

EACS Young Investigators Conference

Palais des Académies, Brussels
Friday, December 16, 2016

SUMMARY OF THE BREAKOUT SESSIONS

Off label and generic treatment

Moderator: Nathan Clumeck, Belgium

Markus Bickel, Germany
Ignacio Bernardino, Spain

off-label treatment

“Unapproved use of an approved drug”¹

..use in an unapproved age group, dosage,
disease or route of administration.²

1. FDA definition - <http://www.fda.gov>

2. Stafford RS. *N Engl J Med.* 2008 Apr 3;358(14):1427-9

off-label treatment

Common examples

- Unboosted AZV (U.S. vs EU)
- Crushing pills or opening capsules
- Special circumstances (pregnancy, renal impairment, TB..)
- Most salvage or De-escalation therapies

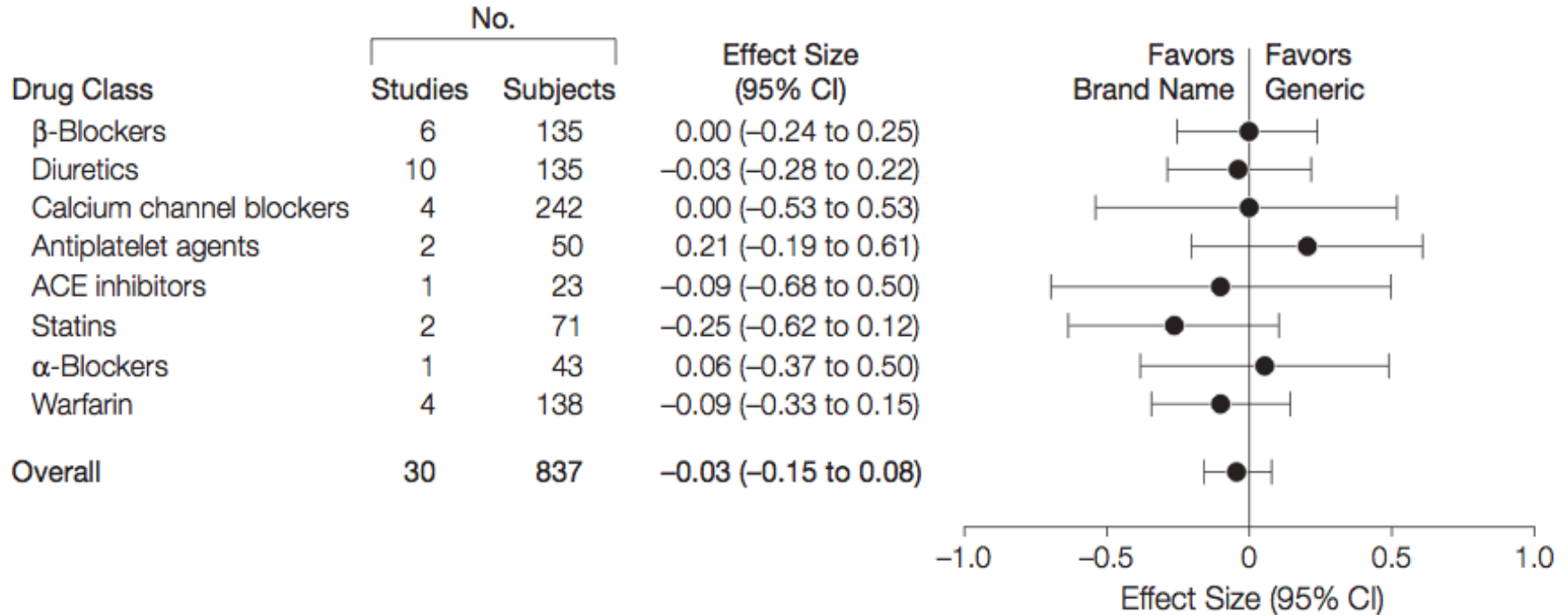
off-label treatment

Pitfalls

- Often anecdotal reports → little or selective follow-up
- Lack of sponsors → no high qual. studies
- Legal issues → inform pt

Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease

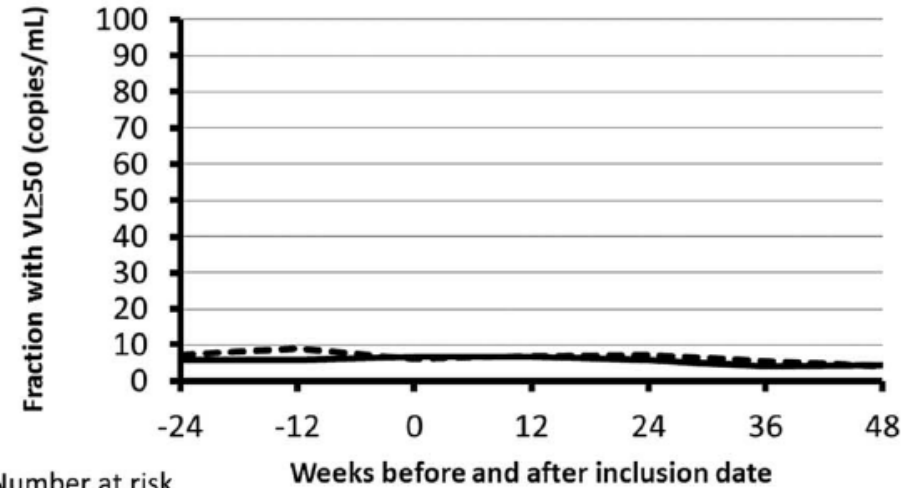
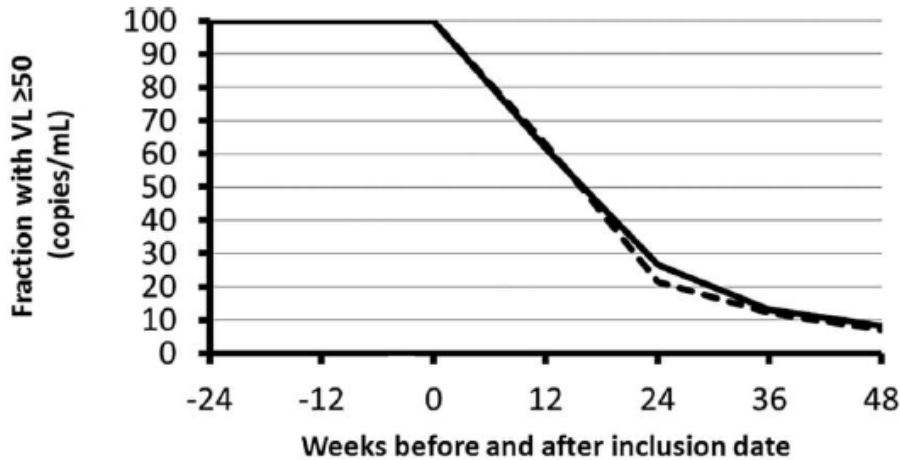
A Systematic Review and Meta-analysis



Switch From a Once-Daily Single-Tablet Regimen to a Triple-Tablet Regimen for Economic Reasons

Naïve patients

Suppressed patients



Number at risk	-24	-12	0	12	24	36	48
STR-TEE ----	47	49	111	105	79	58	43
TTR-TEL ___	22	29	56	47	34	23	12

Number at risk	-24	-12	0	12	24	36	48
STR-TEE ----	351	353	356	349	343	329	274
TTR-TEL ___	510	511	512	504	478	422	322