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Indirect comparisons in 15 years of AMNOG

Background & Objectives

Under the German Act on the Reform of the Market for Medicinal Products (AMNOG), which came into force in 2011, new medicines must undergo an early benefit assessment upon entering the market. The aim is to determine whether there is any evidence for an additional benefit compared to existing standard therapies. Where possible, this comparison should be based on direct randomised controlled trials (RCTs). If such data are unavailable, pharmaceutical companies may include indirect evidence instead. However, as evidence from indirect treatment comparisons (ITC) is less robust than data from RCTs, gaining acceptance for it in the early benefit assessment by the Federal Joint Committee (G-BA) is challenging. Here we ask, what trends regarding indirect comparisons can be identified from 15 years of AMNOG?

Methods

All ITCs are identified by screening the G-BA's resolution justifications since 2011 (excluding orphan drug assessments) and are classified according to recognition, methodology, and therapeutic area. The study examines whether a temporal trend can be identified in the proportion of procedures involving ITCs, and within this, the proportion of recognised ITCs. Furthermore, we identify procedures that can be regarded as important milestones for ITCs in early benefit assessment, e.g. first-time recognition or derivation of substantial additional benefit.

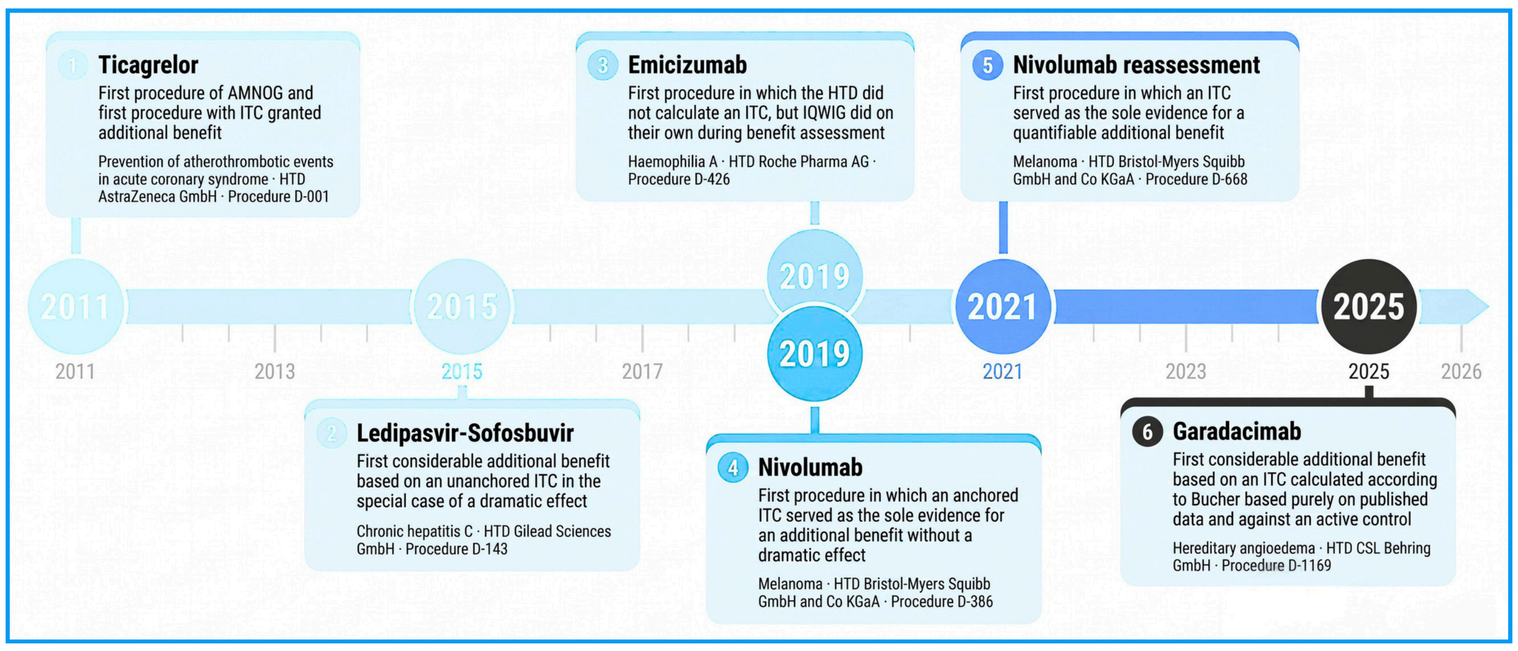

Fig. 1: Key milestones according ITC in assessing the additional benefit of pharmaceutical products in the German market [1]

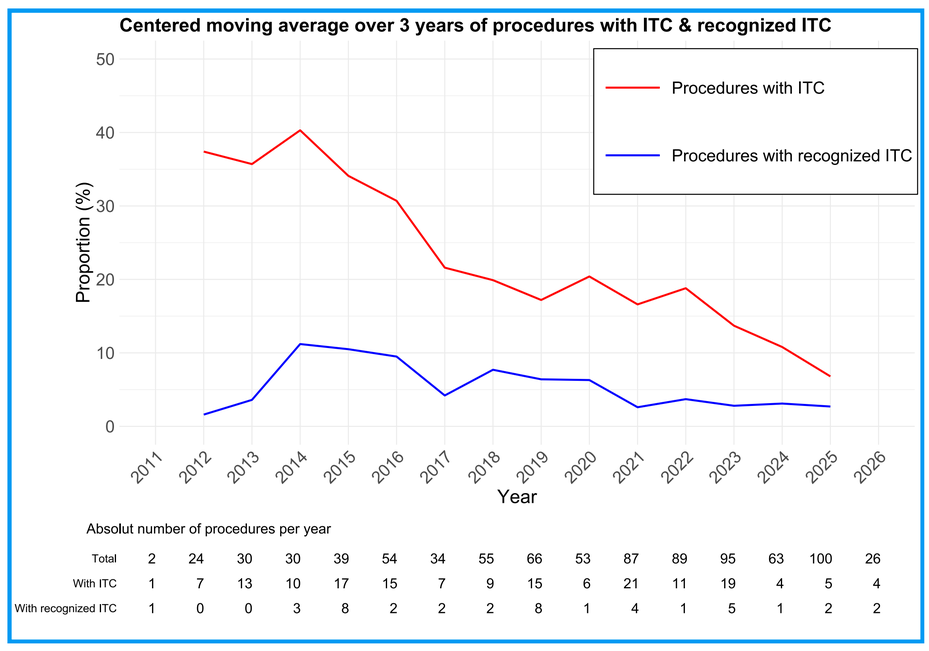

Fig. 2: Trend in the proportion of AMNOG procedures involving an ITC and those with a recognized ITC from 2011 to 2026, shown as a 3-year moving average (%), with underlying annual case numbers listed below

Results

During the 15-year period of the AMNOG, approximately 850 non-orphan assessments were conducted, 162 of which included indirect evidence. Of these, the G-BA recognised additional benefit in only 15 assessments, and accepted indirect evidence in 44. Six key milestones could be identified and are presented in *Fig 1*.

A negative trend over time was observed for the proportion of assessments including ITCs, while a slightly negative trend was found for the proportion of assessments including recognized ITCs (*Fig. 2*). Together, these trends result in an approximately constant acceptance rate of about 30%.

Conclusion

Although they are rarely leading to an additional benefit granted by G-BA and they are nowadays less often part of an AMNOG procedure, ITCs are an important strategic tool for pharmaceutical manufacturers. It will be interesting to observe the influence that the EU HTA launched in 2025 will have on ITCs within the AMNOG in the coming years.

Reference

[1] Gemeinsamer Bundesausschuss (G-BA), www.g-ba.de/bewertungsverfahren/nutzenbewertung

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