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Treatment of Helicobactor pylori infection: analysis of Chinese clinical trials

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INTRODUCTION

Eradication of *Helicobacter pylori (Hp)* infection is generally not easy. Various clinical regimens have been recommended in the literature. With the expe rience from the other countries and the practice in China, Chinese doctors have tried many regimens. In this study, we collected and pooled the data from Chines e literature to evaluate the effect of different regimens in Chinese patients in fected with *Hp*.

MATERIALS AND METHODS

Papers published from 1990 to 1997 were reviewed. The papers were cited from the index "Chinese Literature of Science and Technology, (Medicine)", Published by the Medical Information Institute of China, Beijing, and from the Chinese bio medical disks (CBMDISC). Papers were selected according to the following criteri a: ① the papers must be published in full text; ② data must be from original studies from author's own unit; ③ Hp status must be determined using histology, microbiology and urea breath test; and ④ the studies should be appro priately designed and reported. If several papers were published from the same data source, the one with the best data was included.

RESULTS

Monotherapy Monotherapy has been fully proved to be not effective in Hp eradication, with a eradication rate between 10%-45%.

Dual therapy Proton pump inhibitor (PPI) dual therapy was introduced from western countries to China, whereas furazolidone was developed in Chi na. The data are shown in Tables 1,2.

Triple therapy PPI and bismuth triplies were main regimens recommended. Furazolidone was fully practiced in China. Their results are shown in Tables 3-5.

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Quadruple therapy Only two studies were available using 1 week course of bismuth, PPI and two antibiotics. The eradication rates were 91% and 93%, and the occurrence rate of side effect being 33%[19,20].

Table 1 PPI dual therapy

Authors	Ome	Amo	Eradication(%)	Healing(%)	Side effect
Zhou YH[1]	20 bid×14	500 qid×14	30/33 (91)	31/33 (94)	12%
Zhou YH[1]	20 qd×14	500 qid×14	31/35 (89)	32/35 (91)	
Nie YQ[2]	20 bid×14	500 qid×14	10/13 (77)	12/13 (92)	15%
Li YY[3]	20 bid×14	500 qid×14	8/11 (73)	9/11 (82)	
Hu FL[4]	20 bid×14	750 bid×14	13/22 (59)	18/22 (82)	
Zhou Y[5]	20 bid×14	750 qid×14	30/36 (83)	36/36 (100)	2.7%

Ome: omeprazole Amo: amoxycilline

Table 2 Furazolidone dual therapy

Authors	Furazolidone	Antibiotics	Eradication(%)	Side effect
Xiao SD[6]	100 qid×14	CBS 120 qid×14	66/90 (73)	
Mao PJ[7]	100 tid×28	Ran 150 bid×28	10/17 (59)	8.9%
Mao PJ[7]	100 tid×28	Ome 20 qd×28	15/18 (83)	
Li YN[8]	200 tid×7 100 qid×7	CBS 110 qid×28	34/34 (100)	
Li YN[8]	100 tid×14	CBS 110 qid×28	21/23 (91)	
Li YN[8]	50 tid×14	CBS 110 qid×28	13/21 (62)	
Xi BG[9]	200 tid×14	CBS 110 qid×28	24/24 (100)	

CBS: bismuth Ran: ranitidine Ome: omeprazole

Table 3 Triple therapy with Furazolidone

Authors	Fu	Antibiotics	Antibiotics	Eradication(%)	Side effect
Liu WZ[10]	200 bid×7	CBS 240 bid×7	Cla 500 bid×7	12/12(100)	57%
Liu WZ[10]	100 bid×7	CBS 240 bid×7	Cla 250 bid×7	25/27(93)	7.4%
Huang YS[11]	100 tid×5	Met 400 tid×5	Genta 40 tid×5	25/26(96)	
Xiao SD[6]	100 qid×10	CBS 120 qid×10	Met 200 qid×10	74/75(78)	
Chen JP[12]	100 qid×28	CBS 120 qid×28	Tetra 250 qid×28	35/54(65)	

Cla: clarithromycin Genta: gentamycin Tetra: tetracyclin

Table 4 Hp eradication with CBS triple therapy

Authors	CBS	Amo	Met	Eradication(%)	Side effect
Jia BQ[13]	120 qid×14	250 qid×14	200 qid×14	328/440(87)	7.8%
Jia BQ[13]	240 bid×14	500 bid×14	400 bid×14	139/156(89)	7.8%
Chen SP[14]	240 bid×14	1000 bid×14	400 bid×14	33/46(71)	
Li QN[15]	240 bid×14	500 bid×14	400 bid×14	13/16(81)	37.5%
Geng Z[16]	110 qid×14	500 qid×14	200 qid×14	64/76(84)	
Zhou LY[17]	120 qid×14	250 qid×14	200 qid×14	56/73(77)	
Li YY[18]	120 qid×14	250 qid×14	200 qid×14	20/25(80)	28%

Table 5 PPI triple therapy

Authors	PPI	Antibiotics	Cla	Eradication(%)	Side effect
Chen SP[14]	Ome 20 bid×7	Amo 1000 bid×7	500 bid×7	43/48(90)	21.1%
Chen SP[14]	Ome 20 bid×14	Amo 1000 bid×14	500 bid×14	45/47(96)	
Liu WZ[10]	Lan 30 bid×7	Fu 200 bid×7	500 bid×7	11/12(92)	10%
Liu WZ[10]	Lan 30 qd×7	Fu 100 bid×7	250 bid×7	27/30(90)	
Li QN[15]	Lan 30 bid×7	Met 400 bid×7	250 bid×7	14/16(86)	18.8%
Li QN[15]	Lan 30 bid×7	Met 400 bid×7	500 bid×7	15/16(94)	25%

DISCUSSION

Eradication of *Hp* is considered to be confirmed when the tests of Hp continue to be negative for at least 4 weeks after the discontinuation of treatment[21]. Great efforts have been made to establish regimens with good efficacy and safety. It is recognized in western countries that a good regimen should reach the eradication rate of intention to treat (ITT) > 80% and per protocol (PP) > 90%[22].In most Chinese papers only the rate of PP was available, therefore used in this review. In consideration of high resistant rates to antibiotic and the high pre valence of Hp in the country, a regimen with a PP eradication rate > 85% should be accepted in our practice. With this standard we found that both PPI triple therapy and bismuth triple therapy with a two-week course were good for Chinese patients. The former had high adverse events and the latter was more expensive. In most treatment, the dosage of antibiotics was cut down in or der to reduce the side effects. It was shown that the low-dose triple therapies could yield high eradication rates in Chinese patients because they had lower body weight. The limited data with one-week quadruple therapy showed that it could be a good alternative espec ially for the patients who failed to other regimens. Monotherapy and dual therap y were not suitable in practice because of their poor efficacy. These findings a gree with the data from western literatures[23].

The presence of resistant Hp strains is a severe problem in China and influe nces the efficacy of treatments. The resistant rates to metronidazole were reported to be between 28%-80%, and clarithromycin, <5%. However, there has been no reported resistance to bismuth, amoxycillin, furazolidone and tetracycline. Thes e antibiotics should be used to replace metronidazole if the resistance exists. Some studies recommended furazolidone, which was less expensive, with low resistance but more adv erse events.

Recently the consensus reports from European, American and Asia Pacific areas recommended the following regimens[22,24,25]: ① PPI (ome 20 mg or lan 30 mg) + Cla 500 mg + Amo 1000mg; ② PPI + Cla 250/ 500 mg + Met 400 mg; ③ RBC/Bis + Cla 500 mg + Met 400 mg/Amo; and ④ PPI + Bis + Met + Tetra.

All were used twice daily for the one-week course. These regimens had a good ef ficacy in western countries, but have not been extensively examined in China. RB C is still unavailable in China. The preliminary results from our group showed t hat Lan30 + Cla500 + Met400 regimen reached a 93% eradication rate, but Lan30 + Cla250 + Met400 only 77%[26]. More studies are needed before their establishment in this country.

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