

In the project area in Bissau, all refugees who had gone to Prabis had returned by the end of August, whereas many of those who had gone to areas where the World Food Programme continued distribution had yet to return by October.

Refugees and displaced people have been mainly studied in camp settings where effects may be different. Non-camp settings are, however, probably common in the early phases of emergencies before international agencies organise their programmes. In non-camp settings displacement is likely to lead to increased crowding and deterioration in hygiene and, consequently, to increased morbidity and mortality for both residents and refugees. The international agencies were clearly unaware of this possibility: they insisted on distributing aid only to refugees. It seems important also that concentrations of displaced people should be dispersed as quickly as possible. The most important consequences of general food distribution in an emergency situation may therefore not be the direct impact on nutritional levels but the indirect effects on movements and social behaviour, which have important consequences on exposure to disease. This requires humanitarian agencies to be aware of movement patterns and to be capable of following the population rather than vice versa.

Contributors: PA and IL planned the study. JG, MF, and QD organised and supervised data collection and food distribution. HJ carried out the statistical analyses. PA drafted the first version of the paper, and all authors contributed to the final version. PA and HJ will act as guarantors for the paper.

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### Key messages

- During the war in Guinea-Bissau, most of the population fled from the capital and moved in with relatives, friends, or strangers
- International agencies insisted on only providing help to refugees (internally displaced people)
- During the first month of conflict, there were already profound effects on the nutritional status and mortality of young children
- Food consumption was higher in resident families, but resident children were more malnourished and had higher mortality than refugee children
- Nutritional status and survival improved for both refugee and resident children once the refugees returned to Bissau

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## Prospective, randomised, double blind trial of prophylaxis with single dose of co-amoxiclav before percutaneous endoscopic gastrostomy

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### Abstract

**Objective** To determine the efficacy of antibacterial prophylaxis in preventing infectious complications after percutaneous endoscopic gastrostomy.

**Design** Prospective, randomised, placebo controlled, double blind, multicentre study.

**Setting** Departments of internal medicine at six German hospitals.

**Subjects** Of 106 randomised adult patients with dysphagia, 97 received study medication, and 84 completed the study. The median age of the patients was 65 years. Most had dysphagia due to malignant disease (65%), and many (76%) had serious comorbidity.

**Interventions** A single intravenous 2.2 g dose of co-amoxiclav or identical appearing saline was given 30 min before percutaneous endoscopic gastrostomy performed by the thread pull method.

**Main outcome measures** Occurrence of peristomal wound infections and other infections within one week after percutaneous endoscopic gastrostomy.

**Results** The incidence of peristomal and other infections within one week after percutaneous endoscopic gastrostomy was significantly reduced in the antibiotic group (8/41 (20%) *v* 28/43 (65%),  $P < 0.001$ ). Similar results were obtained in an intention to treat analysis. Several peristomal wound infections were of minor clinical significance. After wound infections that required no or only local treatment were excluded from the analysis, antibiotic prophylaxis remained highly effective in reducing clinically important wound infections (1/41 (2%) *v* 11/43 (26%),  $P < 0.01$ ) and non-wound infections (2 (5%) *v* 9 (21%),  $P < 0.05$ ).

**Conclusions** Antibiotic prophylaxis with a single dose of co-amoxiclav significantly reduces the risk of infectious complications after percutaneous endoscopic gastrostomy and should be recommended.

### Introduction

Percutaneous endoscopic gastrostomy is commonly used for long term enteral feeding of patients with

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severe dysphagia.<sup>1-5</sup> The most common complication is peristomal wound infection,<sup>5-11</sup> and some centres routinely use antibiotic prophylaxis.<sup>2,12</sup> Conflicting results, however, have been obtained in prospective clinical trials of antibiotic prophylaxis in percutaneous endoscopic gastrostomy, and its value in reducing wound infection rates is controversial.<sup>8-11</sup> To resolve the issue, we planned a large, prospective, randomised, double blind, multicentre study of antibiotic prophylaxis in percutaneous endoscopic gastrostomy.

## Participants and methods

Eligible patients were at least 18 years of age and were referred for percutaneous endoscopic gastrostomy because of dysphagia. Exclusion criteria were a contraindication to percutaneous endoscopic gastrostomy; known allergy to a penicillin, treatment with any antibiotic within the past 4 days, neutropenia (< 500 cells/ $\mu$ l), or serum creatinine concentration > 300  $\mu$ mol/l. Patients could be entered into the study only once. Written informed consent was required, and the study was approved by the ethics boards of the participating centres.

We conducted a double blind, placebo controlled, clinical trial at six German hospitals and the full version of this manuscript is reported on the *BMJ*'s website according to the CONSORT statement. The trial was prematurely stopped after an adaptive interim analysis showed a significantly higher infection rate in the control group.

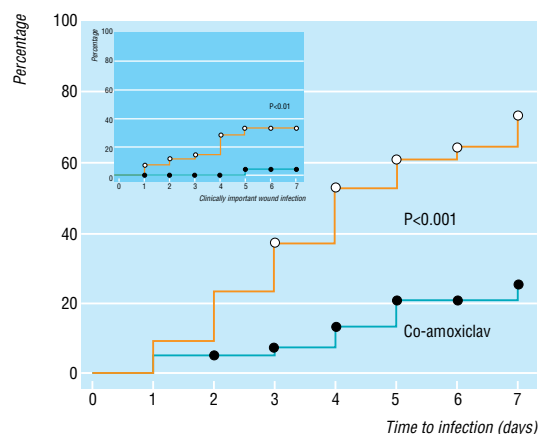
About 30 minutes before endoscopy patients received either 2.2 g co-amoxiclav or identical appearing saline by short intravenous infusion. Percutaneous endoscopic gastrostomy was performed by the thread pull method.<sup>1</sup>

**Table 1** Demographic and baseline clinical characteristics of evaluable patients. Values are numbers (percentages) of patients unless stated otherwise\*

Characteristic	Co-amoxiclav (n=41)	Placebo (n=43)
Sex (M/F)	30/11	31/12
Median (range) age (years)	69 (45-88)	60 (36-93)
Median (range) body weight (kg)	60 (40-113)	60 (39-85)
Underlying disease:		
Epipharyngeal/hypopharyngeal tumour	15 (37)	17 (40)
Oesophageal tumour	8 (20)	7 (16)
Other malignancy	5 (12)	3 (7)
Neurological disease	13 (32)	16 (37)
Previous method of feeding:		
Oral	31 (76)	28 (65)
Nasogastric tube	5 (12)	6 (14)
Parenteral	5 (12)	9 (21)
Comorbidity:		
Any	30 (73)	34 (79)
Multiple	24 (59)	25 (58)
Diabetes mellitus	5 (12)	3 (7)
Cardiovascular disease	22 (54)	21 (49)
Pulmonary disease	6 (15)	5 (12)
Cancer	4 (10)	3 (7)
Neurological disease	7 (17)	5 (12)
Performance status†:		
1-2	9 (22)	14 (33)
3-4	15 (36)	11 (26)
5-6	6 (15)	5 (12)
>6	11 (27)	13 (30)

\*Both groups were comparable in demographic and baseline clinical characteristics.

†Karnofsky index.



Kaplan-Meier plots showing time to infection (any site) and time to clinically important wound infection (requiring medical or surgical treatment) after percutaneous endoscopic gastrostomy among 84 evaluable patients receiving co-amoxiclav or placebo for prophylaxis. P values are from log rank tests

The patients were followed for at least 7 days. Monitoring included the measurement of body temperature three times daily, recording of peritoneal irritation and abdominal pain, and assessment of potential adverse events and clinical complications.

The peristomal region was examined daily, cleaned, and bandaged dry without antiseptic ointments. Peristomal erythema, induration, and wound secretions were noted and scored as proposed by Jain et al.<sup>9</sup> When purulent secretion was suspected we collected material for microscopy and culture. Peristomal wound infection was defined either as a score > 8 points or as microscopic evidence of suppurating secretion. The infection was considered clinically important if surgery or systemic antibiotics were required. We recorded the occurrence of peristomal wound infection as defined above and of any other infection that required surgery or systemic antibiotics within 7 days after gastrostomy as a primary efficacy variable.

Fisher's exact test was used to compare proportions. Wilcoxon's test was used to assess quantitative variables. The time to onset of infection was analysed by Kaplan-Meier estimates and a log rank test.

## Results

Of the 106 patients enrolled, 97 were included in the intention to treat analysis and 84 were evaluable according to protocol. Three patients developed non-infectious complications including bleeding, hypotension, and peritoneal irritation with abdominal pain. None of these complications was fatal.

Most of the patients had dysphagia due to malignant disease (65%), and many patients had serious comorbidity (76%). Patients in both arms had comparable baseline characteristics (table 1).

Eight of 41 (20%) patients in the antibiotic arm developed any infection compared with 28 of 43 (65%) patients receiving placebo ( $P < 0.001$ ). Peristomal wound infection was diagnosed in six (15%) patients who had received co-amoxiclav and 19 (44%) who had received placebo ( $P = 0.004$ ). Only one patient who

received co-amoxiclav developed clinically important wound infection compared with 11 who received placebo ( $P = 0.003$ ). The figure shows the time to infection in the two groups.

An intention to treat analysis confirmed the differences in infection rates (table 2).

A total of 20 adverse events were reported in 19 patients who received co-amoxiclav and 26 in 18 patients who received placebo. Adverse events that were possibly or probably related to the study medication included nausea (one patient) and seizure (one) in the co-amoxiclav group and vomiting (one) and suspected allergic exanthema (one) in the placebo group. Seven patients in the antibiotic arm and eight in the placebo arm died within 30 days after gastrostomy. One patient in the antibiotic arm died of pneumonia (on day 16) compared with three in the placebo arm (days 5, 10, and 21); the remaining deaths were due to underlying disease.

## Discussion

Our study shows that antibiotic prophylaxis with a single dose of co-amoxiclav reduces infection after percutaneous endoscopic gastrostomy. The study was larger than previous studies of antibiotic prophylaxis in percutaneous endoscopic gastrostomy,<sup>8-11</sup> two of which found no reduction in the incidence of peristomal wound infection.<sup>8, 11</sup>

We studied mainly patients at increased risk of infection such as cancer patients and patients admitted to hospital for various reasons. Many of our ambulatory, healthier patients were not randomised because they could not be followed up for at least 7 days. Malignancy has previously been associated with an increased risk of complication after percutaneous endoscopic gastrostomy.<sup>13, 14</sup> The risk of infectious complications after percutaneous endoscopic gastrostomy is high: in one study the overall incidence of infection was 42%,<sup>10</sup> and patients receiving placebo had a 32% increased risk of wound infection.<sup>9</sup> Previous studies have reported low rates of wound infection requiring treatment among patients given antibiotic prophylaxis.<sup>9, 10</sup> These rates are comparable with the 2% that we observed.

The choice of prophylactic regimen is unlikely to account for the differing results of previous trials. A

**Table 2** Intention to treat analysis for infection after percutaneous endoscopic gastrostomy with and without antibiotic use

	No (%) in co-amoxiclav group (n=46)	No (%) in placebo group (n=47)	% difference (95% CI)	P value
Infection:	10 (22)	31 (66)	44 (24 to 64)	<0.001
Minor wound	6 (13)	9 (19)	6 (-12 to 27)	>0.01
Clinically important wound	1 (2)	12 (26)	23 (7 to 43)	<0.002
Other	3 (7)	10 (21)	15 (-2 to 35)	<0.07
Antibiotic use*	6 (13)	24 (51)	38 (19 to 58)	<0.001

\*Includes patients who were given new antibiotics within 7 days after percutaneous endoscopic gastrostomy.

single dose of co-amoxiclav (and probably of other comparable antibiotics) may be sufficient prophylaxis against wound infections after percutaneous endoscopic gastrostomy, as it is for prophylaxis in gastrointestinal surgery.<sup>15</sup>

The mortality within 30 days after gastrostomy was in both groups similar to that reported in other studies.<sup>16-18</sup> Although we observed a lower rate of non-wound infections (including pneumonia) in antibiotic recipients than placebo recipients, this did not seem to affect survival. This is not surprising since a single dose of an antibiotic is unlikely to affect rates of infection and associated complications several weeks later.

We recommend giving antibiotic prophylaxis before percutaneous endoscopic gastrostomy. It is well tolerated, easy to perform, and reduces morbidity and the need for treatment because of infection. Our results show that a single intravenous dose of co-amoxiclav is effective.

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Competing interests: KM is employed by SmithKline Beecham, which makes co-amoxiclav.

### Key messages

- Percutaneous endoscopic gastrostomy for enteral feeding can be associated with substantial rates of infectious complications, notably peristomal wound infection
- Small, single centre studies on prevention of wound infection by antibiotic prophylaxis have given conflicting results
- This prospective, randomised, placebo controlled, double blind, multicentre study showed that a single dose of 2.2 g co-amoxiclav significantly reduced the rate of infection
- The favourable effect of antibiotic prophylaxis included a reduction in the rate of clinically important peristomal wound infection

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## Injection with methylprednisolone proximal to the carpal tunnel: randomised double blind trial

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### Abstract

**Objective** To assess the effect of a 40 mg methylprednisolone injection proximal to the carpal tunnel in patients with the carpal tunnel syndrome.

**Design** Randomised double blind placebo controlled trial.

**Setting** Outpatient neurology clinic in a district general hospital.

**Participants** Patients with symptoms of the carpal tunnel syndrome for more than 3 months, confirmed by electrophysiological tests and aged over 18 years.

**Intervention** Injection with 10 mg lignocaine (lidocaine) or 10 mg lignocaine and 40 mg methylprednisolone. Non-responders who had received lignocaine received 40 mg methylprednisolone and 10 mg lignocaine and were followed in an open study.

**Main outcome measures** Participants were scored as having improved or not improved. Improved was defined as no symptoms or minor symptoms requiring no further treatment.

**Results** At 1 month 6 (20%) of 30 patients in the control group had improved compared with 23 (77%) of 30 patients the intervention group (difference 57% (95% confidence interval 36% to 77%)). After 1 year, 2 of 6 improved patients in the control group did not need a second treatment, compared with 15 of 23

improved patients in the intervention group (difference 43% (23% to 63%)). Of the 28 non-responders in the control group, 24 (86%) improved after methylprednisolone. Of these 24 patients, 12 needed surgical treatment within one year.

**Conclusion** A single injection with steroids close to the carpal tunnel may result in long term improvement and should be considered before surgical decompression.

### Introduction

The carpal tunnel syndrome is caused by compression of the median nerve at the wrist and is a common cause of pain in the arm, particularly in women. Injection with corticosteroids is one of the many recommended treatments.<sup>1</sup>

One of the techniques for such injection entails injection just proximal to (not into) the carpal tunnel. The rationale for this injection site is that there is often a swelling at the volar side of the forearm, close to the carpal tunnel, which might contribute to compression of the median nerve.<sup>2</sup> Moreover, the risk of damaging the median nerve by injection at this site is lower than by injection into the narrow carpal tunnel. The rationale for using lignocaine (lidocaine) together with corticosteroids is twofold: the injection is painless, and diminished sensation afterwards shows that the injection was properly carried out.

We investigated in a double blind randomised trial, firstly, whether symptoms disappeared after injection with corticosteroids proximal to the carpal tunnel and, secondly, how many patients remained free of symptoms at follow up after this treatment.

### Participants and methods

#### Participants

The participants were patients referred to the Medical Centre Alkmaar with signs and symptoms of the carpal tunnel syndrome of more than 3 months' duration confirmed by electrophysiological tests. In those with bilateral symptoms, the arm with the most severe symptoms was chosen, and treatment of this arm was randomised. We excluded patients aged under 18 years or patients who had already been treated for symptoms of the carpal tunnel syndrome.



Fig 1 Site for injecting corticosteroid to treat carpal tunnel syndrome