



PEG TUBE; PROPHYLAXIS OF PEG TUBE SITE INFECTION, COMPARISON OF EFFICACY OF CEPHALEXIN AND CO-AMOXICLAV

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ABSTRACT... Objectives: To determine the efficacy of Cephalexin and Co-amoxiclav in preventing Peristomal infection after PEG tube placement in head and neck and other cancer patients. **Study Design:** Prospective, randomized clinical trial. **Setting:** Internal Medicine Department Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore. **Period:** February 2009 to September 2009. **Material and Methods:** A total of 160 patients including both males and females were selected by Non probability purposive sampling. Patients meeting inclusion and exclusion criteria were registered in the study from outpatient department after informed consent. These patients were randomly assigned into two groups. Group A was started on Cephalexin 500mg q6h Per-orally started 24 hrs before the procedure and continued it as q6h for five days after the procedure. Group B was given Co-amoxiclav 1G Per-orally 12 hrs before the procedure with the second dose of 1G, one hour before the procedure and then same dose advised q12h for five days after PEG tube placement. **Results:** Male to female ratio in both groups was 2:1 with 63.3% males and 33.8% females. Patients were aged between 19-80years, divided in four age groups with 38.8% falling in age group 50-64 years. Mean age is 52.11+-13.59 years and median age 54 years. The efficacy of Cephalexin and Co-amoxiclav was 84.7% and 78.6% respectively with no significant statistical difference among two groups. **Conclusion:** We concluded that Cephalexin and Co-amoxiclav were both equally effective in preventing peristomal infection.

Key words: Peri-stomal infection, Antibiotic Efficacy, Antibiotic prophylaxis.

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INTRODUCTION

The most common method of maintaining nutritional intake in patients unable to swallow is through a nasogastric tube using one of the commercially available fully supplemented enteral feeds. While preferable to parenteral feeding a number of well documented complications are associated with nasogastric feeding.¹ Enteral access must be obtained for tube feeding to begin. Temporary access can be achieved with a nasogastric or naso-enteral (small bowel) feeding tube. These tubes are easily placed at the bedside and can also be easily removed. Unfortunately, they often fail secondary to clogging or inadvertent dislodgement and do not provide a secure access route for the provision of calories, medications, or fluids.² More permanent enteral access can be obtained either

endoscopically, surgically or with interventional radiology, resulting in either a gastrostomy or jejunostomy. Percutaneous endoscopic gastrostomy (PEG) has developed into a common procedure to obtain gastric access; accounting for approximately 200,000 procedures per year in the United States. Operative gastrostomy remains the most commonly used technique although the procedure is associated with significant morbidity and occasional mortality. The procedure is generally considered safe with the procedure related complications of between 1-2%.³ Survival at one month is a commonly reported endpoint in PEG studies. A 30 day mortality rate may reach up to 6% depending upon the serious co morbidities, natural history of the disease and difficulty in selecting appropriate patients.⁴ The commonest complication after PEG insertion is peristomal

infection or wound sepsis with infection rates varying from 3% to 30%.⁵ Other complications include peritonitis, septicemia, hemorrhage, tube dislodgement, aspiration, perforation and gastro colic fistula.^{6,7}

To prevent these infectious complications antibiotic prophylaxis has been among the recommendations of British society of gastroenterology since 2001⁸. Patients with malignant conditions (for example head and neck cancers) are usually immunocompromised and have chances of developing more infections as compared to healthy individuals.⁹ There is evidence that antibiotic prophylaxis at the time of PEG insertion decreases post procedure infection rate from 18% in placebo group to 3 % taking antibiotics in those who are immunocompromised or have malignant diseases.^{9,10}

There is limited data available in Pakistan to compare the efficacy of antibiotics in prophylaxis of PEG⁷, so this study was conducted at Shaukat Khanum Memorial Cancer Hospital and Research Centre Lahore (SKMCH&RC) to assess these findings in patients with head , neck cancers, stroke or having other malignancies. Although both cephalixin and co-amoxiclav are effective in preventing the skin and soft tissue infections¹¹, but studies showing comparison between these two are very few. To introduce more efficacious antibiotics for the prevention of Peristomal infection this study was conducted.

MATERIALS AND METHODS

This study was a prospective, randomized clinical trial conducted at Internal Medicine Department SKMCH&RC Lahore, Pakistan. Study Duration was 8 months. Study extended for further two months to complete the calculated sample size. A total of 160 patients were selected by Non probability purposive sampling with 10% margin of error. Patients were divided in two groups with 80 patients in each group, Group A was labeled as Cephalixin group and Group B was labeled as Co-amoxiclav group. 80% power of the study taking expected percentage of efficacy of Cephalixin i.e. 83.6% and Co-amoxiclav i.e. 65%

in patients with PEG tube placement. Antibiotic Efficacy was assessed in terms of prevention of peri stomal infection, which is absence of local erythema/tenderness, fever, purulent discharge and raised total leukocyte count in the presence of above over a period of one week. The patients were then followed up for any signs of infection with the variables like Presence or absence of Peri-PEG erythema/tenderness, Fever (pyrexia > 38.5c), Purulent discharge and Raised TLC counts. All data was processed and analyzed using SPSS 12 for windows. Descriptive statistics were calculated. Outcomes were measured as the comparative measure of efficacy of both antibiotics in preventing peristomal infection. Chi square test was used for the comparison between the two groups. P value less than or equal to 0.05 was considered as significant.

Peristomal infection was assessed by clinical assessment in terms of presence of local peri-PEG erythema/ tenderness, purulent discharge, fever and raised total leukocyte count on laboratory investigation on follow up visits. All patients coming for PEG with age > 18 years (either with dysphagia, prophylactic PEG insertion before radiation to head and neck tumors or any other neurological conditions). Patients who received either Cephalixin or Co-amoxiclav 24 hrs before PEG tube insertion.

RESULTS

Regarding variables of efficacy measurement of antibiotics, Peri PEG erythema and tenderness was absent in 59 (79.7%) and 76 (90.5%) patients in Group A and B respectively on Day 1, while this result was 60 (83.3%) and 62 (86.1%) on Day 3 and day 7 respectively for Group A, while 71 (83.5%) on same days for Group B (Table-I). Both antibiotics were equally effective as there was no statistically significant difference (p value >0.05).

Purulent discharge was present in 7 patients in group A and 8 patients in Group B on D7, While 5 patients in each group on day 3 and no purulent discharge noted on day 1 in each group (Table-II).

Most of the patients were afebrile on day 1, in each group, while 9 (12.7%) and 14 (16.7%) patients were febrile (with temp. > 38.5c) on day 3 in group A and B respectively. Only 8 patients in group A (11.1 %) and B (9.5%) were having significant temperature on day 7. Overall 140 (90.3%) were having no significant temperature in both groups in all three days (Table-III).

We also measured the TLC (total leucocytes count) on different occasions to assess the presence or absence of infection. Counts were in normal ranges in most of the patients on day1. On day 3 TLC was disturbed (either >11000/mcl or <4000/mcl) in 10 (14.3%) patients in group A and 10 (11.6%) patients in Group B. While On day 7 11(15.3%) patients had disturbed TLC in Group A and 10 (11.9%) patients in Group B respectively (Table-IV).

The overall efficacy of antibiotics was measured on basis of above mentioned variables. Cephalexin i.e. group A was efficacious in 61 (84.7%) patients, while Co-amoxiclav i.e. group B was efficacious in 127 (81.4%). 11 patients in group A and 18 patients in group B failed to respond to antibiotics (Table-V).

There was no significant difference between the efficacy of two antibiotics in prophylaxis of PEG Tube site infection (p value 0.325) (Figure-I).

Peri-PEG Erythema/ tenderness	Group A		Group B		Group B	
	N	%	N	%	N	%
Day-1						
Present	13	17.6	08	09.5	21	13.5
Absent	59	79.7	76	90.5	135	86.5
Day-3						
Present	12	16.7	13	16.5	26	16.7
Absent	60	83.3	71	83.5	130	83.3
Day-7						
Present	10	13.9	13	16.5	23	14.8
Absent	62	86.1	71	83.5	133	85.2

Table-I. Assessment of Peri PEG erythema/ tenderness

Peri-PEG Erythema/ tenderness	Group A		Group B		Group B	
	N	%	N	%	N	%
Day-1						
Present	0	0	0	0	0	0
Absent	72	100	84	100	156	100
Day-3						
Present	05	06.8	05	06.0	10	06.4
Absent	67	90.5	79	94.0	146	93.6
Day-7						
Present	07	09.7	08	09.6	15	08.6
Absent	65	90.3	76	90.4	141	90.4

Table-II. Assessment of Purulent discharge after PEG tube insertion

Peri-PEG Erythema/ tenderness	Group A		Group B		Group B	
	N	%	N	%	N	%
Day-1						
>38.5	03	05.5	08	09.5	11	07.6
<38.5	69	94.5	76	90.5	145	92.4
Day-3						
>38.5	09	12.7	14	16.7	23	14.8
<38.5	63	87.3	70	83.3	133	85.2
Day-7						
>38.5	08	11.1	08	08.5	16	10.3
<38.5	64	88.9	76	90.5	140	89.7

Table-III. Presence/ absence of Pyrexia (Temp. >38.5)

TLC /mcl	Group A		Group B		Group B	
	N	%	N	%	N	%
Day-1						
>11000 or <4000	06	08.3	14	16.7	20	12.9
4000-11000	66	91.7	70	83.3	136	87.1
Day-3						
>11000 or <4000	10	14.0	10	11.6	20	13.0
4000-11000	62	86.0	74	88.4	136	87.0
Day-7						
>11000 or <4000	11	15.3	10	11.9	21	13.5
4000-11000	61	84.7	74	88.1	135	86.5

Table-IV. TLC after PEG placement

EFFICACY	Group A		Group B		Total	
	N	%	N	%	N	%
Yes	61	84.7	66	78.6	127	81.4
No	11	15.3	14	21.4	29	18.6
% ² value	09	12.7	14	16.7	23	14.8
	63	87.3	70	83.3	133	85.2
Total	34.72***		27.47***			

Table-V. Assessment of efficacy of antibiotics
*** P,001

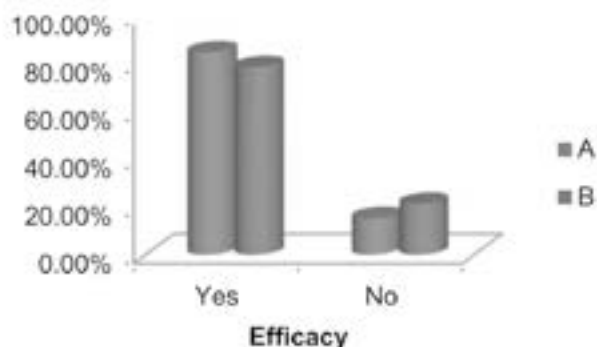


Figure-1. Assessment of efficacy of antibiotics

DISCUSSION

Our study shows that antibiotic prophylaxis with either Cephalexin or Co-amoxiclav reduces the infection after percutaneous endoscopic gastrostomy and there is no significant statistical difference between the efficacy of both the antibiotics. The study was quite a large study of antibiotic prophylaxis in PEG tube placement. This is the first study to compare two antibiotics for prophylaxis of peristomal infection. It showed similar results in efficacy of Co-amoxiclav in PEG prophylaxis as in previous study.¹² However Cephalexin efficacy was 84.7% as compared to 93.8% in previous study of Cephalexin vs. Cefdinir in controlling skin infection.¹³ This study was carried out at a cancer centre and almost all patients were having malignancy, mostly having head and neck cancer. Malignancy has previously been associated with an increased risk of complication after percutaneous endoscopic gastrostomy.¹⁴ Other studies indicate that patients with neurological diseases may be more prone to infection than patients with cancer.⁴ This factor of immunocompromise state in cancer

patients may explain the lower efficacy results of Cephalexin as compared to previous ones. Several previous studies noted a high risk of infectious complications.

In a previous study in which over half of the patients were having the cancer overall incidence of infection after percutaneous endoscopic gastrostomy was 42%.⁷

G.Perlick et al. studied that single prophylactic dose of 2.2g of co-amoxiclav had efficacy of around 80% by preventing peristomal infection.¹² While our study shows the efficacy of Co-amoxiclav slightly less i.e. 78.6%. Similarly Kenneth J et al showed that Cephalexin had cure rate of 93.8% for treatment of skin infection in pediatric patients.¹³

An important area of oncology in which PEGs appear to have a relatively proven record is in patients with head and neck cancers. Head and neck cancers are commonly diagnosed when they are already in advanced stages. Aggressive chemotherapy and radiotherapy can lead to dysphagia, odynophagia, dehydration, and malnutrition, which can result in interruption of treatment and frequent hospitalization.¹⁵ These immunocompromised patients are vulnerable to any infections while on chemotherapy, so upon receiving prophylactic antibiotics, peristomal infections are reduced with reports showing better tolerance of chemo-radiation.^{8,10}

As PEG placement is via endoscopy, there is much higher risk of having bacterial infection while doing the procedure. Highest rates of bactremia have been reported with esophageal dilatation and sclerotherapy that can be associated with so many other factors but one of them will be low immunity in preexisting liver cirrhosis.¹⁶ Doing procedures in these circumstances is wise able to prevent any future infection by giving pre procedure or post procedure antibiotics. As shown in previous data there is higher incidence of bactremia with dilatation of malignant strictures rather than benign one.¹⁶

Survival benefits due to feeding through PEG have been noted in certain indications for example acute stroke and prophylactic ally used in head and neck cancers but not in all like dementia.¹⁷ While survival remains multifactorial in such patients we believe that nutritional support through PEG along with pre procedural and post procedural use of antibiotics improve care conveniently.

The choice of prophylactic regimen is unlikely to account for the differing results of previous trials. In one study, three doses cefoxitin were used and found no effect on wound infection¹⁸, whereas in other study it was reported that significant protection with a single dose cefazolin⁶, a drug less effective against anaerobic bacteria than cefoxitin or co-amoxiclav but similarly effective against aerobic organisms from the upper gastrointestinal tract and mouth flora.¹⁹ In our study there is statistically significant data about the prevention of peri-PEG infection and statistically no antibiotic is superior to other (p value 0.325). It looks that giving 5 day course of either Cephalexin or Co-amoxiclav as a prophylaxis just after PEG tube insertion is more appropriate. As compared to other intravenous antibiotics, both Cephalexin and Co-amoxiclav are cheaper and easily available in the market.

As most of our patients were having cancers, they were started on chemo radio therapy immediately (on average 5-7 days) after PEG tube placement, so immunosuppression at this stage may have possibly affected the overall results of this study.

Antibiotic prophylaxis before and five days after percutaneous endoscopic gastrostomy is very useful by preventing peri-stomal infection on basis of results of this study. It is well tolerated, easy to perform and reduces morbidity and the need for treatment because of infection. Our study results show that both Cephalexin and Co-amoxiclav are equally effective against prophylaxis of peristomal infection. So we recommend using any of the antibiotics, either Cephalexin or Co-amoxiclav as prophylaxis after PEG tube placement. Future studies should compare the antibiotic efficacy in different groups of patients like cancers, dementia

or in stroke patients with PEG tube.


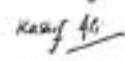

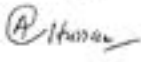
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