

Balancing benefits and adverse effects in individual patients

Scenario: Consider 2 hypertensive patients (mean blood pressure 170/100 mm Hg); one patient (Pat) is asymptomatic, and the other (Dorothy) has a history of stroke. Both are being considered for a new antihypertensive, drug X, with relative risk reduction for stroke of 33% over 3 years. Drug X also increases the risk of severe gastric bleeding 3-fold over 3 years.

1. a) Estimate Pat's baseline risk of stroke as 1% per year, 3% over 3 years.
b) Learners calculate Pat's 3-year risk of stroke with drug X (2%).
c) Learners calculate Pat's 3-year risk difference (RD) for stroke (1%).
2. a) Estimate Dorothy's baseline risk of stroke as 10% per year, 30% over 3 years.
b) Learners calculate Dorothy's 3-year risk of stroke with Drug X (20%).
c) Learners calculate Dorothy's 3-year RD for stroke (10%).
3. a) Estimate Pat's and Dorothy's risk of severe gastric bleeding as 0.1% per year.
b) Learners calculate the RD for severe gastric bleeding over 3 years for Pat and Dorothy (baseline risk = 0.3% over 3 years; on drug X = 0.9%; RD = 0.6%.)
4. a) Learners compare the RD's for Pat and Dorothy for stroke and severe gastric bleeding.
b) Learners discuss whether they would treat either of these 2 patients with drug X.

	Risk of stroke without Drug X	Risk of stroke with Drug X	Risk difference for stroke	Risk of severe gastric bleeding without Drug X	Risk of severe gastric bleeding with Drug X	Risk difference for severe gastric bleeding
Patricia	3%	2%	1%	0.3%	0.9%	0.6%
Dorothy	30%	20%	10%	0.3%	0.9%	0.6%

Summary Point:

Trial data can be individualized by calculating and comparing RD's for benefits and harms if a patient's risk of the relevant outcomes with and without treatment are known or can be estimated.