

PB-PG-0107-12240 – NIHR Research for Patient Benefit Programme – Final report

Project title: Determination of the ideal medication characteristics for the safe and effective administration of medications via enteral feeding tubes

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Plain language summary

Background

Many patients are unable to take nutrition by mouth and therefore enteral feeding tubes (EFTs) have to be inserted directly into the stomach either via the nose or straight through the abdomen. Over 37,000 patients in the UK use these tubes long term. Medicines given by this route are unlicensed and therefore patients and carers have no guidance available to them to decide how best to prepare and administer medicines for delivery via this route. GPs prescribing for these patients in the community are unsupported as technical information on this route of administration in primary care is limited.

A survey of practice amongst nutrition nurses, dietitians, nursing homes and patients was undertaken to determine what methods were used for medication administration and which medication were associated with problems.

Laboratory work was undertaken to find out if the liquid medicines associated with problems had similar properties and if the methods used for tablet administration, dispersion or crushing, delivered an accurate dose.

Findings

The methods and flushing volumes used to administer medication via EFTs are varied.

Tablet crushing is common and obtaining a liquid formulation can be difficult. Administration practices advocated by nutrition nurses and dietitians are not routinely applied by healthcare staff and patients in primary care.

Tablet dispersion did not affect the dose delivered however, the crushing methods used lead to a significant reduction in the dose

Liquid medications are associated with administration problems if they have a high viscosity or granular properties. Non-granular viscous liquids can be diluted to make administration easier.

Conclusions

Clearer guidance on enteral tube drug administration is required for patients and carers. Not all liquid formulations are suitable for EFT administration however tablet crushing should be strongly discouraged.

Benefit to patients

Freely accessible information for General Practitioners and nursing homes on safe administration of medication via enteral feeding tubes for the most commonly prescribed medication and improved signposting for further information should improve the quality and safety of prescribing for patients with enteral feeding tubes.

Publicising this information via patient support groups should also empower patients to encourage their GPs to seek further information.

Keywords

Enteral tube, Medication, Administration, Tablet crushing

Summary of research findings

Background

The increase in awareness of the importance of adequate nutritional intake has increased the use of enteral feeding tubes (EFT) in all areas of healthcare. An EFT provides a means of maintaining nutritional intake when there is limited access to the gastrointestinal tract. The British Artificial Nutrition Survey published data indicating that there are currently more than 37,000 patients in the community on home enteral feeding.

Identifying a suitable drug formulation for administration to a patient with limited GI access or dysphagia is difficult. In these patients the enteral feeding tube is often the only means of enteral access and increasingly is being used as a route for drug administration.

Administering drugs via an enteral feeding tube usually falls outside of the terms of the drugs product license, this has implications for the professionals responsible for prescribing, supplying and administering the drug as they become liable for any adverse event that the patient may experience. The pharmaceutical companies can provide very limited information on medication use outside of product license. The quality of data published relating to medication administration via EFTs is largely anecdotal and individual case report based. A robust method for assessing new medicine formulations for appropriateness for this route of administration is lacking and hence licensing for this route is exceptionally rare.

The NPSA safety alert number 19, 'promoting safer measurement and administration of liquid medicines via oral and other enteral routes', further highlights the common use of this method of drug administration and mandates the inclusion of guidance in medicines policy for this route of administration. However, robust evidence to inform such policies and protocols is lacking. Tube blockage due to medication remains a significant problem.

Marcuard and Stegall (1990) found that medication administered via narrow bore feeding tubes was the cause of tube occlusions in 63% of cases. A study by Benson et al (1990) found that even following an irrigation protocol, a significant relationship was observed between the number of medications administered through the tube and tube blockage, with the likelihood of tube blockage increasing in proportion to the number of medications administered.

In two studies investigating administration by nurses through EFTs (seifert et al, 1995; belknap et al, 1997), those nurses who received assistance from the pharmacy were

significantly more likely to administer liquid forms than those nurse who reported no pharmacy assistance and less likely to experience tube occlusion due to medications. Despite this evidence, the automatic selection of a liquid formulation may not be appropriate. Edes et al (1990) estimated the incidence of osmotic diarrhoea in tube fed patients directly due to the osmolality of the liquid medicines to be about 48%. Furthermore some liquid formulations are too thick or sticky to administer via EFTs. Although it is suggested to healthcare professionals that appropriate liquid formulations are chosen, (Wright, 2006) the ideal characteristics of liquid preparations for administration via EFTs have not been identified.

Frequently carers and patients resort to crushing tablets and capsules (Wright, 2002; Strachen, 2005). Unstandardised approaches to medicine preparation and administration may also contribute to tube blockage. Although guidance frequently includes information on preparation and administration this is usually based on custom and practice (Wright, 2003). An evidence based approach to preparing and administering solid oral dosage preparations is required.

Aims

Identify the medicines and formulations which are commonly used and those that are perceived to be associated with tube blockage or administration problems

Identify the preparation and administration techniques commonly used for medicines administered via EFTs in residential care facilities, on the ward and in patients' homes.

Determine the rheological properties of liquid medicines and solid particle characteristics which are most suited to administration via an EFT

Determine which administration and preparation techniques produce appropriate solid particle characteristics for administration via EFTs

Develop evidence based guidance to inform future medication formulation development and disseminate to all stakeholders

Objectives

Determine the methods commonly used to administer medication in clinical practice.

Identify medication and formulations associated with administration problems via enteral feeding tubes.

Define the characteristics of liquid medication associated with problems.

Assess the effect of methods used to manipulate tablets prior to enteral tube administration on dose delivery.

Methods

Surveys

Questionnaires were designed to survey practice and experience of drug administration via enteral feeding tubes, identify problem drugs and frequently administered medication. Postal surveys have a low response rate therefore all methods practicable were used to optimise the response rate.

Target groups for the survey were nutrition nurses and dietitians, patients on enteral feeding and community residential care facilities. Purposive sampling was achieved through dissemination of the questionnaire through patient and professional support groups. A complete distribution to residential care facilities was achieved through the use of local directories.

Liquid medication properties

A simple model was designed to replicate administration of liquid medication in practice. A range of liquid medications were studied using this method. A determination of viscosity properties was undertaken and a comparison made to the administration model.

Evaluation of tablet manipulation methods

6 different methods of manipulating tablets for EFT administration were identified from the survey results. These methods were compared to determine accuracy of dose delivery via enteral feeding tubes. HPLC methods were developed to ascertain dose recovery.

Key findings

Survey findings

A total of 175 professional, 71 patient and 21 residential care facility surveys were returned giving a response rate of 42%, 55% and 41% respectively.

All patients in nursing homes with enteral tubes also used them for medication.

86% of patients at home with enteral tubes also used them for medication.

Administration practices recommended by healthcare professionals are largely consistent and in line with published guidelines, although there is some variability in practice.

Practice in nursing homes and by patients is varied and does not reflect professional advice in all cases.

13 liquid formulations were associated with tube blockage or administration problems.

6 methods of tablet manipulation were identified, 2 involved dispersion in water, 4 involved crushing the tablet in a closed or open system.

Liquid medicines findings

A simple method to determine suitability of a liquid preparation for undiluted administration under gravity identified a number of medications that would be associated with issues in clinical practice. These matched the problem liquid medication identified in the survey work and also identified other liquid medications that were highly likely to be associated with administration problems. Rheological study revealed that all liquid formulations associated with problems had a high viscosity (more than 6 times that of standard enteral feed), granular nature or were thixotropic with a high viscosity at low shear stress.

Dose recovery findings

The 6 different methods identified in the survey were applied to 3 different tablet medications. The pestle and mortar and screw-down crushing device delivered a significantly lower percentage dose for all three medications. Dispersion in a syringe delivered an equivalent dose to the control.

Expected impact on the relevant field

More robust information on the implications of tablet crushing on dose delivery will impact on medicines management of patients with enteral feeding tubes and with swallowing

difficulties, potentially significantly influencing clinical practice. This is particularly relevant for medication with a narrow therapeutic index.

Several commonly used liquid medicines are associated with administration problems, these should be targeted for the development of alternative formulations.

At a local level, pro-active dissemination of information on prescribing for patients with enteral tubes may improve prescribing practice for these patients, and possibly reduce the inappropriate prescribing of liquid specials, thereby reducing medicines expenditure.

At a national level improved accessibility of information on medication formulations and their suitability for enteral tube administration will improve prescribing practice.

Appropriate targeting of publications will increase awareness of these issues relating to this route of medication administration.

Raising the issues associated with tablet crushing amongst patients and carers will empower them to seek further advice from appropriate healthcare professionals.

Conclusions

Administration practice is varied, clearer accessible guidance is required to standardise practice.

Liquid medication properties can be defined to determine appropriateness for enteral tube administration. More work needs to be done to develop a repository of information for these products.

The pharmaceutical industry should be encouraged to undertake and publish viscosity studies for liquid formulations

Tablet dispersion may be a suitable effective method of administration for enteral feeding tubes for a range of medicines. Further work needs to be undertaken to evaluate a larger range of drugs and varying dispersion volumes and flush volumes to inform practice in fluid restricted and paediatric patients.

Patient and public involvement

The patient support charity, PINNT (patients on artificial nutrition) was involved in piloting and proofing the patient survey and distribution of the survey to their members on enteral nutrition. Members of the charity have also reviewed the GP prescribing guide and made suggestions for publication and distribution.

PINNT have agreed to publish an update in their magazine about the project and signposting further information for interested patients.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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