Helicobacter pylori salvage therapies: evaluating outcomes of outpatient regimens utilised at St Vincent's Hospital Melbourne

Tara Menichelli[1], Yves Poy Lorenzo[1,2]

[1] Pharmacy, St Vincent's Hospital Melbourne; [2]Department of Medicine, The University of Melbourne

ST VINCENT'S HOSPITAL MELBOURNE

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Background: *H. pylori* is a common gastrointestinal infection that is an important cause of gastric cancer and peptic ulcer disease[1]. First line treatment failure is becoming increasingly common however due to emergence of antibiotic resistant strains of *H. pylori*[1,3,4].

The optimal salvage therapy is yet to be determined. Current recommendations in Australia are based largely on international studies with minimal local data available[2,4]. Therapeutic guideline (TG) endorsed regimens include a proton pump inhibitor (PPI) plus levofloxacin-amoxicillin (LEVO-AMOX), rifabutin-amoxicillin (RIFB-AMOX) and quadruple therapy containing tetracycline, bismuth, metronidazole (QUAD-BISM)[2.] All salvage therapies recommended by the TG contain drugs which are not registered in Australia and can be difficult to access in the community, have increased cost to patient and potentially delay treatment.

Despite several published studies showing moxifloxacin-amoxicillin-proton pump inhibitor (MOXI-AMOX) as an effective salvage regimen[4], it is not listed in the TG. All agents in the MOXI-AMOX regimen are TGA-registered medications, do not require SAS Cat B approval, and provide the advantage of same-day supply after the outpatient appointment.

To improve access and reduce delay of treatment, the Antimicrobial Stewardship team and Gastroenterology unit approved MOXI-AMOX as an appropriate salvage regimen.

Aim: To measure the eradication rate of *H. pylori* salvage therapies utilised at an Australian hospital-outpatient setting with a focus on efficacy of moxifloxacin-amoxicillin regimens.

Method: Single centre, retrospective cohort study on patients prescribed *H. pylori* salvage therapy between August 2014 and May 2016. Cases were identified using pharmacy dispensing records, pathology and medical imaging records. Data were collected on demographics, treatment details and outcome by reviewing medical records. Patients were included if they had failed first-line therapy and prescribed a subsequent regimen other than those recommended in TG as first-line therapy. "Approved regimen" is defined as those listed in TG for salvage therapy plus MOXI-AMOX. "Non-approved regimen" is defined as a regimen to the contrary.

Primary outcome was eradication of *H. pylori* defined as a negative urea breath test, stool antigen or gastric biopsy post salvage therapy. **Secondary outcomes** measured included regimen used, cost and days taken to supply salvage therapy.

Results: Thirty patients were identified and met inclusion criteria. Patient and treatment characteristics are shown in Table 1.

Table 1. Patient characteristics and indications for treatment

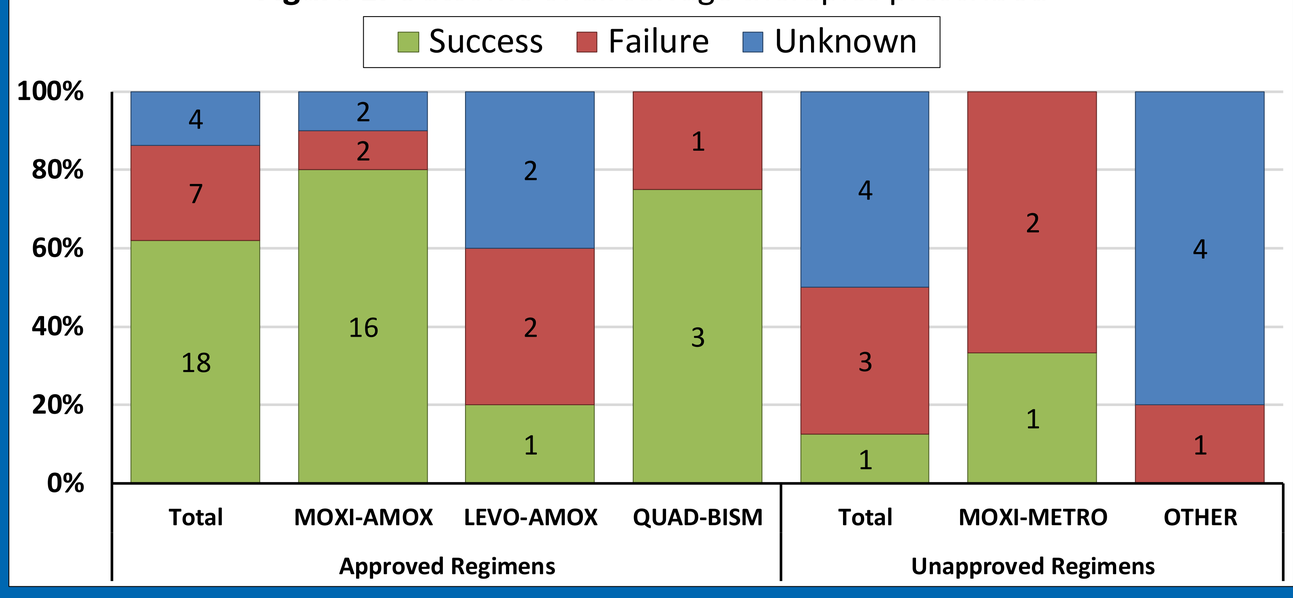
Total number of patients	30		
Age (years ± SD)	57 ± 15		
Female	20 (67%)		
Prior treatments	median 1 (range 1-4)		
1	19 (63%)	3 or more	5 (17%)
2	6 (20%)		
Birthplace			
Asian	9 (30%)	European	11 (37%)
Australian/Oceania	6 (20%)	Africa	4 (13%)
Treatment indication (can be more than one)			
Gastritis/Dyspepsia	27	Family History of Gastric Cancer	2
Gastric Ulcer	3	History of Gastric Cancer	1
Duodenal Ulcer	1		

Results (continued): Successful eradication was achieved in 21 patients, 8 patients were lost to follow up and 1 patient declined further therapy. Eradication was achieved in 18 with the first salvage regimen prescribed and in 2 after the second salvage regimen. One patient required 4 different regimens to achieve eradication.

A total of 37 salvage therapies were prescribed. Total eradication rate was 69% for approved regimens and 13% for unapproved regimens. MOXI-AMOX achieved 80% eradication rate. Eradication rates for all other regimens are shown in Figure 1.

Cost of MOXI-AMOX was 60-75% lower compared to LEVO-AMOX and QUAD-BISM. Time from prescription to supply was a median of 0 days (range 0-37) and 47 days (range 14-217 days) respectively.

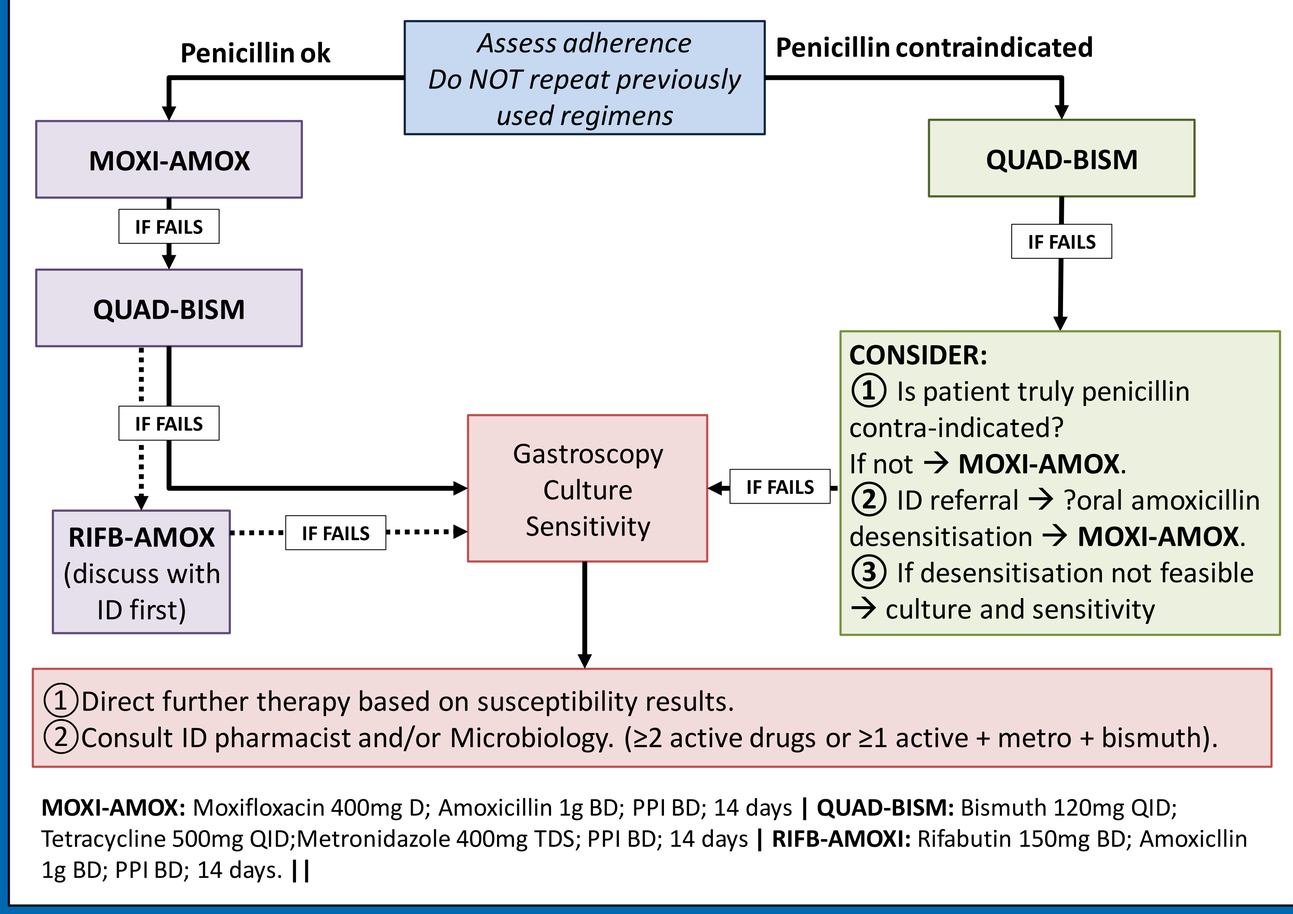
Figure 1. Outcome of all salvage therapies prescribed



Discussion and Conclusion: The eradication rate observed with MOXI-AMOX support its use as an appropriate salvage regimen associated with lower cost and increased accessibility in both the community and hospital-outpatient setting. QUAD-BISM had an acceptable eradication rate which was similar to that previously described in the literature. In our cohort, low rates of eradication were achieved when non-approved regimens were prescribed. The TG and other international guideline recommend avoiding use of non-approved regimens (also known as "ad hoc" regimens) due to low rates of success with eradication. This low rate was consistent with our cohort treated with non-approved regimens and suggests an area where Antimicrobial Stewardship could target in the outpatient setting.

Based on the results of this audit an algorithm was developed to guide medical staff in the outpatient clinics for prescribing salvage therapies (Figure 2).

Figure 2. Treatment algorithm for *H. pylori* salvage therapy



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Contact: Tara Menichelli, St Vincent's Hospital Melbourne (email: tara.menichelli@svha.org.au)