

Nationwide extrapolation of economic impact of therapeutic innovation: a 10-year retrospective budget impact model of direct oral anticoagulants (DOAC) introduction in France

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Introduction

Atrial fibrillation (AF) is the most common cardiac rhythm disorder in adults. AF can be life-threatening immediately or through complications such as stroke or systemic thromboembolism (STE).

Patients with AF were traditionally managed with vitamin K antagonists (VKA), inducing major bleeding (MB) risk.

In 2013, the French Health Technology Assessment (the HAS) requested a nationwide study (NAXOS study¹) comparing the effectiveness of DOACs (apixaban, dabigatran, rivaroxaban) and VKAs in matched cohorts of over 400,000 AF patients. The study found that DOACs were more effective and safer, with lower costs than VKAs.

Objective

This study aims to evaluate the budget impact of DOACs over 10 years for the French National Health Insurance, specifically in decreasing strokes/STE and MB in AF patients.

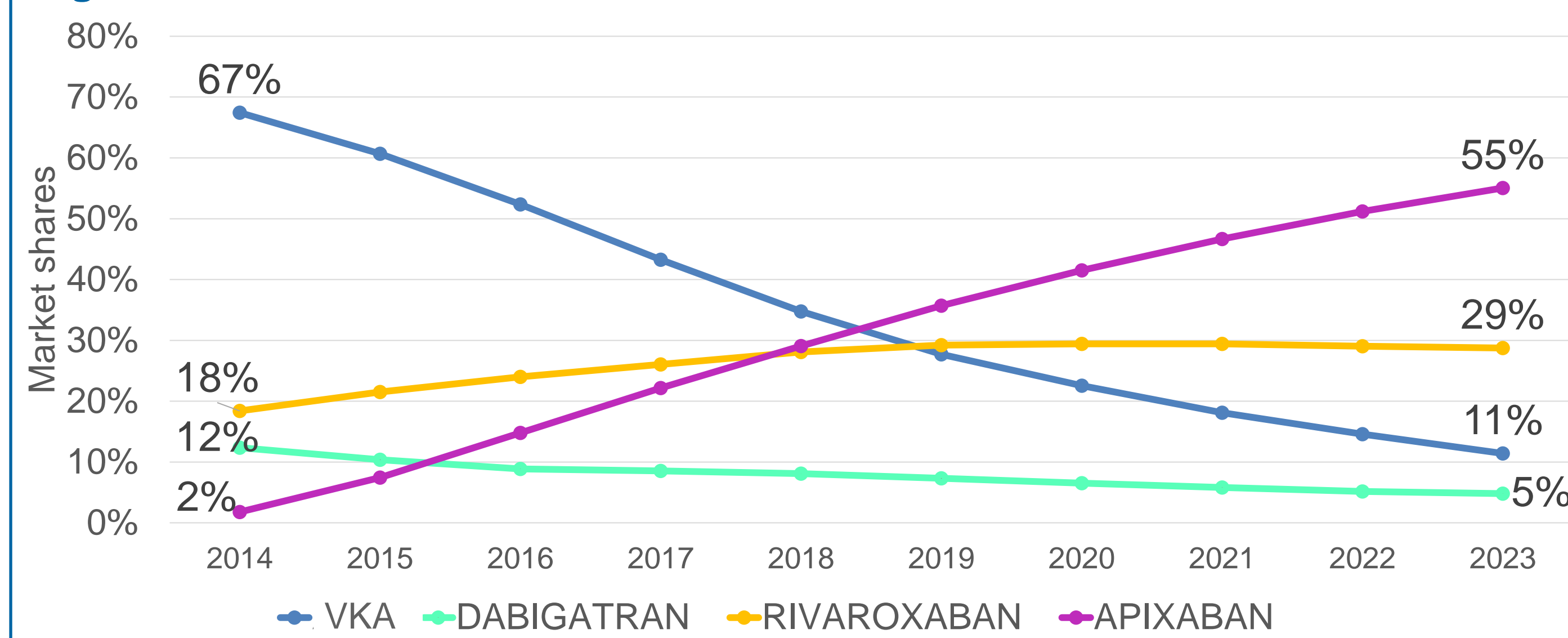
Methods

A retrospective budget impact model from 2014 to 2023 was developed, comparing scenarios "with DOACs" and "without DOAC".

Target population values were estimated from ELIQUIS transparency committee opinions^{2,3} at 725,000 in 2014 and increased progressively to 1.4 million patients in 2023.

Yearly market shares for the scenario "with DOACs" were obtained from the public MEDIC'AM⁴ database and calculated based on the number of boxes reimbursed by the national health insurance over the last 10 years. The data shows that VKA use decreased by 84% over this period, while DOACs increased significantly, particularly for apixaban and rivaroxaban (Figure 1).

Figure 1: Market share estimates



Strokes/STE and MB probabilities occurring at 1 year and beyond were calculated based on cumulative incidence observed in the NAXOS study¹. Stroke-related deaths probabilities were calculated based on the publication from Gabet et al.⁵.

Treatment acquisition costs were based on official public prices each year and discounts were not considered.

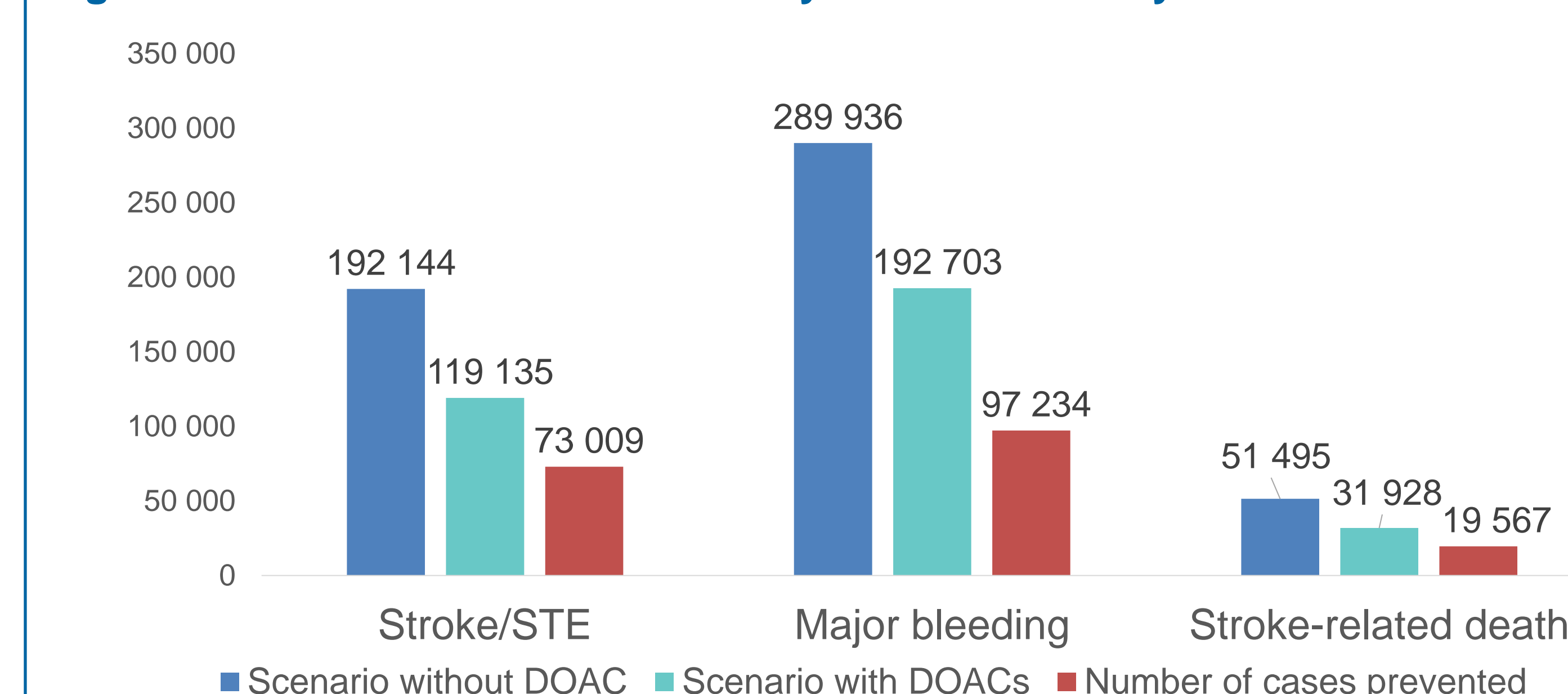
Management costs for strokes/STE, MB events and the costs of INR monitoring for VKAs were based on the costs reported in the NAXOS study⁶.

Results

Clinical results

The introduction of DOACs prevented **73,009 strokes**, **97,234 MB**, and **19,567 stroke-related deaths** over 10 years (Figure 2).

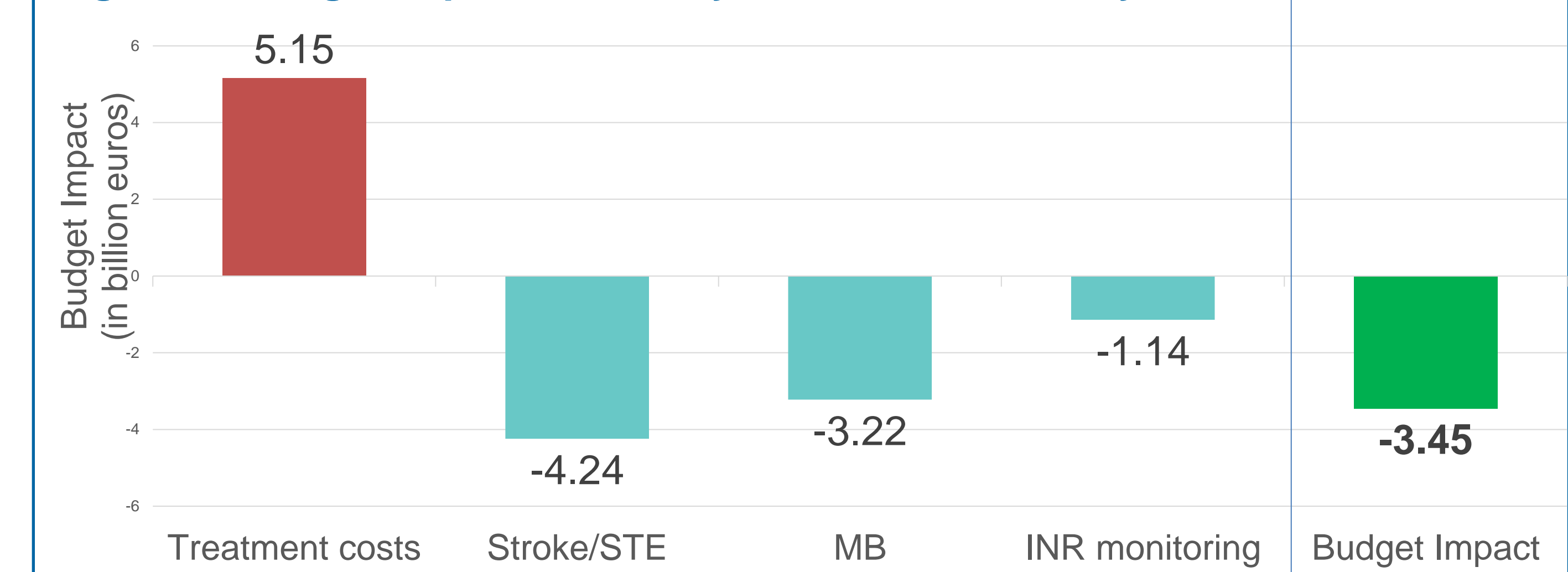
Figure 2: Number of events avoided by DOACs over 10 years



Budget Impact result

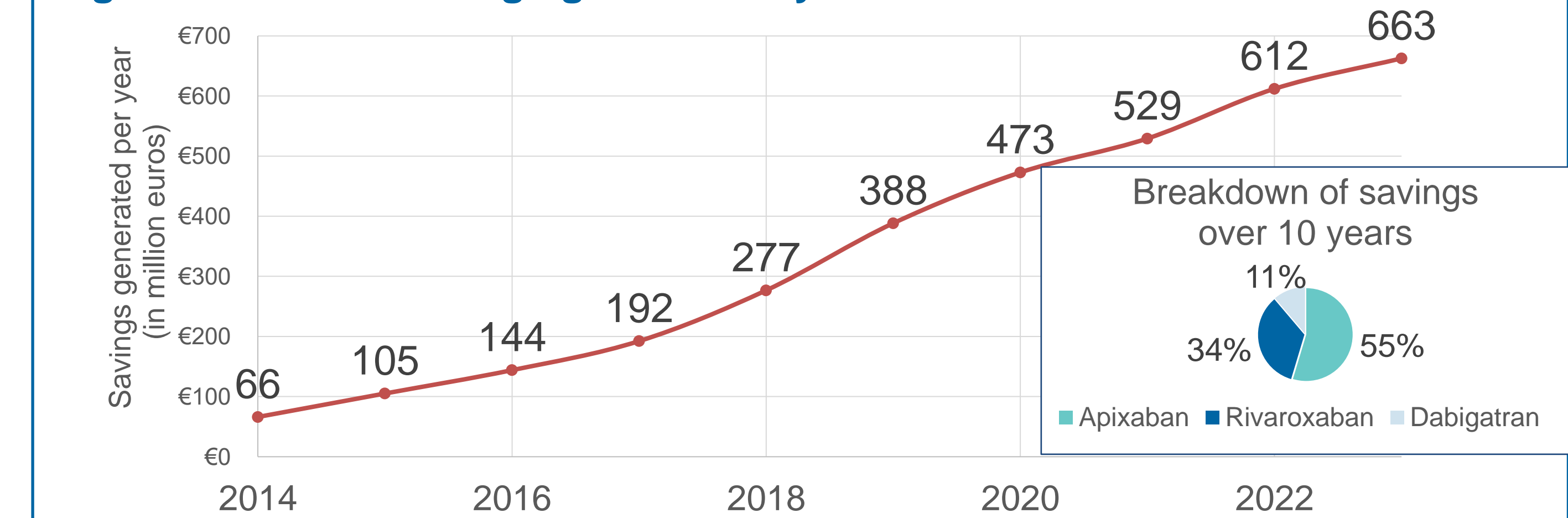
The introduction of DOACs resulted in a budget impact of **-€3.45 billion** over 10 years (Figure 3).

Figure 3: Budget impact results by cost items over 10 years



From the first year, DOACs induced savings for the French national insurance: €66 million in 2014, progressively reaching €655 million in 2023 (Figure 4).

Figure 4: Annual Savings generated by DOACs



Deterministic sensitivity analysis (DSA)

In the deterministic sensitivity analysis, all parameters were varied by $\pm 20\%$. The parameters with the greatest impact on results were costs associated to strokes/STE and MB management. Despite these variations, the 10-year budget impact ranged between -€4.8 billion and -€2 billion, confirming the robustness of our analysis.

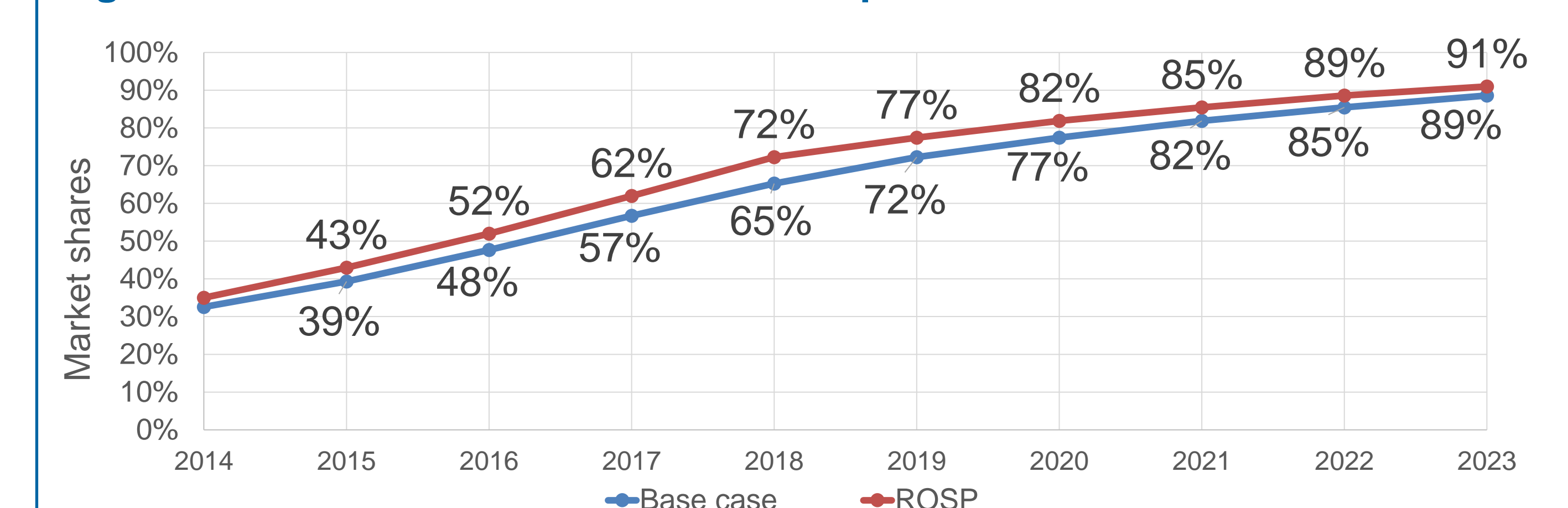
Scenario analyses

A scenario analysis evaluated the potential impact if a Remuneration for Public Health Objectives (ROSP) had been introduced by the French National Health Insurance to accelerate DOACs prescription in France. The target market shares was fixed at 72% in 2018, as it was observed in the Netherlands⁷.

Cardiologists' remuneration of €7.4 million per year⁸ (average of €1,947 per doctor) linked to the ROSP incentive by the health insurance was considered during the 2014-2018 period.

Assumptions of market shares evolution used in this scenario are presented in Figure 5.

Figure 5: Market shares evolution assumptions with ROSP scenario



This scenario resulted in a budget impact of **-€3.59 billion**, showing that the incentives to cardiologists to accelerate DOAC prescriptions could have increased the savings by 4.08% compared to the base case.

Conclusions

Considering AF-associated costs only, the introduction of DOACs has led to substantial savings over 10 years, demonstrating long-term economic value of an innovative therapeutic class introduction.

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Disclosures

This study was sponsored by Pfizer and Bristol Myers Squibb. Romain Moreau and Henri Lesage are employees of Public Health Expertise who were paid consultants to Pfizer and Bristol Myers Squibb in connection with the development of this manuscript. Claire Marant-Micallef, Mélanie Née and Manon Belhassen are employees of PELyon who were paid consultants to Pfizer and Bristol Myers Squibb in connection with the development of this manuscript. Nicolas Danchin received remuneration from Pfizer and Bristol Myers Squibb for his service as a member of the Steering Committee for this modelling work. Caroline Guilmet and François-Emery Cotté are employees of BMS.

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