Evaluation of the Bacteriological Contamination of a Closed Feeding System for Enteral Nutrition

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Introduction
Isocal, both powder and ready-to-use (RTU) liquid, has been used extensively over the past 10 years in the nutritional management of patients in many institutions around the world. Both reconstituted powder and liquid RTU products have been transferred to enteral feeding reservoirs (bags or bottles) for administration by feeding tubes. However, diarrhoea is one of the most commonly reported side-effects of enteral tube feeding, at times attributed to bacterial contamination of the open enteral system1,2.

Contaminated enteral feeding has also been implicated as the cause of Pseudomonas and Enterobacter species septicemia3,4 and has been shown to induce persistent colonisation and sepsis in mice5.

The availability of a closed feeding system should minimise the possibility of microbial contamination of Isocal RTU by eliminating the need for transfer of product from the original container to a feeding reservoir.

The main objective of the study was to evaluate the bacteriological contamination of a closed tetrapack-administration enteral delivery system, called the Entera-Flo Spike System (Fresenius AG Pharma, New Brunswick, NJ) in an intensive care unit.
EVALUATION OF THE BACTERIOLOGICAL CONTAMINATION

Materials And Methods

Ten patients in the Intensive Care Unit were entered into the study. They fulfilled the following criteria:

1. > 18 years old;
2. requiring tube feeding for nutritional support;
3. no hepatic or renal failure.

They were on routine H₂ receptor antagonist for stress ulcer prophylaxis. They were not septic but were still receiving broad spectrum antibiotics for an earlier sepsis that precipitated their admission into the Intensive Care Unit.

The patients received Isocal RTU Aseptic (Mead Johnson) for a minimum of three consecutive days. Isocal RTU Aseptic was the only formula studied as this is an aseptic preparation. Full strength formula (1kcal/ml) was administered continuously using gravity drip, at a rate necessary to meet estimated energy needs. All 10 patients had 1500-1800ml Isocal per day.

Isocal was administered directly from the tetrapack using the Iso-Flow Spike System connected to a naso-gastric tube. The naso-gastric tube was placed in the stomach. The spike system consisted of a spike and tubing set. The spike was inserted aseptically into the Isocal package to allow delivery from the package through the tubing which connected to the naso-gastric feeding tube. The Spike system contained a filter valve to allow air to enter the package to equalise pressure inside and outside the package as the Isocal flowed down the spike system. Near the distal end of the tubing, 30cm from its connection to the naso-gastric tube, is an injection port which served as a site for sampling and flushing.

The feeding tube was flushed with approximately 20ml of sterile water or sterile normal saline every eight hours to prevent clogging of tubes. No medications were mixed and administered with the Isocal but they could be given in conjunction with flushes.

Isocal samples were collected at 0 hour on Day 1 from the tetrapack itself (Sample 1); when it flowed down from the tetrapack into the tubing, taken at 0 hour on Day 1 from the first tubing (Sample 2); at the end of 24 hours from the first tubing (Sample 3); at the end of 24 hours from the new second tubing immediately after the change to new tubing and new tetrapack (Sample 4); collected at the end of 48 hours from the second tubing before switching to a third tubing and a new tetrapack (Sample 5).

Twenty ml of Isocal were collected aseptically using a sterile syringe, the needle carefully recapped without any hand contact and then sent to the Microbiology Laboratory immediately. One ml of the Isocal was syringed into Nutrient Broth and serially diluted to determine viable counts by the Miles and Misra method. The remainder 19ml were put into Brain-Heart Infusion (BHI) Broth for incubation at 37°C for 18 to 24 hours and subsequently subcultured onto blood and MacConkey agar plates. For samples which did not yield visible growth on the agar plates after 24 hours incubation, a second subculture was made from the BHI Broth at 48 hours. Negative culture plates were incubated for 48 hours before they were discarded. Colonies grown were identified by Gram-staining and conventional microbiological tests.

Careful handwashing by the personnel was practised before and after collection of samples. Disinfection of the sampling site was made with a swab containing 70 per cent alcohol.
Approval from the Hospital Ethics Committee was obtained for the project.

Results

No bacteria was cultured from samples taken from the tetrapack and fresh tubing set on day one (samples 1 and 2). Thus the enteral nutrition was sterile at the time it was spiked with the administration set. However, significant bacterial growth occurred within 24 hours in the first tubing in eight patients (sample 3). At the end of 24 hours, with a change of tetrapack and administration set, one patient, (number 7 had *Pseudomonas* species cultured from his enteral feed with a viable count of $4 \times 10^3$ organisms/ml (Sample 4).

At the end of 48 hours, bacterial growth was found in seven patients (sample 5).

Only one patient, that is, patient number 5, had no growth identified in all five samples of Isocal collected as above.

Table 1 shows the quantitative and qualitative bacteriological testing on samples 3 and 5 in the 10 patients.

Four patients had similar organisms identified in nasal swabs and/or tracheal secretions which were taken for bacteriological testing on Day 1. In three of these four patients the organisms isolated from both patients and Isocal had similar antibiograms.

For the five days the patients were under study, no diarrhoea or vomiting was noted in the 10 patients while they were on Isocal feeding.

Discussion

Studies have shown the great potential for enteral feeding solution to support bacterial growth and that bacterial overgrowth in the enteral feeding solution occurs with considerable frequency in the actual clinical setting.

The purpose of this study was to evaluate the bacteriological contamination of a closed enteral feeding system, in an intensive care setting. Our data showed significant bacterial contamination with the use of this enteral feeding system, even though all tetrapacks and administration sets were found initially sterile on Day 1.

The study was undertaken based on the encouraging invitro report by Susan Curtas et al. In their evaluation of the bacteriological safety of the system, bacterial contamination was insignificant under 24 hours hanging time in controlled laboratory conditions. In a clinical setting in an intensive care unit, contamination of the system occurred by 24 hours. The system was functionally not a closed system. It was an open system in practice, because of the necessity of having a port of entry for flushing and medication, which could be the port of entry for bacterial contamination. The exit port could also be a route of entry for retrograde infection, even though retrograde route of infection was not significant in a study by Schreiner.

The positive cultures in the enteral feed after a change to a new pack and tubing set must show that the environment was a source of contamination for patient number 7.
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Table 1
Quantitative and qualitative results of Isocal samples 3 and 5.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sample 3</th>
<th>Sample 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.8x10^6* Ac.cal., Kl.pn.</td>
<td>2.5x10^2* St.vir.</td>
</tr>
<tr>
<td>2</td>
<td>2.5x10^6 Kl.pn.</td>
<td>2.5x10^2 St.vir.</td>
</tr>
<tr>
<td>3</td>
<td>7x10^5 Bac.sp., Ac.sp.</td>
<td>ng</td>
</tr>
<tr>
<td>4</td>
<td>1.5x10^4 Kl.pn., Ent.sp., Ac.sp.</td>
<td>6.3x10^3 Kl.sp., Ent. sp., Ac.sp.</td>
</tr>
<tr>
<td>5</td>
<td>ng</td>
<td>ng</td>
</tr>
<tr>
<td>6</td>
<td>7x10^5 Ac.sp.</td>
<td>ng</td>
</tr>
<tr>
<td>7</td>
<td>2.5x10^2 Ps.ae.</td>
<td>3.3x10^3 Ps.sp.</td>
</tr>
<tr>
<td>8</td>
<td>2.5x10^6 Ac.sp., Kl.sp.</td>
<td>3.2x10^6 Ac.sp., Kl.sp., St.fae.</td>
</tr>
<tr>
<td>9</td>
<td>1.3x10^7 Kl.pn., S.epid., St.fae.</td>
<td>1.6x10^6 Kl.sp., St. vir.</td>
</tr>
<tr>
<td>10</td>
<td>ng</td>
<td>2.8x10^6 Ac.sp., Kl.sp., Ps.sp.</td>
</tr>
</tbody>
</table>

* = viable count, colonies per ml.
ng = no growth
Ac.cal. = Acinetobacter calcoaceticus
Ac.sp. = Acinetobacter species
Kl.pn. = Klebsiella pneumoniae
Kl.sp. = Klebsiella species
St.vir. = Streptococcus Viridans
Bac.sp. = Bacillus species
Ent.sp. = Enterobacter species
Ps.ae. = Pseudomonas aeruginosa
St.fae. = Streptococcus faecalis
S.epid. = Staphylococcus epidermidis

Environmental bacterial contamination has been commonly identified with enteral feeding. A variety of factors have been shown:

1. mixing or diluting nutrient solution prior to feeding it to patients, increases the likelihood of contamination;
2. use of non-sterile water as diluent to prepare formula.

These factors are avoided by using Isocal Aseptic (RTU).

In this study, the staff were meticulous in their aseptic techniques. Hand-washing before and after sampling was carried out by the nursing staff. The site to be sampled was disinfected by a 70 per cent alcohol swab.

Contamination could have been from endogenous or exogenous sources. The bacteria identified in our study could have come from the patients, their attending medical and nursing staff or the hospital environment. Nineteen of 26 isolates (73%) were Gram-negative bacteria, *Klebsiella*, *Enterobacter*, *Acinetobacter* and *Pseudomonas* species, which are commonly isolated from hospitalised patients. They are associated with colonisations of the gut, upper respiratory tract, and the skin, but are also frequently found in hospital food, water and other moist sites such as in ventilators, suction apparatus and wash bowls. Of the other isolates, *Streptococci* are human commensals but *Bacillus* and coagulase-negative *Staphylococci* are also common contaminants in the air, dust and other dry environments. In this study we have not established the source of contamination for the enteral feeds.

Anderton *et al* listed specific organisms that were unacceptable in tube feeds at any level of contamination, namely, *Escherichia coli*, *Staphylococcus aureus*, *Bacillus cereus* and species of *Klebsiella*, *Salmonella* and *Clostridium*.

Our patients did not demonstrate any signs of infection directly related to feeds like diarrhoea, vomiting or fever during the time of administration. Diarrhoea may be due to a number of causes in the intensive care, for example, unwise feeding of hyperosmolar feeds or overfeeding, but it is commonly associated with an infected feed. The period of our observation might have been short, but in clinical practice, gastro-intestinal symptoms occur with explosive immediacy. However, the patients were still on courses of antibiotics for the infection that precipitated their admission into intensive care. The signs of an infection originating from a contaminated feed may have been masked by this.

It has also been shown fairly clearly that sepsis in critically ill patients is often preceded by oropharyngeal and gastric colonisation of aerobic Gram negative bacilli. Some of the cultures grown showed Gram negative bacilli, and the contaminated enteral feed as a source of potential pathogens to the patient would be like an insult added to a grievous injury.

Equally worrying are the H2 receptor antagonists that are prescribed for routine prophylaxis of stress ulceration. It has been reported that subsequent alteration of gastric pH also predisposes to colonisation by Gram negative bacillus.

A closed enteral feeding system in the intensive care would be ideal for feeding critically ill patients. These patients are frequently hypermetabolic and nutritional support is an essential therapeutic measure, maintaining lean body mass and the integrity of the gut. A functioning gut that has a source of essential nutrients, in particular branched amino-acids and specific amino-acids, glutamine and arginine, can release growth factors that maintain gut integrity, and reduce the incidence of bacterial translocation into the body. This has been implicated as a cause of multi-organ failure syndrome in the critically ill patient.
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Parenteral nutrition for the critically ill is not without its problems. It is more costly and would require the services of a dedicated pharmacist, a sterile preparation room, and more intensive monitoring of the patient's biochemistry. Enteral nutrition is an alternative but enteral feeding in the critically ill patients must be carried out as aseptically as possible, with daily change of the delivery set. Flushing must be with sterile water or sterile normal saline. Routine use of $H_2$ receptor antagonists must be reviewed in these patients.

An early return to oral feeding must be encouraged. Total parenteral nutrition may still have to be considered in patients where enteral feeding has failed.

Acknowledgements

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We wish to express our thanks to the nursing staff and doctors involved in the study in the Intensive Care Unit, University Hospital Kuala Lumpur, for their cooperation; and Mr. Ong Kok Wah from the Microbiology Department for his technical assistance.

References