

Implications on Drug Labeling

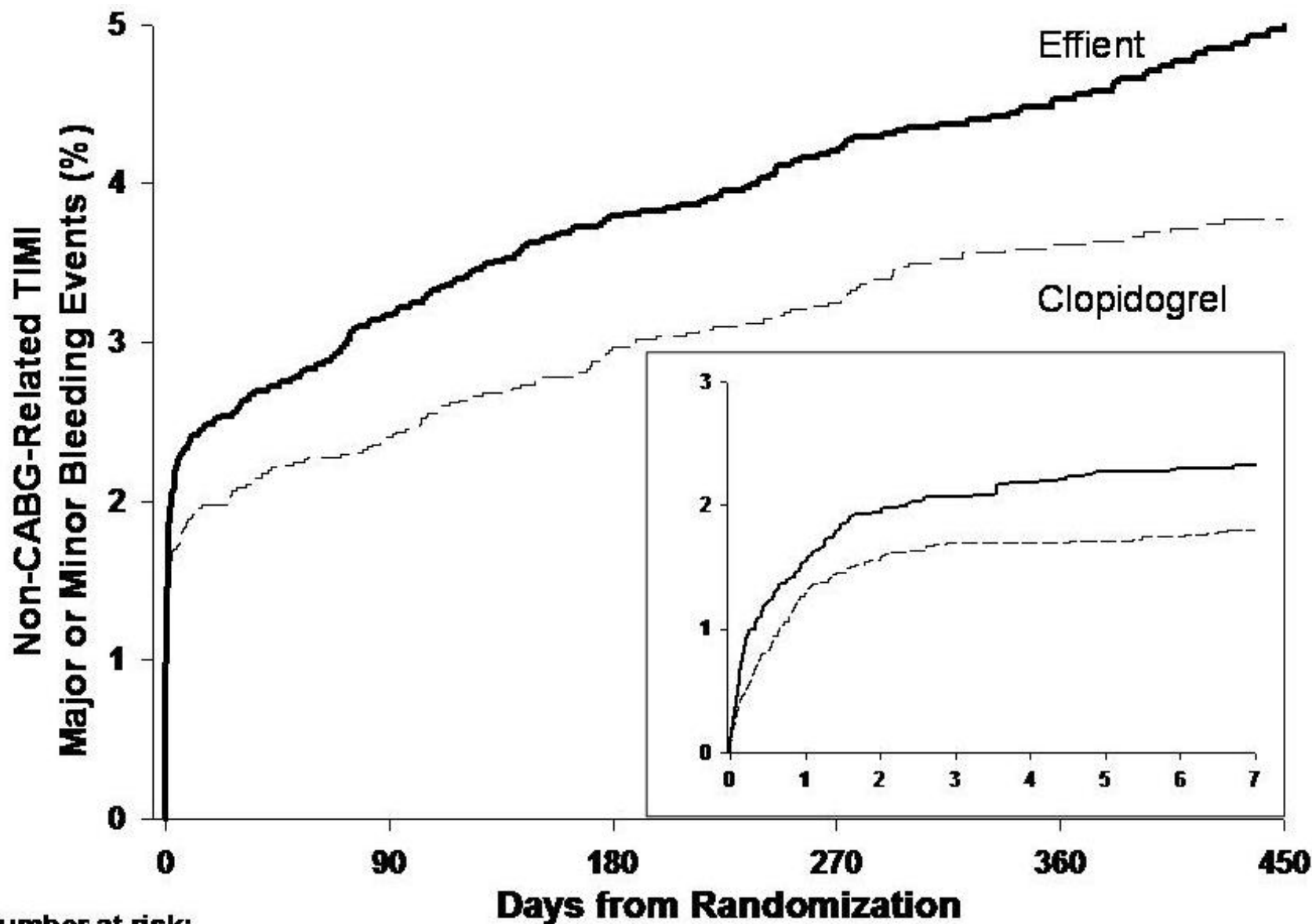
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Strong priors

- Radial artery bleeding will be easier to manage
- Opportunity to have a fatal retroperitoneal-equivalent bleed is low

This probably suffices to overcome usual reservations regarding reliance upon a non-randomized registry to support assessment of comparative safety



Number at risk:

| | | | | | | |
|-------------|------|------|------|------|------|------|
| Effient | 6741 | 6042 | 5707 | 4813 | 4078 | 2747 |
| Clopidogrel | 6716 | 6023 | 5764 | 4883 | 4138 | 2792 |

Labeling likely

- Adverse Reactions section?
- Probably not cite specific TREATT results
- Agents with approved use based on studies with fPCI
- Cited bleeding results can be expected to be less with rPCI

Other (labeling?) considerations

- TREATT no help in concluding rPCI outcome as good as fPCI
- If the dose of antiplatelet agent that you use with fPCI is not already providing maximal inhibition, ought not the dose with rPCI be increased?