

Prevention Trials of 2020

Don't miss the boat !

Asst. Prof. Pairoj Chattranukulchai MD, MSc

Division of Cardiovascular Medicine
Faculty of Medicine, Chulalongkorn University
King Chulalongkorn Memorial Hospital





PolyIran trial

Effectiveness of polypill for primary and secondary prevention of cardiovascular diseases (PolyIran): a pragmatic, cluster-randomised trial

Lancet 2019; 394: 672-83

Cluster-Randomized Trial 1 : 1

Preventive interventions

- Healthy: low salt, sugar and fat diet
- BW control
- Quit smoking
- Quit opium

Fixed-dose polypill (no titration)

- ASA **81** mg
- Enalapril **5** mg/Valsartan **40** mg
- HCTZ **12.5** mg
- Atorvastatin **20** mg



Inclusion

- 40-75 y
- No prior stroke
- No bleeding disorder
- No active UGIB
- No OAC use
- SBP > 90 mmHg
- eGFR > 30 ml/min

Primary Endpoint (MACE)

: SCD, fatal MI, ACS or HF hospitalization, PCI, stroke

ITT analysis

5-year follow up

Effectiveness of polypill for primary and secondary prevention of cardiovascular diseases (PolyIran): a pragmatic, cluster-randomised trial

Lancet 2019; 394: 672-83



N = **6,838**, mean age **60 y**

Women **50%**, known CVD **10%**

DM **15%**, HT **40%** (**30%** on Rx)

Baseline LDL **121 mg/dL**, SBP **134 mmHg**

Adherence **80%**

Mean difference of SBP = **3 mmHg**

Mean difference of LDL = **20 mg/dL**

Primary Endpoint (MACE)

8.8% (301) vs 5.9% (202)

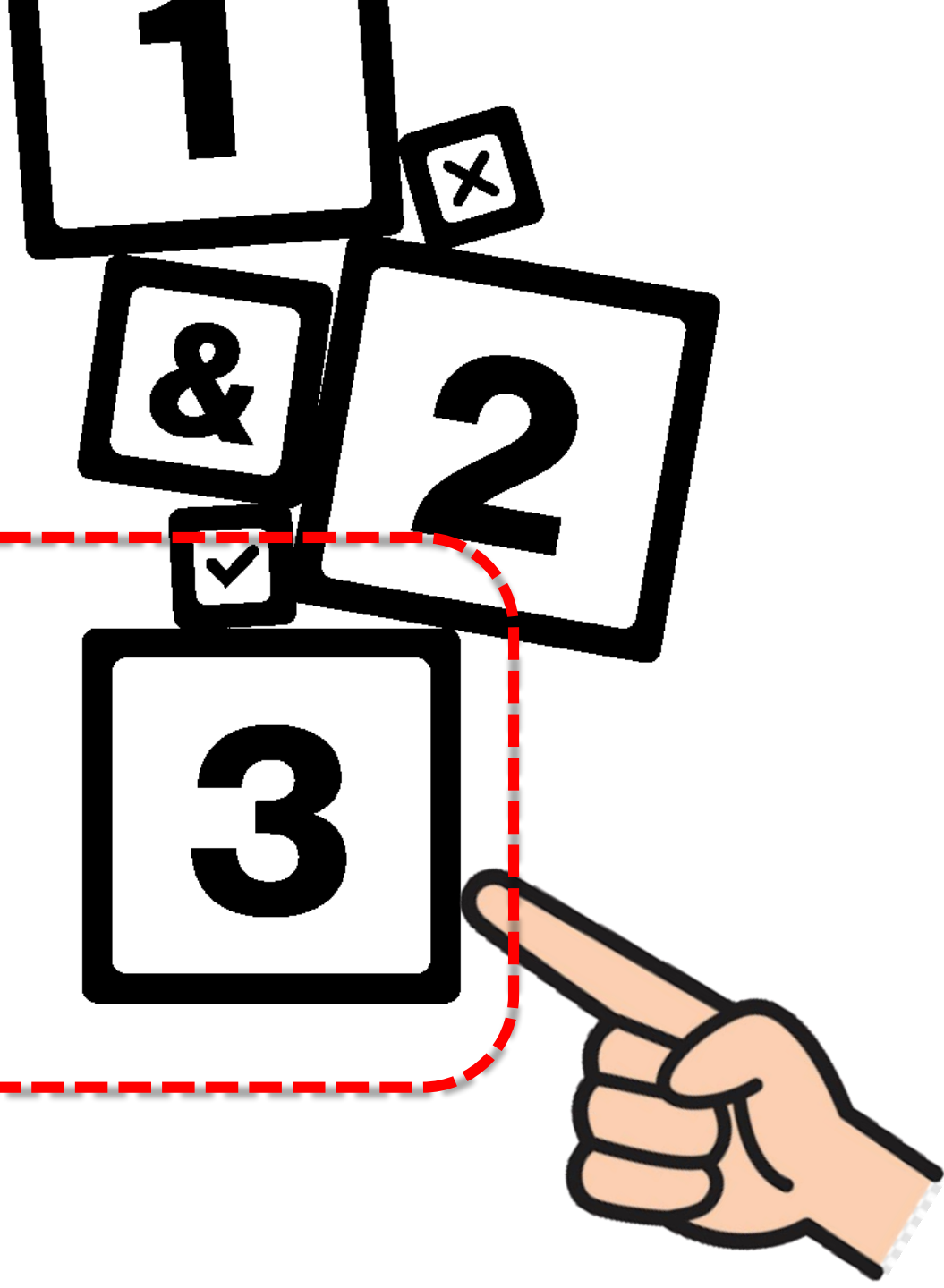


Comparable Safety

21 ICH : 11 (**0.3%**) vs 10 (**0.3%**)

22 UGIB : 9 (**0.3%**) vs 13 (**0.4%**)

Quick tips

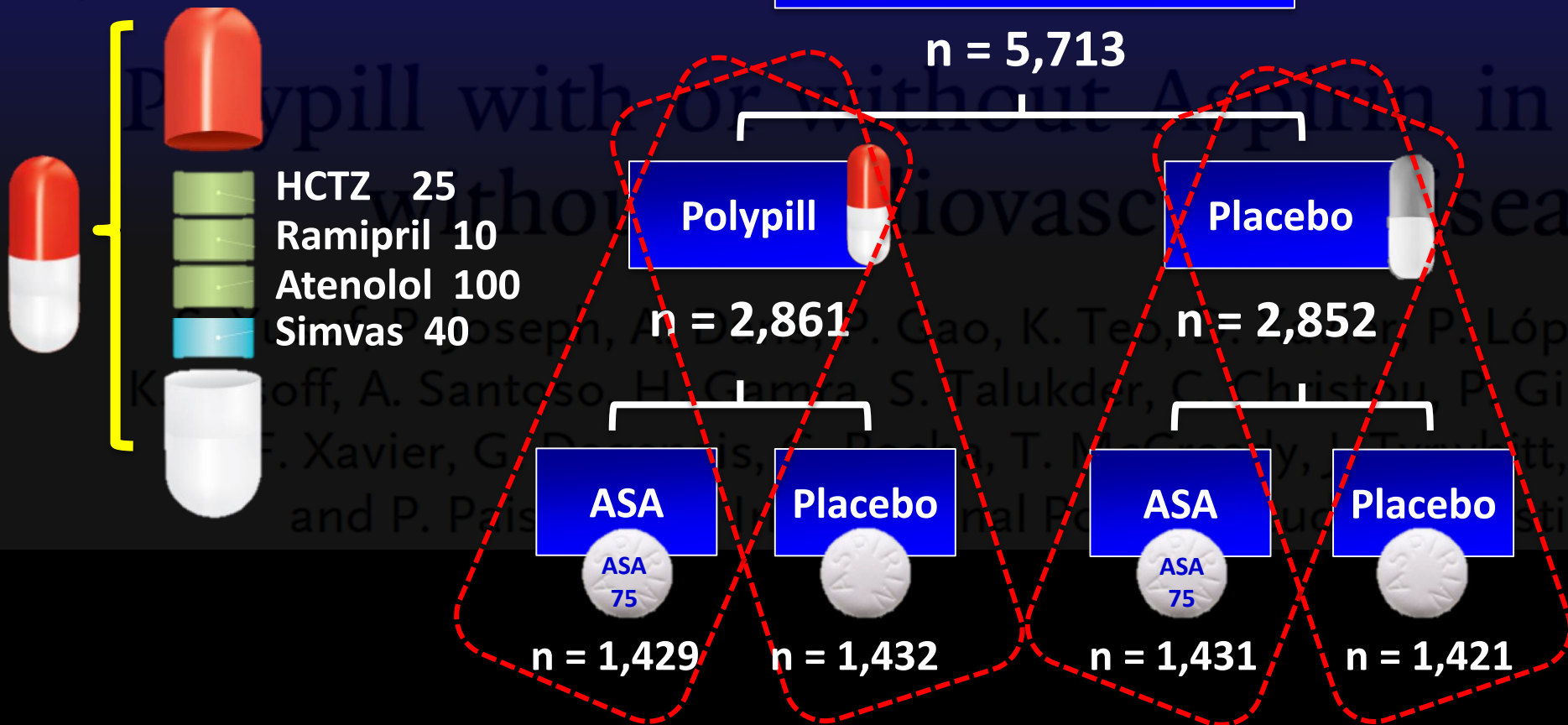


ORIGINAL ARTICLE

Polypill with or without Aspirin in Persons without Cardiovascular Disease

S. Yusuf, P. Joseph, A. Dans, P. Gao, K. Teo, D. Xavier, P. López-Jaramillo, K. Yusoff, A. Santoso, H. Gamra, S. Talukder, C. Christou, P. Girish, K. Yeates, F. Xavier, G. Dagenais, C. Rocha, T. McCready, J. Tyrwhitt, J. Bosch, and P. Pais, for the International Polycap Study 3 Investigators*

The International Polycap Study 3 (TIPS-3): Primary prevention



| | N Rand |
|--------------|-------------|
| India | 2739 |
| Philippines | 1676 |
| Colombia | 489 |
| Bangladesh | 295 |
| Canada | 131 |
| Malaysia | 119 |
| Indonesia | 118 |
| Tunisia | 107 |
| Tanzania | 39 |
| Total | 5713 |

Polypill with or without Aspirin in Persons without Cardiovascular Disease



Inclusion

- Target CV disease risk: >1.0%/year
- M ≥ 50 y and F ≥ 55 y with an INTERHEART Risk Score (IHRS) of ≥ 10
- M and F ≥ 65 y with an IHRS of ≥ 5



Exclusion

- Known CV disease
- SBP <120 mm Hg
- Symptomatic hypotension during run-in
- Peptic ulcer, dyspepsia, bleeding
- Contraindication to pills

Primary Endpoint (MACE)

: CV death, MI, stroke, PCI, HF hospitalization, or resuscitated cardiac arrest

ITT analysis

Mean follow up 4.6 years

Polypill with or without Aspirin in Persons without Cardiovascular Disease

N = **5,713**, mean age **64** y

Women **53%**, DM **37%**

HT or SBP > 140 mmHg **80%** (**11% on Rx**)

Baseline LDL **120** mg/dL, SBP **144** mmHg

Adherence at 2nd year **81%**

Adherence at ending **57%**

(similar results for placebo and ASA)

Mean difference of SBP = **5.8** mmHg

Mean difference of LDL = **19** mg/dL

Safety

Hypotension: **2.7 %*** vs **1.1 %**

Cough: **1.1 %*** vs **0.6 %**

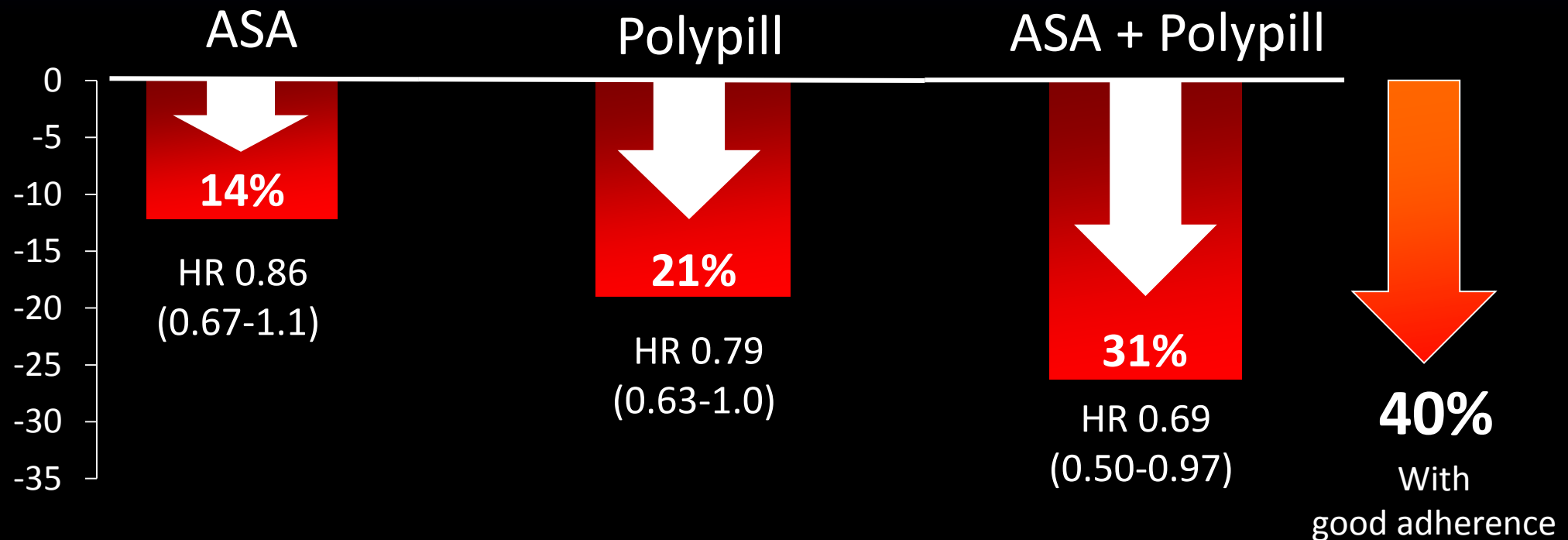
Myalgia: **0.5 %** vs **0.5%**

Major bleeding: **0.7 %** vs **0.7%**

Polypill with or without Aspirin in Persons without Cardiovascular Disease

Primary endpoint (ITT analysis)

- **MACE**: CV death, MI, stroke, HF, PCI or resuscitated cardiac arrest



HEART DISEASE

Thank you

