Helicobacter Pylori Screening after Acute Myocardial Infarction

The Cluster Randomized Crossover HELP-MI-SWEDEHEART Trial

Robin Hofmann, M.D., Ph.D., FESC

Department of Clinical Science and Education, Södersjukhuset

Karolinska Institutet, Stockholm, Sweden

August 31, 2025

Conclusions

In this nationwide cluster-randomized, crossover, registry-based clinical trial among unselected patients with acute myocardial infarction, routine *H pylori* screening did not significantly reduce the risk of upper gastrointestinal bleeding.

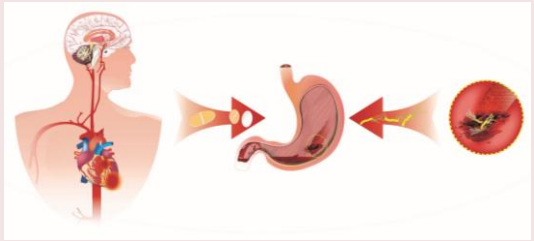
However, a clinically relevant benefit of *H pylori* screening in patients at higher baseline risk of bleeding may exist.

HELP-MI SWEDEHEART

Setting

A nationwide, cluster randomized, crossover, registry-based clinical trial

Background and Aim



Aim and Intervention

To investigate, in a real-world setting, the effectiveness of adding routine *H pylori* screening by urea breath test to usual care on upper gastrointestinal bleeding (UGIB) after acute myocardial infarction.

N=18,466 patients with MI in SWEDEHEART from 35 hospitals grouped into 18 clusters (PCI networks)

R

H pylori screening	Usual care
N=4,905	N=4,659

X

Usual care	*H pylori* screening
N=4,562	N=4,341

F

R Cluster randomization

X Crossover after 1 year

F Follow-up for 1 year

Endpoints

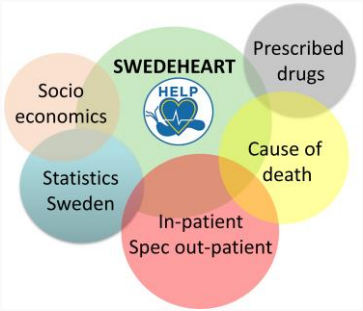
Primary endpoint: UGIB

Secondary endpoints:

NACE (All-cause death, UGIB, MI, or stroke)

MACCE (CV death, MI, or stroke)

Individual components of composite endpoints in the primary **intention-to treat** and secondary **per-protocol** populations.



UCR Uppsala Clinical Research Center

SWEDEHEART

Karolinska Institutet

SÖS SÖDERSJUKHUSET

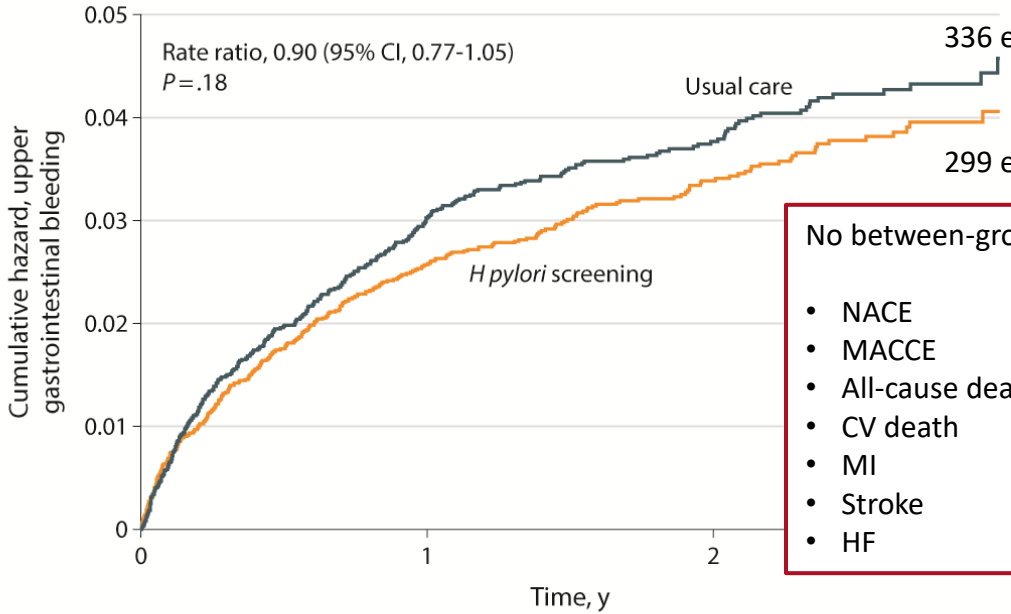
Characteristics of the Patients

Characteristic	No. (%) of patients: *Helicobacter pylori* screening (n = 9245)	Usual care (n = 9221)
Demographics		
Age, median (IQR), y	71 (61.0-79)	71 (62-79)
Sex		
Female	2636 (28.5)	2692 (29.2)
Previous cardiovascular disease		
Myocardial infarction	3124 (33.8)	3012 (32.7)
Medication at admission		
Aspirin	2360 (26.2)	2340 (26.0)
Proton pump inhibitor	2284 (24.7)	2275 (24.7)
In-hospital course		
Helicobacter pylori		
Screened	6480 (70.1)	0
Tested positive	1532 (16.6)	
Eradication prescribed	1481 (16.0)	
Medication at discharge		
Dual antiplatelet therapy	6522 (70.6)	6429 (69.7)
Proton pump inhibitor	5207 (56.3)	4550 (49.3)

H pylori prevalence: 23.6
Eradication rate: 96.6

Primary end point

Upper Gastrointestinal Bleeding (UGIB)



336 events; cumulative hazard, 4.6%

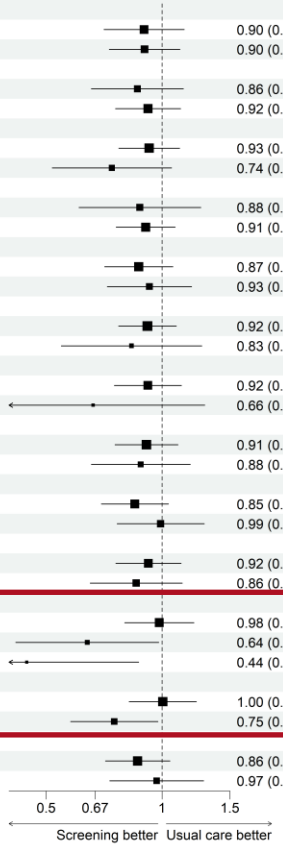
299 events; cumulative hazard, 4.1%

No between-group differences with regard to:

- NACE
- MACCE
- All-cause death
- CV death
- MI
- Stroke
- HF

UGIB in prespecified subgroups

Subgroup	H pylori screening N	H pylori screening N/100 years	Usual care N	Usual care N/100 years	Rate ratio (95% CI)
Age					
Below 75 years	131/5,563	1.16	146/5,514	1.34	0.90 (0.71, 1.14)
75 years or above	168/3,682	2.57	190/3,707	2.88	0.90 (0.73, 1.11)
Sex					
Female	97/2,636	1.96	114/2,692	2.29	0.86 (0.66, 1.13)
Male	202/6,609	1.57	222/6,529	1.77	0.92 (0.76, 1.12)
Current smoking					
No	233/7,260	1.66	250/7,188	1.83	0.93 (0.77, 1.11)
Yes	53/1,718	1.55	76/1,765	2.27	0.74 (0.52, 1.06)
Hypertension					
No	56/2,861	0.96	64/2,820	1.16	0.88 (0.61, 1.26)
Yes	243/6,384	2.03	272/6,401	2.27	0.91 (0.76, 1.08)
Diabetes					
No	177/6,773	1.33	207/6,805	1.57	0.87 (0.71, 1.07)
Yes	122/2,472	2.69	129/2,416	2.97	0.93 (0.72, 1.19)
Chronic kidney disease					
No	255/8,383	1.56	283/8,386	1.75	0.92 (0.77, 1.09)
Yes	41/714	3.67	51/742	4.37	0.83 (0.55, 1.27)
Previous alcohol use disorder					
No	190/5,912	1.78	219/5,955	1.83	0.92 (0.75, 1.12)
Yes	16/266	3.27	20/237	4.58	0.66 (0.34, 1.29)
Previous gastroduodenal pathology					
No	213/7,679	1.42	236/7,692	1.60	0.91 (0.75, 1.10)
Yes	86/1,566	3.00	100/1,529	3.66	0.88 (0.66, 1.18)
Previous MI					
No	182/6,121	1.52	216/6,209	1.82	0.85 (0.70, 1.04)
Yes	117/3,124	2.00	120/3,012	2.14	0.99 (0.76, 1.29)
Infarct type					
NSTEMI	200/5,750	1.83	219/5,667	2.03	0.92 (0.76, 1.12)
STEMI	96/3,347	1.47	115/3,461	1.75	0.86 (0.65, 1.13)
Anemia on admission					
No anemia	182/6,042	1.55	194/6,113	1.62	0.98 (0.80, 1.21)
Mild anemia	37/878	2.50	54/842	3.78	0.64 (0.42, 0.98)
Moderate to severe anemia	15/193	5.41	26/161	11.75	0.44 (0.23, 0.87)
Kidney failure on admission					
No	195/6,986	1.40	199/7,019	1.45	1.00 (0.82, 1.23)
Yes	104/2,222	2.72	135/2,181	3.60	0.75 (0.58, 0.97)
Proton pump inhibitor on admission					
No	200/6,961	1.46	231/6,946	1.74	0.86 (0.71, 1.05)
Yes	99/2,284	2.39	105/2,275	2.50	0.97 (0.73, 1.28)

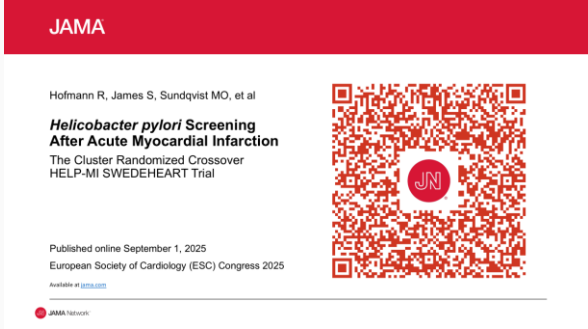


Per-Protocol analysis

	H pylori screened patients		*H pylori* positive patients		Patients receiving eradication	
End point	Hazard ratio (95% CI)	P Value	Hazard ratio (95% CI)	P Value	Hazard ratio (95% CI)	P Value
UGIB	0.84 (0.65-1.08)	0.16	0.47 (0.22-1.01)	0.05	0.49 (0.23-1.06)	0.07

Lower point estimates but no significant difference in secondary outcomes.

Key messages



Impact on clinical practice and take away message

- In unselected patients with acute myocardial infarction, routine ***H pylori*** screening did not significantly reduce the risk of UGIB and can therefore not generally be recommended in all patients.

- However, ***H pylori*** testing during the hospitalization period for myocardial infarction appears to be a meaningful addition to usual care in patients with elevated risk of upper gastrointestinal bleeding, e.g. as indicated by concomitant anemia or kidney failure.

- Further analyses and new studies are need to define the optimal target population.