Aspiration of gastric residual contents was performed every 4 hours during continuous infusion in the C group and before each feeding in the I group. Significant aspirated volumes of >100 ml were recorded daily.

Factors which may be related to diarrhoea or nutritional status of the subjects were recorded. These included the Body Mass Index (BMI), with body height derived from fibula length measurements in bed bound patients [16], serum albumin level, total lymphocyte count, concurrent use of antibiotics, syrup medications, fibre content of the feeding formula, total daily volume and osmolality of the feeding. The use of anti-diarrhoeal drugs was also recorded. The clinicians in charge were free to dilute the formula or prescribe anti-diarrhoeal drugs as needed.

Stool specimens from each subject were sent for pathogen culture as well as for CD cytotoxin assay. Those who were subsequently found to have infective causes of diarrhoea were excluded from data analysis.

**Diarrhoea score**

Severity of diarrhoea was graded according to a previously validated diarrhoea scoring system [15]. The
The original scoring system was expanded to accommodate a moderate grade for stool volume in accordance with the standard nursing practice in our wards. The grades of 1, 2 and 3 were assigned to small, moderate and large stool volumes respectively. The stool consistency was described as soft, loose and watery, and the grades of 1, 2 and 3 were then also assigned respectively. The score for each bowel motion is the product of the grading for both consistency and volume. The total diarrhoea score for each day was the sum of scores for all bowel motions during the day. Hence the highest possible score for any day would be 54 (9 for each motion and maximum 6 times per day), and the lowest possible score would be 0. Higher scores meant more severe diarrhoea.

Statistical analysis

Our study was designed to detect a 10% difference between the diarrhoea scores of the 2 groups, at a power of 0.9. Within a score range of 0–54, any difference of <10% was not likely to be clinically significant. The required sample size was calculated to be 36 in each group.

The Statistical Package for Social Sciences (SPSS) version 9.0 was used for statistical analysis. Student’s unpaired t-test was used for parametric data analysis while Chi-square test was used for dichotomous data. Fisher’s Exact Test was used when the expected number in any cell fell below 5. The Mann-Whitney U test was used for the comparison of the diarrhoea scores in the 2 groups.

Results

A total of 105 patients older than 60 years of age were recruited. Of these, 86 patients completed the 3-day study. Reasons for dropouts included discharge from hospital (8), transfer to another facility (2), being kept nil by mouth (3), resumed oral intake (2), or death (4). Twelve patients (14%) were subsequently found to carry CD cytotoxin in their stools and hence were excluded from data analysis. A total of 74 patients were entered into the final analysis (Figure 1).

There were 37 patients in the C group and 37 in the I group. The mean age of patients was 81.3 years (C) and 82.8 years (I). The baseline characteristics and other possible factors that might be related to diarrhoea were compared and are tabulated in Table 1. None of these baseline values differed significantly between the 2 groups (Table 1).

The median diarrhoea scores at the baseline were 12 (C) and 10 (I) (\(P=0.175\)). The median scores on day 3 were 4 (C) and 6 (I) (\(P=0.230\)). Among those who were able to have extended trial days (28 in the C group and 20 in the I group), the diarrhoea scores were 5 (C) and 4 (I) (\(P=0.833\)). There was no statistical difference between the 2 groups in terms of the median diarrhoea scores at baseline, day 3 and day 5 (Table 2).

Two of 37 subjects in the continuous feeding group were detected to have significant gastric residual volume, defined as >100 ml in this study. In the intermittent group, the number of subjects was 4 out of 37 (\(P=0.674\), Fisher’s Exact Test).
Discussion

Continuous infusion feeding of milk formula has been recommended in textbooks and guidelines [17–20] as a means of reducing the incidence of diarrhoea, but published data are limited. In our trial, which is the largest at present, we could not find enough evidence to support the idea that changing to continuous pump feeding can significantly alleviate diarrhoea in tube-fed patients. The volume, frequency and consistency of the stool as reflected by the diarrhoea scores in either group did not differ significantly after 3 or 5 days despite different modes of feeding.

Our sample was able to detect a 10% difference between the two groups at the power of 0.9. As any reduction of <10% in the score would be clinically insignificant, we therefore conclude that changing to continuous feeding does not appear to alter the course of diarrhoea.

However, it is obvious from the data in this study that diarrhoea in these patients tends to subside after 3 days (Table 2). This may reflect the natural course of diarrhoea in tube feeding. In that case we may conclude that diarrhoea in tube-fed patients is a self-limiting disorder and may require simple supportive measures only.

Twelve out of the 86 patients (14%) with diarrhoea were found to carry CD cytotoxin in their stool specimens. However, no patient had a positive culture for stool bacterial pathogen. This is similar to the incidence of CD related diarrhoea in other series [21]. This high incidence could not be accounted for by a ward outbreak as the patients were dispersed in both space and time. It is probably related to the frequent antibiotic usage in this frail elderly group suffering from recurrent infections. Other bacterial pathogens were found to be a negligible cause of diarrhoea in tube-fed patients in this study, as is consistent with studies elsewhere. It is prudent to conclude, therefore, that CD is an important cause of diarrhoea in tube-fed patients, and all patients with this problem should be screened for the cytotoxin.

There was a high prevalence of antibiotic use in both groups of subjects, 68% in the continuous feeding group and 70% in the bolus feeding group. This is consistent with the findings in previous studies where broad spectrum antibiotics were found to be the main cause of diarrhoea in tube-fed patients [1, 4, 22, 23]. In one study, all antibiotic-related diarrhoea was controlled with syrup codeine phosphate 30–150 mg daily. It has also been recommended that broad spectrum antibiotics should be withheld or stopped if diarrhoea does occur during tube feeding [19, 24].

The incidence of significant gastric residual volume (> 100 ml) was higher in the intermittent bolus feeding group in this study, although due to the small number of events statistical significance could not be reached. It is an attractive theory that a smaller residual gastric volume would lead to a lower chance of regurgitation and hence tracheal aspiration of gastric contents. As aspiration pneumonia is one of the commonest causes of hospital admission and death in these patients, the use of continuous feeding with a low rate of feed delivery may be desirable in this aspect.

### Table 1. Comparison of baseline characteristics

<table>
<thead>
<tr>
<th>Continuous infusion (n=37)</th>
<th>Intermittent bolus (n=37)</th>
<th>P</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>81.3±1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (female/male)</td>
<td>32/5</td>
<td>31/6</td>
<td>0.744</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>22.0±0.8</td>
<td>21.0±0.9</td>
<td>0.425</td>
</tr>
<tr>
<td>Total lymphocyte count (10⁹/mm)</td>
<td>1.2±0.1</td>
<td>1.2±0.1</td>
<td>0.914</td>
</tr>
<tr>
<td>Volume of formula (litre/day)</td>
<td>1.2±0.0</td>
<td>1.2±0.0</td>
<td>0.809</td>
</tr>
<tr>
<td>Antidiarrhoeal use (%)</td>
<td>25 (68)</td>
<td>26 (70.3)</td>
<td>0.330</td>
</tr>
</tbody>
</table>

Plus-minus values denote means ± standard error.

BMI = Body Mass Index.

### Table 2. Median diarrhoea scores at baseline, day 3 and day 5 in both groups

<table>
<thead>
<tr>
<th>Feeding method</th>
<th>Baseline P=0.175</th>
<th>Day 3 P=0.230</th>
<th>Day 5 P=0.833</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous infusion</td>
<td>12 (4–35) n=37</td>
<td>4 (0–29) n=37</td>
<td>5 (0–19) n=28</td>
</tr>
<tr>
<td>Intermittent bolus</td>
<td>10 (3–40) n=37</td>
<td>6 (0–27) n=37</td>
<td>4 (0–23) n=20</td>
</tr>
</tbody>
</table>
This study was conducted in a hospital setting and the results may therefore not be applicable to nursing home residents. Our results may not be applicable to younger patients in other settings, such as in intensive care or burns units, or in post-operative states.

Conclusions
Contrary to common belief and recommendations, we could not find evidence that a change to the continuous mode of feeding can result in any additional reduction in diarrhoea in elderly tube-fed patients, as compared with those who continued with intermittent feeding. CD cytoxin has been found to be a cause of diarrhoea in a significant proportion of patients in our study, and routine stool assay of the toxin is recommended in these situations. A higher proportion of patients on intermittent bolus feeding were found to have high gastric residual volumes on routine aspirations. However, whether this finding is related to the incidence of aspiration pneumonia awaits further elucidation.

Key points
- Changing to continuous pump feeding does not provide additional benefit to tube-fed patients with diarrhoea.
- The diarrhoea in tube-fed patients is usually self-limiting and abates in a few days.
- Clostridium difficile related diarrhoea is an important cause of diarrhoea in tube-fed patients and the cytotoxin should always be screened for in such circumstances.

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Disclaimer
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References
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