Beyond direct costs: individual and societal financial burden of asthma in young adults in a Danish nationwide study

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ABSTRACT

Introduction As a common chronic disease seen across all ages, asthma has the potential to incur high societal and individual costs from both direct healthcare costs and loss of productivity. Most previous studies use smaller, selected populations to assess the cost of asthma, possibly reducing generalisability. We, therefore, aimed to assess the total, nationwide economic burden of asthma by severity from both an individual and a societal perspective.

Methods The annual cost of asthma was assessed in a Danish nationwide cohort of patients aged 18–45 during 2014–2016 as excess healthcare costs, loss of income and welfare expenditure compared with controls (matched 1:4) using national registries. Asthma severity was defined as mild-to-moderate (steps 1–3 or step 4 without exacerbations) or severe (step 4 with exacerbations or step 5).

Results Across 63 130 patients (mean age 33, 55% female), the annual excess cost of asthma compared with controls was predicted to €4095 (95% CI €3856 to €4334) per patient. Beyond direct costs related to treatment and hospitalisations (€1555 (95% CI €1517 to €1593)), excess indirect costs related to loss of income (€1060 (95% CI €946 to €1171)) and welfare expenditure (eg, sick pay and disability pensions) (€1480 (95% CI €1392 to €1570)) were seen. Crude pooling of excess costs resulted in an annual societal cost of €263 million for all included patients.

Severe asthma (4.5%) incurred 4.4 times higher net costs (€15 749 (95% CI 13 928 to €17 638)) compared with mild-to-moderate disease (€3586 (95% CI €3349 to €3824)). Furthermore, patients with severe asthma experienced an annual loss of income of €3695 (95% CI €4106 to €3225) compared with controls.

Conclusion In young adults with asthma, a significant societal and individual financial burden of disease was seen across severities. Expenditure was mainly driven by loss of income and welfare utilisation, rather than direct healthcare costs.

INTRODUCTION

With an estimated €72 billion of annual costs attributed to asthma, it represents one of the costliest respiratory diseases in young adults in Europe. As a chronic respiratory disease seen in individuals of all ages, asthma can affect the entire lifespan and thus incur costs on both personal and societal levels over several decades.

In young adults with asthma, severe asthma-related limitations in their daily lives, influenced by low adherence to ICS-based maintenance treatment, low referral rates of high-risk patients to specialists or even complacency towards the risks associated with uncontrolled asthma.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Asthma is often considered to be a mild disease without larger impact by patients, and physicians are known to underestimate the impact of asthma on patients’ lives, yet the full financial consequences of asthma are unknown and difficult to assess.

WHAT THIS STUDY ADDS

The present study estimates the financial burden of asthma in 63 130 Danish young adults in a nationwide fashion and finds annual excess costs of approximately €263 million. Furthermore, a considerable loss of income was seen for patients with severe disease.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

The present study serves as an important reminder for patients, care providers and policy-makers that asthma is a chronic disease with significant financial implications for both individual patients and on a societal level.
burden to healthcare and welfare systems, as well as impairing quality of life for individual patients. Previous studies on the cost of asthma, including those carried out in Denmark over two decades ago, have most often used self-reported data or population samples and extrapolated the costs found in selected individuals to the assumed prevalence of asthma. As such, there is a scarcity of studies using nationwide cohorts for cost of asthma analyses without the need for extrapolation and with a reduction in the risk of selection bias, and thus allowing for precise estimation of the financial burden of asthma.

In the present study, we aimed to describe the cost of asthma in Denmark across disease severities, compared with the background population. Using a cohort comprising all ICS-treated young adults with asthma, we hypothesised that asthma carries a substantial financial burden for society at large and for young adults typically expected to be under education or be active participants of the workforce.

METHODS

Data sources and sharing

Data were linked on an individual basis by Central Person Registry (CPR) numbers and collected using the nationwide registries from Statistics Denmark, The Danish National Prescription Registry and The Danish Health Data Authority. Data are available on application to data sources, as required by Danish law.

Patients or the public were not involved in the design or conduct of the present research, yet patient organisations will be involved in dissemination of the present manuscript.

Study population

All Danish residents aged 18–45 redeeming at least two canisters of ICS-containing prescriptions during a 365-day period within the inclusion period of 2014–2016 were defined as having actively treated asthma and consequently included in the cohort. ICS redemption was defined as redeemed prescriptions belonging to the Anatomical Therapeutic Chemical codes R03BA, R03AK06–09, R03AK10–14, R03AL11–12, R03AL08–09.

A control group from the background population was supplied by Statistics Denmark based on 1:4 matching for age, sex, civil status (defined as married/cohabiting or living alone in the CPR), and residence at the case index date. Individuals without a valid CPR number (non-permanent residency, tourists, etc), with missing data in matching variables, or where no matching controls were found, were excluded (figure 1).

Individuals aged 18+ redeeming inhaled corticosteroids during 2014–16 (n = 262,824)

Excluded:
Redeemed a single canister (n = 15,083)

Excluded:
Age above 45 (n = 190,329)

Excluded:
Missing data required for matching
(n = 376)
No matches found (n = 6)

Final cohort (n = 65,130)

Figure 1 Flow chart describing patient inclusion and exclusion flow into the final cohort.

Observation period

Individual observation periods where created based on the index date (date of first ICS redemption) and patients were followed for up to 2 years post-index unless censored by date of emigration or death.

Asthma severity, control and definitions

Asthma severity is described by Global Initiative for Asthma (GINA) 2020 Treatment Steps, based on annualised and standard-particle beclomethasone normalised doses, long-acting bronchodilators and leukotriene antagonist use as previously described. Possible severe asthma was defined according to GINA/International Severe Asthma Registry as GINA 2020 step 4 treatment with either ≥2 moderate or ≥1 severe/very severe exacerbation or GINA 2020 step 5 treatment. Moderate exacerbations were defined as redemption of at least 37.5 mg prednisolone for 5 days (totalling 187.5 mg). Severe exacerbations were defined as asthma-related hospitalisations (A-diagnosis of International Classification of Diseases (ICD)-10 DJ45 or A-diagnoses DJ96, DJ13–18 paired with a B-diagnosis of DJ45), with very severe exacerbations defined as admission to an intensive care unit and/or any severe exacerbations with a procedure code for intubation and/or mechanical ventilation. A wash-out period of ±14 days between exacerbations was used when calculating costs to distinguish new exacerbations from treatment failure/exacerbation progression.

Comorbidity

A modified, non-respiratory Charlson Comorbidity Index (‘Charlson score’) with updated weights was used to describe comorbidity burden in the cohort.
Calculation of costs

Asthma-related costs

For hospitalisation, outpatient or emergency department contacts, costs were considered asthma-related if they were linked to events with an ICD-10 A-diagnosis of any DJ45-code, or costs linked to events with an ICD-10 A-diagnosis of DJ96, DJ13–18 in a patient with a concurrent ICD-10 B-diagnosis of DJ45. The latter always counts as asthma-related costs yet will only add to exacerbation burden if prednisolone has been redeemed according to the exacerbation criteria. All redemptions of medications with ATC code R03 were classified as asthma related. All remaining costs were classified as non-asthma expenditure.

Definitions of other costs

Direct costs: includes acquisition costs for drugs, healthcare visits in the primary sector, outpatient hospital visits including ER visits and hospital admissions.

Indirect costs: constitutes the difference in earnings between asthma patients and the control population, based on information on earned income.

Welfare-related costs: non-healthcare-related forms of welfare expenditure (eg, student grants, pension, early retirement, at-home assisted care, living at assisted homes and the state-paid portion of sick leave payments).

Exacerbation costs: costs for exacerbations are calculated based on healthcare resource utilisation (not including individual or societal costs) during 28 days from the start of the exacerbation event. Exacerbations with less than 28 days of follow-up due to censoring were not included.

Statistical analyses

A generalised linear model regression model with a gamma distribution and a log-link was used to predict costs and test differences in costs between cases and controls as described in.18 The gamma-distributed log-link model is used due to a continuous outcome variable (cost) where zeroes are present and a need to weight individuals’ exposure time as described in.19 Costs were estimated for a 2-year period postindex and subsequently annualised. Weighting for exposure time was used should individuals censor before the end of the 2-year period. Models are adjusted for Charlson score and education, besides the matching already performed. Costs were estimated for an individual with primary education and no comorbidity. For regression models comparing subgroups of patients without the use of controls, age, sex, marital/cohabiting status and residence was adjusted for. Due to non-convergence, GINA step-stratified and disease severity-stratified analyses are only reported as pooled costs. Costs presented are unadjusted for inflation and are converted to Euro at an exchange rate of €1=DKK7.45.

All statistical analyses were performed using SAS V.9.4 (SAS Institute). Graphics were generated using ggplot2.

RESULTS

The current cohort comprises 6130 patients with actively treated asthma (mean age was 33% and 55% of patients were female). One-third of patients resided in the Capital Region, and most patients were either employed (61%) or were currently under education (20%). Minor differences in education level and socioeconomic status were found between patients and their controls. Patients were assigned to GINA 2020 Treatment steps, with step 1 (33%) and step 3 (31%) being the most common (table 1).

The overall economic burden of asthma

Across the entire cohort, the net cost per patient was estimated to €4095 (95% CI €3856 to €4334), representing the difference in direct healthcare costs, indirect costs due to loss of income, and welfare transfer payments between patients and their controls.

Direct healthcare costs for asthma patients totalled €3025 (95% CI €2977 to €3073) annually, approximately twice of the expenditure for controls without asthma, corresponding to an increase in direct expenditure of €1555 (95% CI €1517 to €1593) annually (figure 2A). Medication acquisition costs were the largest driver of direct costs (€918 (95% CI €903 to €932) annually), yet only 50.6% (€465 (95% CI €458 to €433)) were classified as asthma related. Asthma-related outpatient care and hospitalisation incurred annual costs corresponding to €188 (95% CI €185 to €191) and €99 (95% CI €97 to €100) per patient, respectively (figure 2B). Out of the direct healthcare costs for patients with asthma, 24.1%-37.7% were directly attributable to asthma, depending on inclusion of primary care expenditure (figure 2C).

Indirect costs were calculated as foregone income as compared with controls and corresponded to €1060 (95% CI €946 to €1171) annually. Societal welfare expenditure was significantly increased compared with controls and amounted to €1485 (95% CI €1392 to €1570) per patient per year (figure 2A). In terms of welfare expenditure, disability pensions (€1639 (95% CI €1595 to €1683)) and social security (€751 (95% CI €714 to €789)) were the largest drivers of cost (table 2).

Economic burden of asthma by disease severity

A U-shaped relationship between cost of disease and GINA steps was observed, with step 2 being associated with the lowest annual cost (1902 (95% CI €1844 to €2161)), as compared with both step 1 (€3181 (95% CI €2800 to €3560)) and steps 3–5 (€3891 (95% CI €3548 to €4413)) to €14496 (95% CI €12 350 to €16 726), respectively). Substantial increases across all types of expenditure were seen, and a full specification of direct costs are available in online supplemental table 1. Indirect costs and welfare expenditure remained the major financial burden across all GINA Steps (figure 3A).

When stratified asthma severity, substantial differences in costs between patients with mild-to-moderate and possible severe asthma were seen. In mild-to-moderate asthma,
annual costs were estimated to €3586 (95% CI €3349 to €3824) with an even spread between healthcare, welfare costs and forgone income at 37.5%, 36.2 and 26.4%, respectively. For possible severe asthma, annual costs were €15749 (95% CI €13928 to €17638), of which 39.3%, 37.2% and 23.5% were attributable to healthcare, welfare costs and forgone income, respectively (figure 3B).

**Patients’ and societal financial burden of asthma**

Cost of disease on a patient level can be further described as forgone income and eventual social security and welfare transfer compensation. For asthma patients overall, an annual earned income loss of €1060 (95% CI €946 to €1171) was seen when compared with controls. The loss of earned income was offset by increases in public welfare transfers to an estimated total annual loss of net income of €310 (95% CI €88 to €502). In contrast to the modest loss of total income for those with mild-to-moderate disease, patients with possible severe asthma experienced an estimate of loss of earned income corresponding to €3695 (95% CI €3225 to €4106), a loss not fully compensated by social security and welfare transfers.
and thus resulting in a total loss of net income estimated to €1387 (95% CI €137 to €2500) annually (table 3).

Pooling of crude, unadjusted differences in mean excess total costs from indirect costs, healthcare and welfare expenditure between patients and controls was used for estimation of the nationwide cost of asthma (table 4). The total annual cost of asthma in patients aged 18–45 in Denmark was estimated to €263 million.

DISCUSSION

Based on a nationwide cohort of 63,130 young adults with asthma, we estimated the annual cost of asthma per patient to be €4095, of which 37.9% represented direct costs, 25.9% indirect costs and 36.1% increases in welfare-related societal costs. Costs of disease were highly dependent on severity of disease, with possible severe asthma demonstrating a 4.4-fold increase in costs compared with mild-to-moderate disease. Finally, we show that in patients with possible severe asthma, a significant drop in annual net income is seen and is only partly compensated by societal welfare measures.

In previous Scandinavian studies, the annual cost of asthma has been estimated to range between €176815 and €1270 (after adjustment for inflation, €1=DKK7.45), both significantly lower than the average annual cost of €4095 seen in the present study. However, we use a nationwide cohort with complete, individual-level records of all publicly funded healthcare and welfare costs, as well as taxation records for estimating loss of income and adjust for incremental expenditure using a control group, in
In the present study, indirect costs were represented by foregone income and societal costs by welfare expenditure. Indirect costs are highly reliant on the societal context on which they are analysed, as well as the choice of design. Pertinent examples of context-dependent differences are the American cost of asthma studies, where absenteeism-related indirect costs represented 3.7%–6.7% of total annual costs, presumably attributable to significant differences in welfare and healthcare organisation in the USA compared with the Danish universal healthcare and ‘flexicurity’ welfare models.

While the present study estimates loss of productivity as forgone income, it fails to address intangible productivity losses attributed to asthma, such as presenteeism, which is often defined as attending school or work with a consequent lower rate of productivity due to disease. Sadatsafavi et al. reported that the prevalence of presenteeism is approximately threefold to that of absenteeism, corroborated by a Singapore-based study by Finkelstein et al. who found presenteeism to account for 67%–87% of the total cost of asthma depending on level of disease control. Furthermore, due to limitations in the databases used, sick leave payments for periods below 30 days are not included in the present cost analyses, calling for prospective studies to estimate the impact of asthma on shorter-term absenteeism. As such, while the indirect costs found in the present study seem high compared with earlier studies, they are arguably still to some extent underestimating the societal impact of asthma, both in terms of absenteeism and presenteeism-related costs.

In line with most previous studies, disease severity was highly associated with increased cost of disease. Interestingly, we found GINA 2020 step 2 to be associated with approximately 40% lower annual excess costs than step 1, a difference arguably driven by patients with poor adherence and thus low ICS exposure leading to increased asthma burden. Overall, cost of asthma was disproportionately driven by increases in welfare expenditure and forgone income by individuals with the Danish welfare system. While the exact annualised numbers pale in comparison to previous studies on asthma costs, primarily relying on self-report and extrapolation of costs, we therefore argue that the present study could provide a more robust estimate of the actual costs of asthma. Despite differences in methods, the distribution of direct, indirect and societal costs of asthma were comparable both to previous Scandinavian and international studies, reflecting approximately 30%–40% of the total costs.
Reducing the cost of asthma

With an increasing prevalence and rising medical costs, the cost of asthma is expected to—and has historically—increased.27 Direct, patient-facing medical expenditure increased with 15.1% (after adjusting for inflation) in the present study when compared with a previous Danish analysis by Mossing and Nielsen,12 contrasting the relatively unchanged levels in Finland.28 However, when seen from a societal level, a quadrupling of medication costs was seen in the USA, and a threefold increase was observed in Finland.8 28 The increasing costs combined with a higher number of patients call for initiatives to improve asthma care to reduce the financial burden on society.

On a smaller scale, many of the treatments used for asthma, including ICS in combination with long-acting beta₂ agonists, are cost-effective,3 yet despite this the financial burden of asthma remains significant. Larger scale asthma programmes, such as the Finnish Asthma Programme holds promise in reducing the financial burden of asthma. Despite seeing a threefold increase in asthma patients and overall medication expenditure, Finland experienced a 14% reduction in overall costs of asthma between 1987 and 2013, often attributed to a 10-year asthma programme that significantly decreased hospitalisation rates and productivity losses.28 The Finnish Asthma Programme serves as proof that early diagnosis, increased attention to ICS-based maintenance treatment and close collaboration between primary and secondary care, as well as promotion of asthma knowledge, can significantly impact the overall costs of asthma.

While larger national initiatives such as the Finnish Asthma Programme are few and far between, recent developments in asthma treatment such as ICS/formoterol for maintenance and reliever use2 and the advent of more widespread use of biologic treatments could lead to future reductions in the disease burden of asthma, calling for further studies to assess cost-effectiveness and perhaps even cost-saving properties of these novel treatment strategies once broader scale implementation is seen. It should be noted, however, that the cost-effectiveness of biologics has been challenged, primarily due to the current high prices and the highly selective criteria used.
Table 3  Overview of indirect costs (forgone income) and welfare expenditure in 63,130 patients aged 18–45 with actively treated asthma

<table>
<thead>
<tr>
<th>Asthma versus controls</th>
<th>Across severity</th>
<th>Mild to moderate asthma (N=60,271)*</th>
<th>Controls (N=2,547,3)*</th>
<th>Possible severe asthma (N=2,859)*</th>
<th>Controls (N=11,436)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma population</strong></td>
<td><strong>Controls</strong></td>
<td><strong>Mild to moderate asthma</strong></td>
<td><strong>Controls</strong></td>
<td><strong>Possible severe asthma</strong></td>
<td><strong>Controls</strong></td>
</tr>
<tr>
<td>Earnings</td>
<td></td>
<td></td>
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<tr>
<td>Earnings</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Earned income†</strong></td>
<td></td>
<td>13,637 (13,420 to 13,857)</td>
<td>14,697 (14,591 to 14,803)</td>
<td>13,636 (13,415 to 13,861)</td>
<td>14,581 (14,475 to 14,639)</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td></td>
<td>−1,060 (−1,171 to −946)</td>
<td>−945 (−1,060 to −778)</td>
<td>−3695 (−4,016 to −3,225)</td>
<td></td>
</tr>
<tr>
<td>Welfare transfers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer income‡</td>
<td></td>
<td>8,862 (8,720 to 9,005)</td>
<td>7,382 (7,328 to 7,435)</td>
<td>8,577 (7,937 to 8,719)</td>
<td>7,279 (7,225 to 7,333)</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td></td>
<td>1,480 (1,392 to 1,570)</td>
<td>1,296 (712 to 1,386)</td>
<td>5,862 (5,040 to 6,765)</td>
<td></td>
</tr>
<tr>
<td>Housing and child benefits§</td>
<td></td>
<td>1,086 (1,069 to 1,104)</td>
<td>1,137 (1,128 to 1,145)</td>
<td>1,059 (1,042 to 1,077)</td>
<td>1,110 (1,102 to 1,118)</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td></td>
<td>−51 (−59 to −41)</td>
<td>−51 (−60 to −41)</td>
<td>−107 (−170 to −37)</td>
<td></td>
</tr>
<tr>
<td><strong>Total net income</strong></td>
<td></td>
<td>23,735 (23,370 to 24,132)</td>
<td>24,045 (23,872 to 24,220)</td>
<td>23,493 (23,111 to 23,882)</td>
<td>23,766 (23,591 to 23,942)</td>
</tr>
<tr>
<td><strong>Annual loss of net income§</strong></td>
<td></td>
<td>−310 (−502 to −88)</td>
<td>−273 (−480 to −60)</td>
<td>−1387 (−2,500 to −137)</td>
<td></td>
</tr>
</tbody>
</table>

Bold values represent calculated values, non-bold values are values from regression model(s).

*A 1:4 age, sex, marital/cohabiting status and residence-matched control group.
†The indirect cost of asthma is defined as the difference in earned annual income between patients and controls.
‡Includes public transfer income from sick pay, student grants, social security, unemployment benefits and disability pension.
§Sources of income that are traditionally not considered to be welfare related for individual patients, but for their families.

Limitations

The present study is strengthened by its nationwide design, a high degree of data completeness in the validated pharmacy redemption data and use of objective data free from selection and recall bias. However, several limitations are worth noting. First, the present study is based on pharmacy redemption data and uses a widely used definition in Danish pharmacoeconomics.31,32 Yet data on formal diagnoses such as objective asthma—a widely used definition in Danish pharmacoeconomics31,32—and data on formal diagnoses such as objective asthma—a widely used definition in Danish pharmacoeconomics—may not be available. Second, we included only patients from the idiopathic asthma group. The present study uses a previously published6 method for assessing ICS treatment adherence. However, the use of a prescribed dose typically used in GINA 2020 steps should be done with caution. Second, the use of actively treated asthma as the case definition makes the use of asthma-related costs incurred by the control population as exposed dose, which is closer to real-world exposure. Third, the definition of asthma used in the present cohort is based on pharmacy redemption data and use of objective asthma—regardless of severity—is far from without financial consequences for both patients and society at large.

Table 4  Overview of mean, unadjusted direct, indirect and welfare expenditure in 63,130 patients aged 18–45 with actively treated asthma compared with controls

<table>
<thead>
<tr>
<th>Asthma versus controls</th>
<th>Asthma population (N=63,130)*</th>
<th>Controls (N=22,473)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All costs</strong></td>
<td>2801 (€7 annually)</td>
<td>1364 (€7 annually)</td>
</tr>
<tr>
<td><strong>Direct costs</strong></td>
<td>296 (€7 annually)</td>
<td>83 (€7 annually)</td>
</tr>
<tr>
<td><strong>Indirect costs</strong></td>
<td>4,578 (€7 annually)</td>
<td>4,864 (€7 annually)</td>
</tr>
<tr>
<td><strong>Welfare costs‡</strong></td>
<td>5,832 (€7 annually)</td>
<td>4,675 (€7 annually)</td>
</tr>
<tr>
<td><strong>Net costs per patient§</strong></td>
<td>263 252 100</td>
<td>161 396 100</td>
</tr>
<tr>
<td><strong>Total pooled</strong></td>
<td>2,264,170 100</td>
<td>1,578,730 100</td>
</tr>
</tbody>
</table>
asthma testing is unavailable. Fourth, while nationwide cohort, artificial selections in terms of age and treatment criteria have been used, possibly reducing generalisability to other age groups. The two ICS canister criterium also exclude patients with the mildest forms of asthma, such as the SABA-only treated population, which further limits generalisability to all asthma patients. Finally, asthma-related primary care costs cannot be reliably characterised due to data limitations.

CONCLUSION

In this nationwide study using public records and healthcare data without self-report and/or data extrapolation, we found that the annual cost of asthma (€4095 per patient) in young adults is approximately twice of what previous Scandinavian studies have reported. Furthermore, possible severe asthma was a driver of overall costs, but patients also suffered a substantial personal loss of net income despite the existence of a robust welfare system. Interventions aimed at reducing asthma-related absenteeism could potentially attenuate both individual and societal financial losses attributable to asthma.

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Competing interests
KEJH has received personal fees from AstraZeneca, Chiesi, GSK, Sanofi and TEVA. AL has received personal fees from AstraZeneca, GSK, TEVA, Chiesi, Sanofi Genzyme, Boehringer-Ingelheim, Orphan Pharma, Novartis, ALK-Abello, Mundipharma and Pfizer. RI has no conflicts to declare. OH has received personal fees AstraZeneca, GSK, TEVA, Chiesi, Sanofi Genzyme, Boehringer-Ingelheim. VB has received personal fees from AstraZeneca, GSK, TEVA, Sanofi Genzyme, MSD, Chiesi, Boehringer-Ingelheim, Novartis, ALK-Abello, Mundipharma and Pharmaxis. CSU has received personal fees from AstraZeneca, GSK, TEVA, Chiesi, Sanofi Genzyme, Boehringer-Ingelheim, Orphan Pharma, Novartis, ALK-Abello, Mundipharma, Pfizer and Actelion.

Patient and public involvement
Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication
Not applicable.

Ethics approval
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Data availability statement
Data are available on reasonable request. Data are available on application to data sources, as required by Danish law.

Supplemental material
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