CORE-MD

Coordinating Research and Evidence for Medical Devices

Risk calculator

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Risk calculator

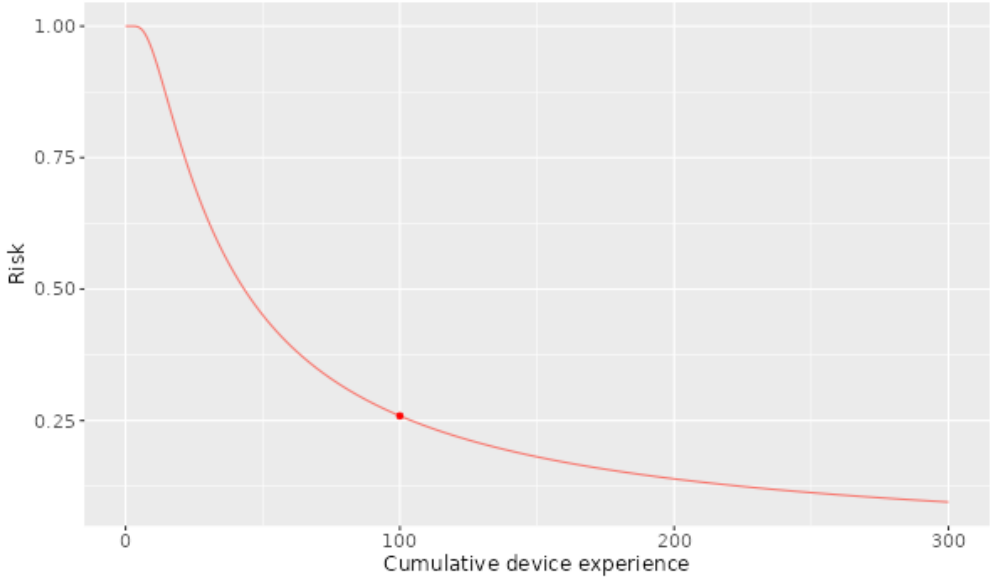
- High risk devices may be approved with limited evidence
- We developed an online tool to inform clinicians/patients implications of this limited evidence

Risk calculator

- Questions the tool answers:
  - Based on the limited evidence, what is the upper limit to the n-year risk for a patient considering the device?
  - How does our confidence in this upper limit change if we were to collect more evidence?
- Input:
  - Cumulative device experience
  - Observed events

Hypothetical scenario 1

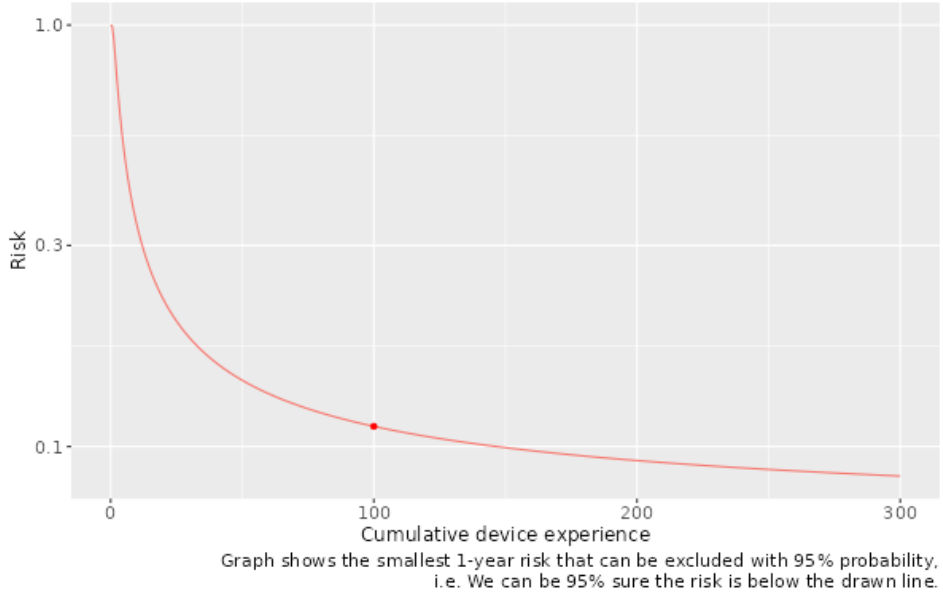
- Device with true event rate of 0, but we have observed only 100 patient years



Graph shows the smallest 10-year risk that can be excluded with 95% probability, i.e. We can be 95% sure the risk is below the drawn line.

Hypothetical scenario 2A

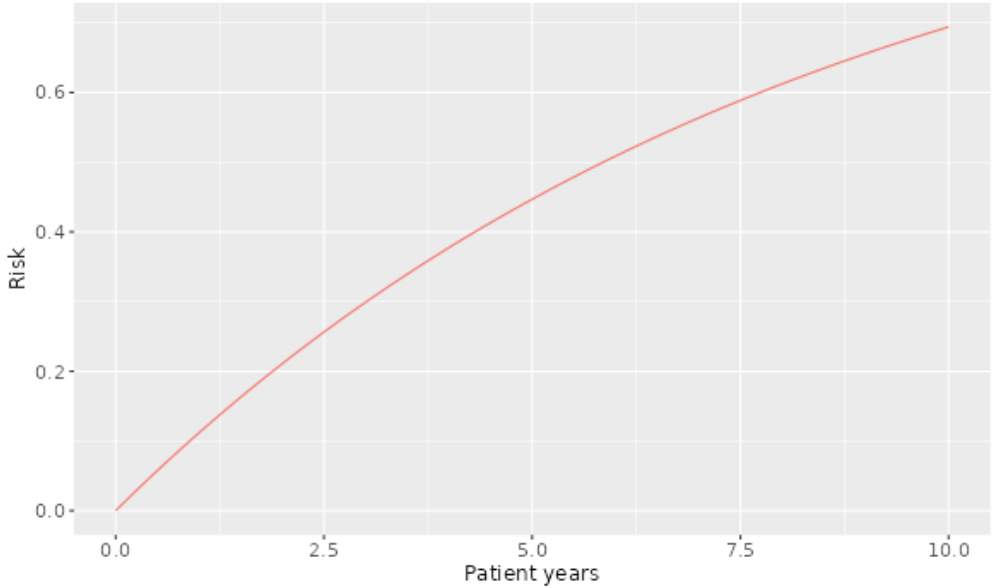
- Device with 6 events in 100 cumulative patient years



Graph shows the smallest 1-year risk that can be excluded with 95% probability, i.e. We can be 95% sure the risk is below the drawn line.

Hypothetical scenario 2B

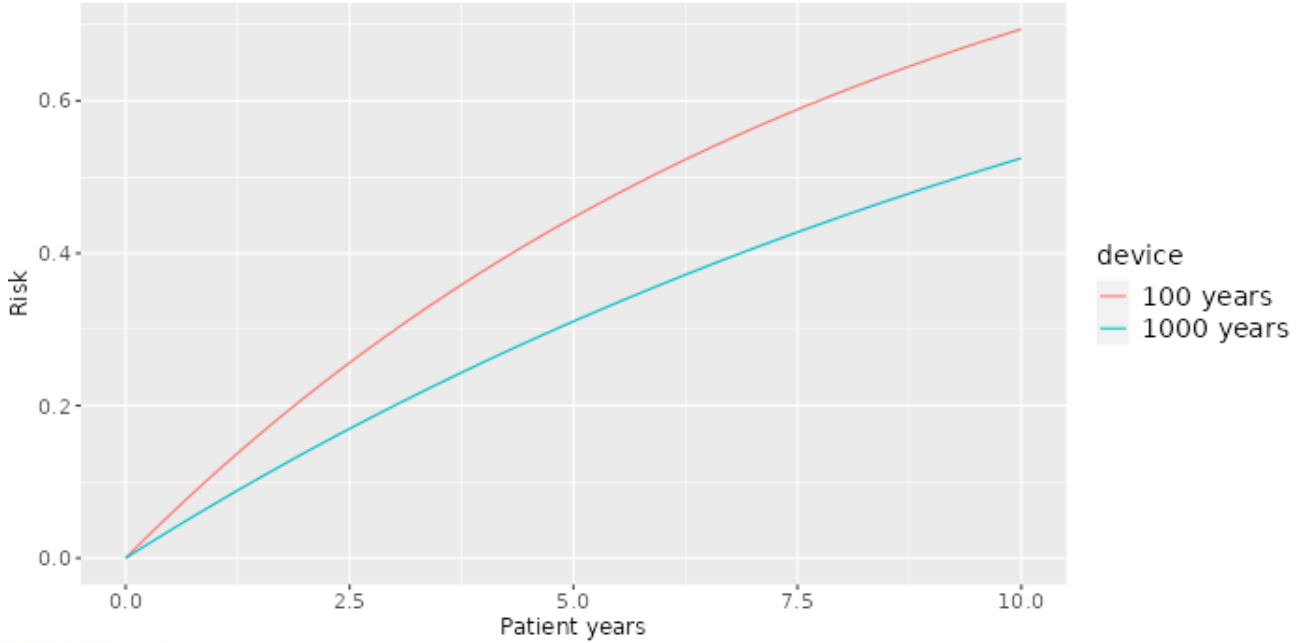
- Device with 6 events in 100 cumulative patient years



Graph shows the smallest risk that can be excluded with95% probability, i.e. We can be 95% sure the risk is below the drawn line.

Hypothetical scenario 2C

- Device with 6 events in 100 cumulative patient years vs 60 events in 1000 years



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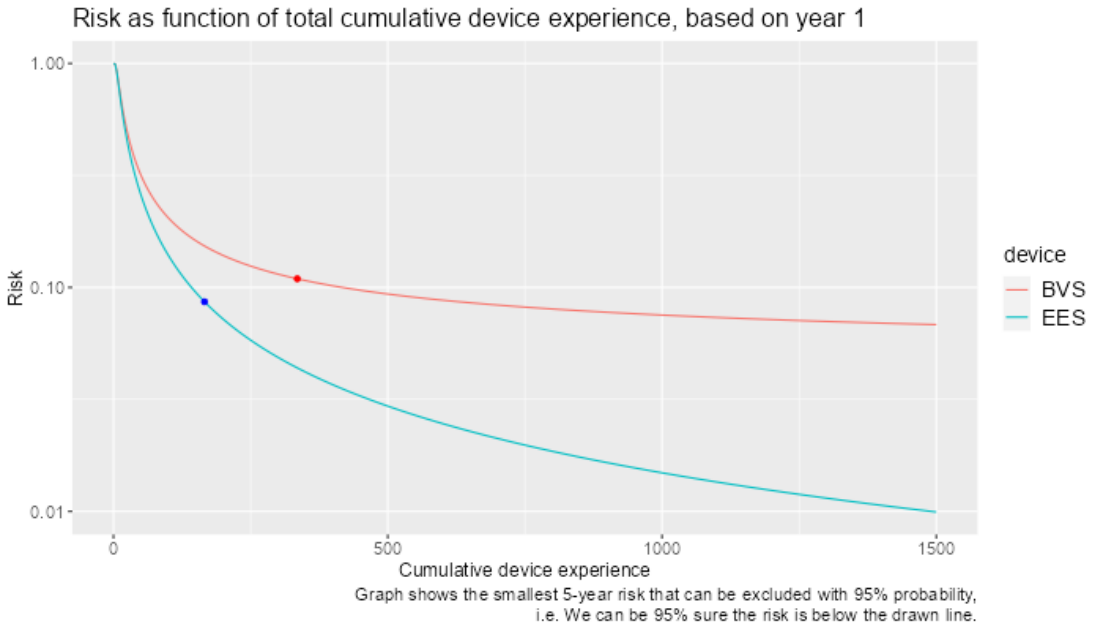
Real world scenario

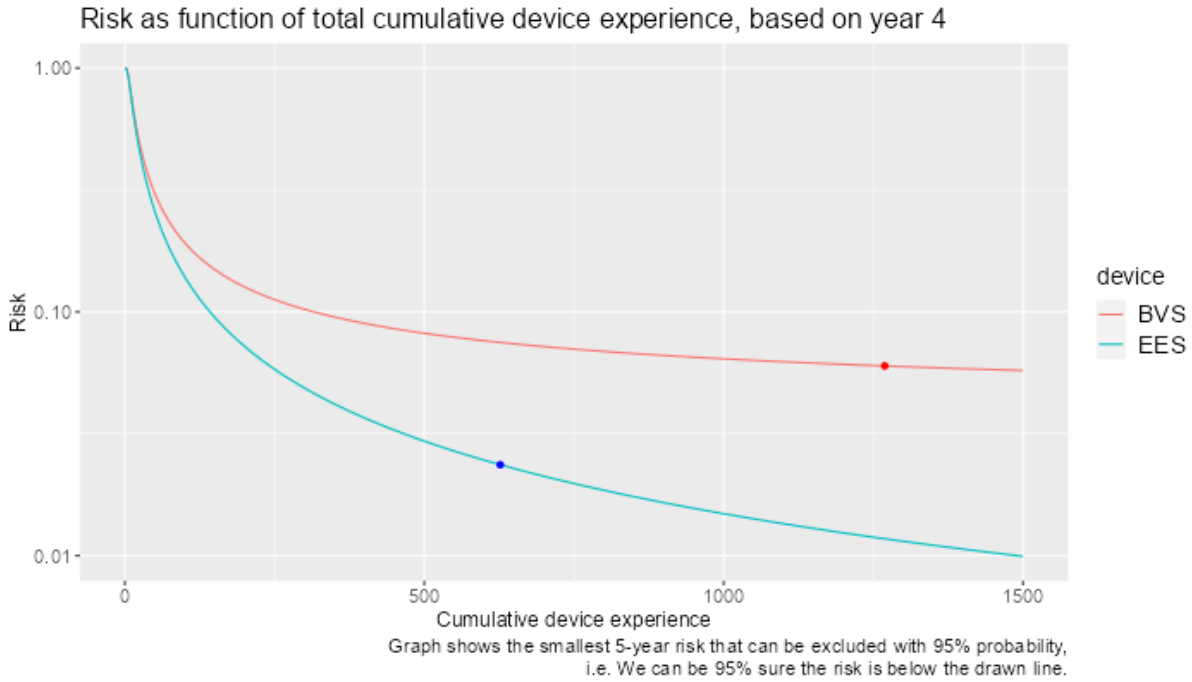
- Tool was tested on results of the ABSORB II trial
  - Bioresorbable vascular scaffold (BVS) vs everolimus-eluting stents (EES)
  - BVS can be considered a failed device

Year	Observed cumulative number of events		Observed cumulative device experience		Observed Rate		Upper limit to 5 year risk	
	BVS	EES	BVS	EES	BVS	EES	BVS	EES
1	3	0	335	166	0,008955	0	0.11	0.09
2	5	0	660	329	0,007576	0	0.07	0.04
3	9	0	980	488	0,009184	0	0.08	0.03
4	9	0	1269	627	0,007092	0	0.06	0.02

Real world scenario



Real world scenario



Ideas for future work

- Tool currently assumes constant risk
- More test cases

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

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For more information, visit: www.core-md.eu

ESC
EFORT
Biomedical Alliance in Europe
European Academy of Paediatrics
EPF European Patients Forum
Leiden University Medical Center
University of Oxford
Region Uppsala
RCSI University of Medicine and Health Sciences
Inselspital Universitätsspital Bern Hôpital universitaire de Berne
KU Leuven
UMIT Tirol
University of Gothenburg
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National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport
Istituto Superiore di Sanità
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