

QUESTION

Should HDDT vs. BQT be used for Hp infection?	
POPULATION:	Hp infection
INTERVENTION:	HDDT
COMPARISON:	BQT
MAIN OUTCOMES:	Eradication rate - Total; Adverse events - Dizziness; Adverse events - Skin rash; Adverse events - Abdominal pain; Adverse events - Nausea; Adverse events - Diarrhea; Adverse events - Taste distortion; Adverse events - Discontinued drugs because of adverse events; Adverse events - Palpitation;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<div><div><div><div><div><div></div></div><div>No</div></div><div><div><div></div></div><div>Probably no</div></div><div><div><div></div></div><div>Probably yes</div></div><div><div><div></div><div>Yes</div></div></div><div><div><div></div></div><div>Varies</div></div><div><div><div></div></div><div>Don't know</div></div></div></div></div>	<div>Helicobacter pylori infection is still one of the world’s most frequent infections and accounts for high morbidity and mortality. About 20% of subjects infected with the bacterium will develop complications of the infection including peptic ulcer disease and gastric cancer, which accounts for at least 738,000 deaths annually [Nagini S 2012]. Given the high prevalence and serious health burden of H. pylori infection, it is crucial to use a highly effective and welltolerated eradication regimen.</div> <div>幽门螺杆菌感染是世界上最常见的感染之一，发病率和死亡率都很高。大约 20% 感染该细菌的受试者会出现感染并发症，包括消化性溃疡病和胃癌，每年至少导致 738,000 人死亡 [Nagini S 2012]。鉴于幽门螺杆菌感染的高流行率和严重的健康负担，使用高效且耐受良好的根除方案至关重要。</div>	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

- Trivial
- Small
- Moderate
- Large
- Varies
- Don't know

Outcomes	No of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with BQT	Risk difference with HDDT
Eradication rate - Total	1903 (6 RCTs)	⊕⊕⊕○ MODERATE <sup>a</sup>	RR 1.04 (1.01 to 1.08)	Study population	
				849 per 1,000	34 more per 1,000 (8 more to 68 more)
Adverse events - Taste distortion	226 (1 RCT)	⊕○○○ VERY LOW <sup>b,c</sup>	RR 0.04 (0.00 to 0.58)	Study population	
				123 per 1,000	118 fewer per 1,000 (123 fewer to 52 fewer)

- Downgraded by one level due to ROB: the study had unclear risk of bias in most of the risk domains
- Downgraded by one level due to ROB: one study had high risk of bias in blind domain
- Downgraded by two level due to imprecision: very low event rate.

Eradication rate of HDDT therapy is 88.4%,  
Eradication rate of BQT therapy is 84.9%.

两组间差异≥10%为大的获益，>5%-10%中度，2%- ≥5%小获益，<2%以下微小获益  
可信区间下限为 1，包含了组间无差异。

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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- Large
- Moderate
- Small
- Trivial
- Varies
- Don't know

Outcomes	No of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects * (95% CI)	
				Risk with BQT	Risk difference with HDDT
Adverse events - Dizziness	402 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b</sup>	RR 1.02 (0.14 to 7.18)	Study population	
				5 per 1,000	0 fewer per 1,000 (4 fewer to 30 more)
Adverse events - Skin rash	402 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b</sup>	RR 0.34 (0.01 to 8.24)	Study population	
				5 per 1,000	3 fewer per 1,000 (5 fewer to 36 more)
Adverse events - Abdominal pain	176 (1 RCT)	⊕○○○ VERY LOW <sup>b,c</sup>	RR 0.34 (0.01 to 8.26)	Study population	
				11 per 1,000	7 fewer per 1,000 (11 fewer to 82 more)
Adverse events - Nausea	402 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b</sup>	RR 1.02 (0.23 to 4.43)	Study population	
				15 per 1,000	0 fewer per 1,000 (11 fewer to 51 more)
Adverse events - Diarrhea	402 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b</sup>	RR 2.38 (0.36 to 15.97)	Study population	
				5 per 1,000	7 more per 1,000 (3 fewer to 74 more)
Adverse events - Discontinued drugs because of adverse events	232 (1 RCT)	⊕○○○ VERY LOW <sup>a,b</sup>	RR 0.20 (0.01 to 4.12)	Study population	
				17 per 1,000	14 fewer per 1,000 (17 fewer to 54 more)
Adverse events - Palpitation	176 (1 RCT)	⊕○○○ VERY LOW <sup>b,c</sup>	RR 3.07 (0.13 to 74.30)	Study population	
				0 per 1,000	0 fewer per 1,000

					(0 fewer to 0 fewer)
	<p>a. Downgraded by one level due to ROB: one study had high risk of bias in blind domain</p> <p>b. Downgraded by two levels due to imprecision: wide confidence interval and very low event rate.</p> <p>c. Downgraded by one level due to ROB: the study had unclear risk of bias in most of the risk domains</p>				

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>● Moderate</li> <li>○ High</li> <li>○ No included studies</li> </ul>	关键结局指标（即根除率）证据体的质量为中等质量；其他诸多重要（但非关键）不良反应证据体的质量均为极低。	

## Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Important uncertainty or variability</li> <li>○ Possibly important uncertainty or variability</li> <li>● Probably no important uncertainty or variability</li> <li>○ No important uncertainty or variability</li> </ul>	<p>H. pylori-infected patients from northern, central, and southern Taiwan, factors that were of most concerns to patients on anti-H. pylori therapy were eradication rate (72.9%) and side effects (11.5%). Of lesser concerns, these factors included duration of regimen (7.0%), convenience (4.5%), number of pills (2.8%), and costs (0.8%) [Yoen-Young Chuah 2017].</p> <p>对来自台湾北部、中部和南部的 H. pylori 感染患者的调研显示根除率 (72.9%) 以及治疗相关的不良反应 (11.5%) 是患者最关心的因素。患者较少关注的因素包括治疗时间 (7.0%)、便利性 (4.5%)、药片数量 (2.8%) 和经济成本 (0.8%) [Yoen-Young Chuah 2017]。</p>	对患者的调研显示绝大部分的患者均最关注根除率和重大不良反应

## Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> <li>○ Favors the comparison</li> <li>○ Probably favors the comparison</li> <li>● Does not favor either the intervention or the comparison</li> <li>○ Probably favors the intervention</li> <li>○ Favors the intervention</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>		总不良事件大剂量二联方案降低不良事件的发生率 68%
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## Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Large costs</li> <li>○ Moderate costs</li> <li>● Negligible costs and savings</li> <li>○ Moderate savings</li> <li>○ Large savings</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<p>A study from China [Yang 2019] shows that, The treatment cost of Dual therapy is \$113.6, The treatment cost of Quadruple is \$130.1.</p> <p>来自中国的一项研究 [Yang 2019] 表明, 二联治疗方案的治疗费用为 113.6 美元, 四联治疗的费用为 130.1 美元。</p> <p>A study from China [Lei 2020] shows that, The treatment cost of Dual therapy is 706.00 RMB, The treatment cost of Quadruple is 916.00RMB.</p> <p>来自中国的另一项研究 [Lei 2020] 显示, 二联治疗方案的治疗费用为 706.00 元人民币, 四联疗法的治疗费用为 916.00 元人民币。</p>	

## Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Very low</li> <li>● Low</li> <li>○ Moderate</li> <li>○ High</li> <li>○ No included studies</li> </ul>	只有两个研究提供了治疗的直接费用信息, 其完整性和外推性均有限。	

## Cost effectiveness

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> <li>○ Favors the comparison</li> <li>○ Probably favors the comparison</li> <li>● Does not favor either the intervention or the comparison</li> <li>○ Probably favors the intervention</li> <li>○ Favors the intervention</li> <li>○ Varies</li> <li>○ No included studies</li> </ul>	<p>A study from China [Yang 2019] shows that, The treatment cost of Dual therapy is \$113.6, The treatment cost of Quadruple is \$130.1.</p> <p>来自中国的一项研究 [Yang 2019] 表明，二联治疗方案的治疗费用为 113.6 美元，四联治疗的费用为 130.1 美元。</p> <p>A study from China [Lei 2020] shows that, The treatment cost of Dual therapy is 706.00 RMB, Eradication rate is 91.7%, The treatment cost of Quadruple is 916.00RMB, Eradication rate is 94.8%.</p> <p>中国的另一项研究[雷 2020]显示，二联治疗的治疗费用为 706.00 元，根除率为 91.7%，四联治疗的治疗费用为 916.00 元，根除率为 94.8%，两组的增量成本效果比为 67.74。</p>	<p>67.74 含义：每增加百分之一的根除率，增加的花费为 67.74 元。</p> <p>不引用数据</p>
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## Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Reduced</li> <li>○ Probably reduced</li> <li>● Probably no impact</li> <li>○ Probably increased</li> <li>○ Increased</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	无纳入研究	

## Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ No</li> <li>○ Probably no</li> <li>● Probably yes</li> <li>○ Yes</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<p>Between 7-day standard triple therapy, 14-day standard triple therapy, 10-day sequential therapy, 14-day bismuth quadruple therapy, 14-day concomitant therapy, 14-day hybrid therapy, It shows the distribution of first-line eradication regimens most frequently used in China, 14-day bismuth quadruple therapy was the most commonly used regimen (38%). [Yoen-Young Chuah 2017]</p> <p>The mean accepted minimal eradication rates of physicians in China is 82.8% and the real-world eradication rates of 14-day bismuth quadruple therapy is 85.5%. [Yoen-Young Chuah 2017]</p> <p>研究显示在以下的治疗方案为中国常见的一线根除方案，7 天标准三联疗法、14 天标准三联疗法、10 天序贯疗法、14 天铋剂四联疗法、14 天伴随疗法、14 天混合疗法）；其中 14 天铋剂四联疗法是最为常用的方案（38%）[Yoen-Young Chuah 2017]。中国医生表示其可接受的平均最低根除率为 82.8%，而 14 天铋剂四联疗法的实际根除率为 85.5% [Yoen-Young Chuah 2017]。</p>	未发现有关大剂量二联治疗方案的可接受度研究

## Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ No</li> </ul>	无纳入研究	

<input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		
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## SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

## TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
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