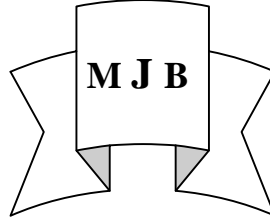


## Once – Daily Therapy for Helicobacter Pylori Infection Using Tinidazol Containing Regimens

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### Abstract

In this study 80 patients were divided into four groups, (20 patients) for each, all of them were infected by H. pylori.

The patients were treated by once daily regimens as follow:

Group (I) (tinidazol+ omeprazol)

Group (II) (I+amoxyllin)

Group (III) (I +azethromycin)

Group (IV) (I + clarethromycin)

The cure rate was 21%,55%,83%,93% respectively ,the results were statistically significant when group II compared with group I ,III. & IV, PV <0.05.

In spite of these results, this regimen needs more evaluation to be used routinely.

### الخلاصة

تم في هذه الدراسة معالجة ٨٠ مريضاً قسموا بالتساوي الى ٤ مجموعات بجرعة واحدة يوميا من العقارات المضادة للبكتريا

الكلزونية (هليكوبكتريايلوري) علما ان جميع المرضى مصابين بهذه البكتريا، وكانت نتائج العلاج الذي استعمل فيه علاج ال (تينيدازول)

في جميع المجموعات مع بعض العلاجات الاخرى كالآتي.

المجموعة الاولى (تينيدازول+امبرازول) الثانية (الاولى+اموكسيل)الثالثة(الاولى +ازيثرومايس) الرابعة (الاولى+الكلارثرومايسين).

وكانت الاستجابة للعلاج كالآتي ٢١%، ٥٥%، ٨٣%، ٩٣% وعلى التوالي لكل المجموعات وكانت النتائج الاحصائية قيمة عند

مقارنة المجموعة الثانية مع الاولى والثالثة والرابعة وغير قيمة بين الثالثة والرابعة وعلى الرغم من هذه النتائج فان استعمال علاج

بجرعة واحدة يوميا لا يزال يحتاج الى دراسات اخرى للتأكد من فعاليته مقارنة مع الطرق الاخرى

## **Introduction**

It is well known that the successful H. pylori therapies are complex [1] and the original standard treatment of H. pylori bismuth- based triple therapy employs (bismuth subsalicylate, metronidazole, and tetracycline) four time a day in addition to an antisecretory agent once a day with eradication rates of approximately 80% in the U.S[2].

To decrease the complexity of H. Pylori eradication regimens, dual therapies were subsequently developed but in well- controlled trials in which omeprazol and clarithromycin were used the eradication rate didn't exceed 75%[3].

The currently popular proton pump inhibitor (PPI) based triple therapy with eradication rate of 85% but these therapies require twice- daily ingestion of three medication for (10-14) days[4].

Anew problem in the treatment and eradication of peptic- ulcer diseases due to H. Pylori is the increasing prevalence of metronidasol resistance, that resulting in treatment failure of most drug regimens applied.

In this study we try to determine the efficacy and tolerability of once daily triple therapy in the treatment of H. Pylori infection by

using tinidazol in state of metronidazole.

## **Material and methods**

Subjects who were eligible for inclusion in the study must have the following criteria:-

1. Not taking antibiotics, bismuth or PPIs.
2. Not allergic to penicillins, Erythromycin, azithromycin, tinidazol or PPIs.
3. Not previously treated for H. Pylori infection.
4. Symptomatic subjects undergoing evaluation for gastrointestinal symptoms and tested for H. pylori and treated if positive.

Exclusion criteria from this study:

1. Patients with serious active disease (renal failure, cancer, chronic obstructive lung disease or asthma requiring hospitalization or emergency room visit in the last year).
2. Patients with moderate to sever cirrhosis.
3. Angina and cardiac arrhythmia requiring therapy
4. Patient with symptomatic heart failure.
5. Pregnant ladies or that went to be pregnant during the course of treatment.

Eligible subjects with evidence of H. Pylori infection by endoscopic biopsy testing and by the use of Gimsa stain or Haematoxylin eosin stain were divided to four groups 20 patients for each.

- Group I treated by omeprazol 80 mg & tinidazol 2g once/ day OT (I), for 10 days.
- Group II [I]OT + Amoxyllin cap 1.5 g once/ day, for 10 days)
- Group III [I]OT + azithromylin 500 mg once/ day, for 7 days)
- Group IV [I]OT + clarethromycin 1g once/ day, for 10 days)

OT(I) was used as a control to assess the benefit of the additional antibiotics to the regimens in this study, tinidazol was the backbone for all regimens.

Subjects were seen for clinical evaluation, assessment of side effects that include, abdominal pain, nausea, vomiting, diarrhea, constipation, rash, fever, Jaundice, taste disturbance.

At the completion of therapy the patients were asked about the pill count to determine the compliance of the patients, and the subjects were considered compliant if they took > 80% of each study medication as prescribed.

Six weeks after the therapy the subjects had a new endoscopy and biopsy to determine the eradication of H. Pylori

The fisher exact test was used to compare pairs of proportional data.

A P. Value <0.05 was considered significant.

### **Results**

Eighty subjects were assigned to treatment.

Table I show the selected characteristic for all group which were similar. The mean age (42) years, 22% of each study groups were smokers.

All subjects were diagnosed (H. Pylori positive) after endoscopy with positive Biopsy, 74% of subjects had dyspepsia, and about 15% of our subjects had ulcer at baseline, nine of all subjects (80 patients) were lost to follow up (table 2), which was more with clarethromycin group (4 patients, 20%, of 20 subject).

P. value for [(IV- I), (IV-II),(IV-III)] was > 0.05 for each pair.

The cure rate (table2) with OT (I) were only 21%,

and was 55% for OTAM (II).

- P value for (I-II) was < 0.05  
Cure rate was 83% for OTAZ (III)
- P value for (II-III) was < 0.05  
Cure rate was 93% for OMCI (IV)

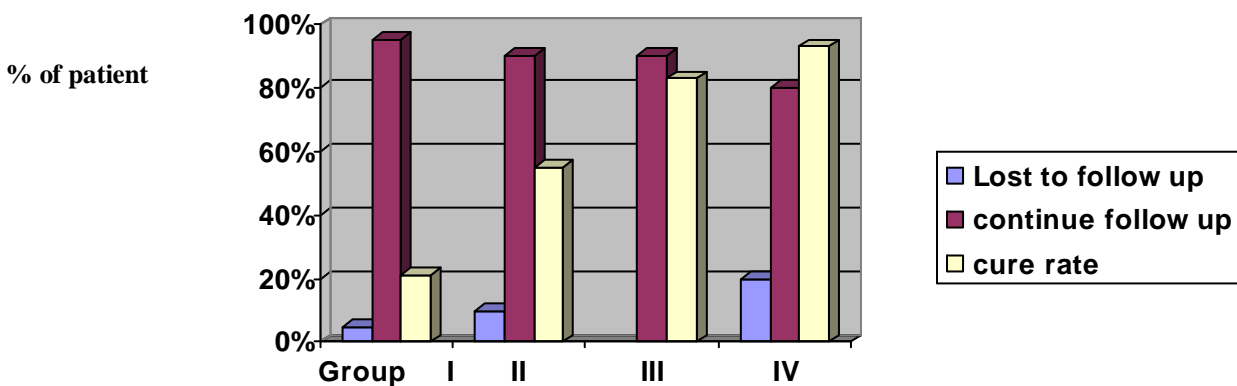
- P value for (II-IV) was < 0.05
- P value for (III-IV) was not significant > 0.05

**Table 1** Selected characteristics of the study groups

	OM(I)	OM Am (II)	OMAZ(III)	OMCI(IV)
No. of pt.	20	20	20	20
Mean age(y)	40	42	40	44
Male%	60%	62%	50%	58%
Smokers	20%	30%	25%	51%
Baseline symptoms				
Dyspepsia	80%	70%	75%	70%
Heart burn	10%	15%	13%	18%
Others	10%	15%	12%	12%
Endoscopy finding				
Ulcer	10%	8%	15%	25%
Erosive esophagitis	13%	19%	8%	12%
Gastroduodenal erosion	25%	13%	22%	18%
Normal	52%	60%	55%	45%

**Table 2** Results after treatment

Group	I	II	III	IV
Lost to follow up No.&%	1 5%	2 10%	2 10%	4 20%
Continue follow-up No.&%	19 95%	18 90%	18 90%	16 80%
Cure rate No.&%	4/19 21%	10/18 55%	15/18 83%	15/16 93%



**Figure 1** Result after treatment

**Discussion**

In this study we try to simplify H. Pylori therapy by using once daily

regimen, using tinidazol, which can be used in a single dose, and compare that with a standard regimens that

containing metronidazol as twice daily triple therapy with a PPI, and other antibiotic like clarithromycin, amoxyllin and azethromycin[4] . In this study the cure rate of triple therapy was 93% with regimen that contain clarithromycin (IV), which is more than the standard regimen twice daily triple therapy (metronidal, PPI, and clarethromycin), which was (80-90%). [5]

Another study in [(U.S.A) Los. Angeles] in which slow released metronidazole was used, in addition to PPI and [amoxyllin, Azethromycin or clercthromycin] as once daily regimens, in which the results were [8% cure rate with PPI omprazol + slow released metronidal OM], and [35% with OM + Amoxyllin], [66% with OM + Azethromycin] and [79% for OM + clarethromycin],[6] these results are less than our results which was 21%, 55%, 83% and 93% respectively.

From this study we can conclude that the use of metronidazole in slow-released form or the usual form will result in lower eradication rate than that of tinidazol.

These results can be explained by the increment of the metronidazol resistant strain of H. pylori which is supported by different western, Asian,

Mediterranean and Latin American studies, which mentioned that the H. pylori resistant strains to metronidazole is a major cause of low eradication rates of H. pylori that resulting in treatment failure of most drug regimens applied.[7]

The resistance to tinidazol during the last twenty years of use still not detected either clinically or statistically, so the use of tinidazol containing regimens may be important in the treatment of H. pylori infection. [8]

The above explanation can be supported by results of some studies from high prevalence areas of metronidazole resistant H. pylori, in which even the extension of the duration of treatment or increasing the daily doses of metronidazole to overcome the resistance was not effective in most cases.[9]

From this study we can conclude that the regimens containing tinidazol are superior to that with metronidazole (even long acting metronidazole) but the question is, (can we replace the well studied effective H. pylori therapies, by once daily therapies).

The problem with this study is not that of tinidazol and metronidazole, but the regimens containing other

drugs and its use once daily may decrease its activity, so further studies are needed to detect the optimal once daily dosing and enhance eradication rates.

### **Refernces**

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