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Evaluating the cost-effectiveness of replacing lansoprazole with vonoprazan for treating erosive oesophagitis

Saeash Jeyarajan ,[1] Thejasvin K ,[2] Sneha Pimpalnerkar ,[1] Emily Zichu Deng ,[1] Zain Ahmad ,[1] Diya Banerjee ,[1] Laure de Preux [3]

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[1]Business School, Imperial College London, London, UK
[2]Whittington Hospital, London, UK
[3]Imperial College Business School, London, UK

Correspondence to
Sneha Pimpalnerkar;
sneha27092@gmail.com

ABSTRACT

Objective This cost-effectiveness analysis compares vonoprazan against lansoprazole, a gold-standard proton pump inhibitor, in managing erosive oesophagitis.

Methods The economic evaluation was carried out using data from a double-blind, randomised control trial. Costs were measured in pounds sterling. Effectiveness was assessed on a binary scale, resolution versus non-resolution of disease, after 32 weeks.

Results The primary analysis produced an incremental cost-effectiveness ratio (ICER) of £3421.27 per resolution. After applying quality-adjusted life year (QALY) data from the REFLUX trial (2008), we derived an ICER/QALY of £34 747.32, marginally exceeding the £30 000 threshold set by the National Institute for Health and Care Excellence. However, further subgroup analysis showed cost-effectiveness when healing severe grades of oesophagitis (ICER/QALY of £22 165.56). The first sensitivity analysis considers the typically non-invasive determination of disease resolution; the ICER/QALY of £15 826.98 supports vonoprazan's use in treating severe oesophagitis. The second considers a longer healing phase alongside a stronger 30 mg maintenance dose of lansoprazole, concordant with current guidelines; the ICER/QALY of £43 998.39 suggests the guidelines (regarding dosage, frequency and duration) must be optimised for vonoprazan. The final sensitivity analysis accounts for variations in quality-of-life measures, which grossly inflate the ICER/QALY (£118 216.32); this emphasises that vonoprazan should mainly be considered for patients with persistent symptoms and high severity.

Conclusion Vonoprazan is potentially cost-effective for the initial healing of severe oesophagitis, after endoscopic diagnosis. Further trials and economic evaluations are necessary for the symptom-based prescription of vonoprazan and to determine the optimal dosage, frequency and duration.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ National Health Service (NHS) guidelines recommend proton pump inhibitors as the treatment of choice for erosive oesophagitis, whereas countries in Asia additionally use vonoprazan. The first Western randomised controlled trial of vonoprazan prompted the need for this economic evaluation to assess its viability within the NHS.

WHAT THIS STUDY ADDS

⇒ This study finds that vonoprazan is potentially cost-effective in treating severe oesophagitis after an endoscopic diagnosis, but not for mild cases.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These findings provoke a discussion regarding the use of vonoprazan within the NHS and consideration of further clinical trials and economic evaluations to better understand when and how vonoprazan can be prescribed most optimally.

INTRODUCTION

In the human digestive system, the oesophagus and the stomach are separated by the lower oesophageal sphincter (LOS). This muscular structure serves a dual role: relaxation enables the passage of swallowed food into the stomach, while contraction prevents the backflow of acidic stomach contents into the oesophagus.[1] When there is LOS dysfunction, abnormal backflow of stomach contents may occur, which is known as gastro-oesophageal reflux disease (GORD). This can result in inflammation of the oesophageal mucosal lining, termed oesophagitis. This typically presents with symptoms of heartburn and acid regurgitation, causing discomfort.[2]

When GORD is persistent, atypical or relapsing, a diagnostic procedure known as oesophagogastroduodenoscopy (OGD) is performed.[2] This examination helps in classifying GORD into (endoscopy-negative) non-erosive or (endoscopically determined) erosive oesophagitis.[3] In non-erosive oesophagitis, the oesophageal mucosa appears normal, while erosive oesophagitis characteristically features breaks within an inflamed oesophageal mucosa. The Los Angeles (LA) Classification of oesophagitis further delineates erosive oesophagitis into grades A/B (mild) or grades C/D (severe).[4]

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Management of GORD can be separated into two phases: healing and maintenance. During healing, the aim is to repair the damaged oesophageal lining, while maintenance prevents relapse.[2]

According to the National Institute for Health and Care Excellence (NICE), the gold-standard medical management for oesophagitis is the prescription of a proton pump inhibitor (PPI).[3] By blocking the H^+/K^+-ATPase pumps lining the cells in the stomach, PPIs prevent the production of hydrochloric acid, consequently relieving discomfort.[5] To heal non-erosive and mild erosive oesophagitis, PPIs are taken for 4 or 8 weeks. To heal severe erosive oesophagitis, PPIs are taken for 8 weeks.[3]

If a patient continues to experience symptoms after the initial healing phase, they will proceed to the maintenance phase, for which NICE recommends a PPI course at the lowest dose. If unsuccessful, the patient will be re-reviewed and switched to a higher dose or another PPI regime. Without further improvement, the patient will be advised to seek specialist advice. Treatment is deemed successful when a patient is asymptomatic; OGDs are not routinely performed to assess a patient's remission.[3]

The estimated prevalence of GORD in the UK is 14.5%,[6] a prevalence that has increased by 77.5% between 1990 and 2019.[7] According to National Health Service (NHS) England, the 2023/2024 annual prescription cost for treating GORD exceeded £28.4 million,[8] posing a significant economic burden. These prescriptions include primarily the PPIs omeprazole and lansoprazole, but other prescriptions also include esomeprazole, rabeprazole and pantoprazole.[2]

Recently, studies in Asia have shown that vonoprazan, a potassium-competitive acid blocker, may offer numerous benefits over PPIs. This includes a higher potency, faster symptom relief[9] and greater cost-effectiveness.[10–13] Additionally, the first Western randomised controlled trial of vonoprazan's use in GORD was conducted by Laine *et al*, using lansoprazole as the comparator.[14]

To better understand the current literature comparing vonoprazan and lansoprazole, a narrative literature review of all relevant publications from the OVID MEDLINE and EMBASE databases was conducted on 17 February 2023. The following search string was implemented ("erosive-esophagitis" OR "erosive-oesophagitis" OR "reflux disease" OR "gastroesophageal-reflux-disease") AND ("lansoprazole") AND ("vonoprazan"). Our inclusion criteria were papers comparing vonoprazan and lansoprazole for treatments of GORD or erosive oesophagitis. Papers that could not be accessed in English were excluded. 99 papers were identified, of which 51 were selected for full-text review. A further scoping review determined that there was no economic evaluation of vonoprazan for GORD in the UK.

The existing literature confirmed both non-inferiority and, in some cases, superior efficacy of vonoprazan compared with lansoprazole as a treatment in the healing phase.[15–18] Additionally, one network meta-analysis suggested that management with vonoprazan can have a shorter timeframe than existing PPIs, with no compromise in efficacy.[19]

This increased effectiveness of vonoprazan was attributed to enhanced acid control throughout the entire day.[20] As a result, some studies concluded greater symptomatic relief through vonoprazan compared with PPIs, including a faster and more sustained relief of heartburn symptoms.[21] Vonoprazan also demonstrated a non-significant difference in safety and adverse effects.[22]

In the maintenance phase, a study demonstrated that 10 mg and 20 mg of vonoprazan were non-inferior to lansoprazole 15 mg.[23] Despite vonoprazan 20 mg resulting in a higher maintenance effect, long-term maintenance therapy using vonoprazan 10 mg is still effective for oesophagitis.[24]

One study also found treatment-emergent adverse effects to be lower for vonoprazan than lansoprazole for the maintenance period, with mild nasopharyngitis and diarrhoea being the most reported adverse effects.[23] Notable limitations of the existing literature include the lack of long-term maintenance analysis.

Although existing economic analyses of vonoprazan compared with PPIs have shown promising results regarding its cost-effectiveness, they have not been conducted in the UK. The trial conducted by Laine *et al* comprised data from the US, UK and European patient cohorts.[14] This provided the data required to conduct an economic evaluation to determine whether vonoprazan can be used to treat GORD in a budget-constrained NHS.

Therefore, adopting the NHS perspective in the UK, this study aimed to perform a cost-effectiveness analysis to compare vonoprazan against lansoprazole, a gold-standard PPI in managing erosive oesophagitis in the UK.

METHODS

Study design

Our cost-effectiveness analysis compared vonoprazan with lansoprazole for the management of erosive oesophagitis in the UK, using data of outcomes from Laine *et al*'s trial[14] and cost data from the British National Formulary (BNF),[25] Cambridge Bioscience,[26] and NHS Tariffs.[27] We adopted the NHS perspective and therefore used UK costs. The published data did not permit us to consider the outcomes for the UK separately, but significant variations across the established healthcare systems in these regions are not expected.

Laine *et al* carried out a double-blind, randomised control trial, across 77 US sites and 34 European sites, including 9 in the UK.[14] Consistent with the erosive oesophagitis treatment pathway,[2] the trial was separated into an initial healing phase, followed by a maintenance phase (figure 1). Before any treatment, all participants underwent an OGD to determine the LA Classification grade of their oesophagitis, as well as a biopsy.

In the healing phase, participants (n=1027) were randomly allocated between two trial arms: vonoprazan

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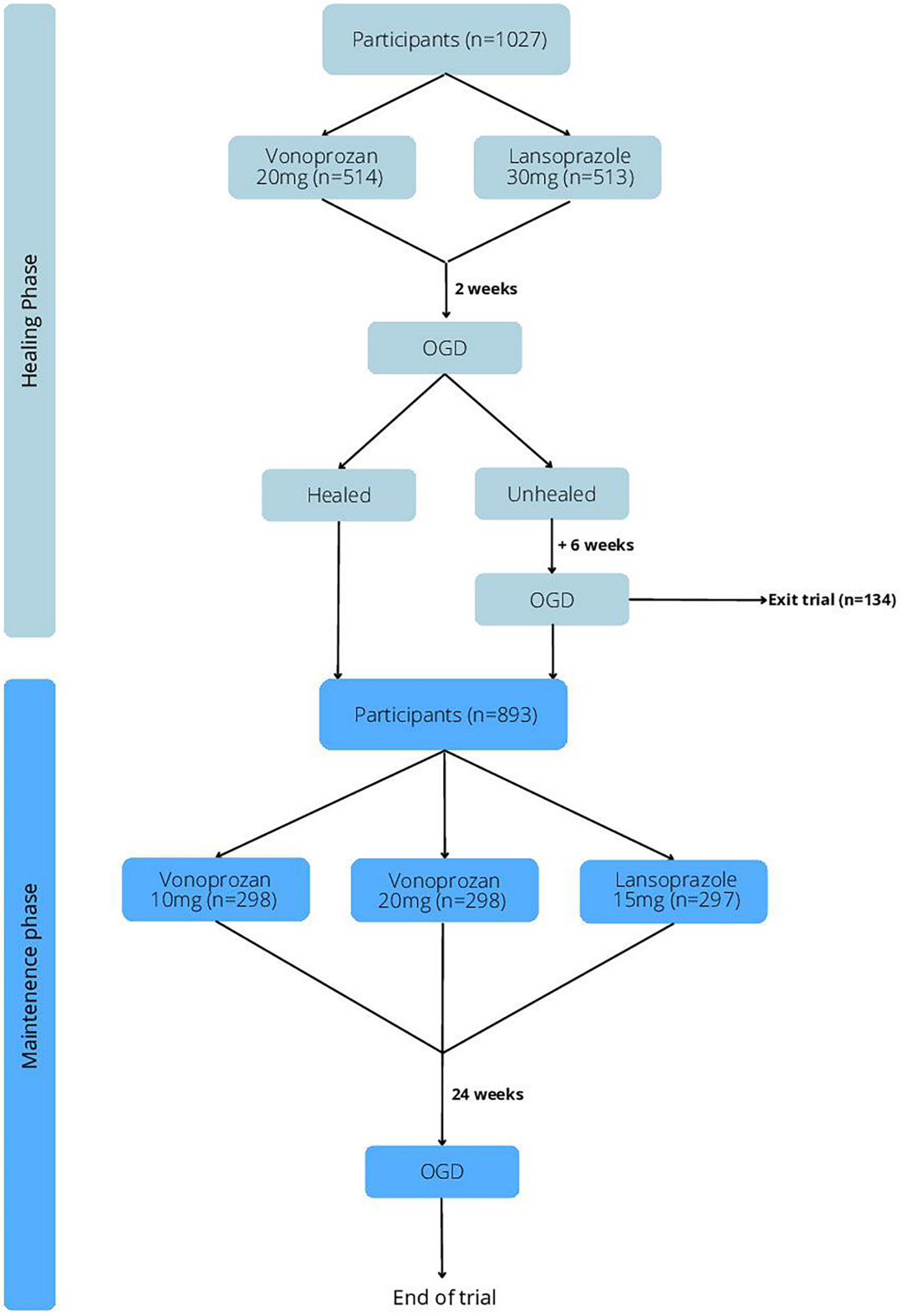


Figure 1 Simplified treatment pathway of study trial by Laine *et al*. OGD, oesophagogastroduodenoscopy.[14]

20 mg (n=514) and lansoprazole 30 mg (n=513). After 2 weeks, treatment responses were determined by OGD. For both arms, if treatment was successful, participants moved on to the 'maintenance phase'. At this stage, those who were unhealed at week 2 continued their treatment for 6 weeks, receiving another OGD at 8 weeks of the 'healing phase'. Healed participants at 8 weeks were assigned to the maintenance phase. Those who did not continue to the maintenance phase were excluded (n=134).[14]

All participants who entered the maintenance phase immediately after (n=893) were rerandomised into three

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trial arms: vonoprazan 10 mg (n=298), vonoprazan 20 mg (n=298) and lansoprazole 15 mg (n=297). The trial was concluded at 24 weeks into the maintenance phase, with OGDs and biopsies to assess the efficacy of maintenance treatment.[14]

The trial was conducted over 32 weeks,[14] equivalent to the midpoint of the 6–9-month optimal management timeframe of erosive oesophagitis.[28] Therefore, this timeframe was adopted in the economic evaluation (see CHEERS checklist in online supplemental file).

Costs were assigned in British pound sterling, and effectiveness was constructed as a binary variable: 1 if healing was effective at 24 weeks into the maintenance phase and 0 if not. Due to the lack of quality-adjusted life year (QALY) data within this trial, a cost–utility analysis was not initially chosen.

The incremental cost-effectiveness ratio (ICER) values were derived from the effectiveness values in Laine *et al*'s trial and complemented with the assigned costs for this economic evaluation. However, for the ICER to be interpretable, it must be related to a suitable willingness-to-pay threshold, typically expressed as cost per QALYs. NICE's QALY threshold value of £30 000[29] was used as the reference. To provide a comparison with this reference, the evaluation then divided the ICER values by the difference in QALYs gained from achieving stable medical management, by using QALY data obtained from the REFLUX trial.[30]

The REFLUX trial was carried out in the UK across 21 hospitals, involving 810 patients. Therefore, these values were used as proxies for the QALY values associated with successful and unsuccessful outcome. Quality-of-life (QOL) values were determined to be 0.72 and 0.56 for those under stable medical maintenance and relapse, respectively.[30]

Modelling of data

The primary outcome was healing at 24 weeks into maintenance following treatment with vonoprazan or lansoprazole. A decision tree was devised to replicate the stages of the erosive oesophagitis treatment pathway as identified in the trial by Laine *et al*. The initial treatment compared 20 mg of vonoprazan with 30 mg of lansoprazole in the healing phase, followed by a comparison in the maintenance phase between 15 mg of lansoprazole, and 10 mg and 20 mg of vonoprazan. The efficacy values were based on the proportion of healed participants at each stage in the trial by Laine *et al*. This led to 52 terminal node points (figure 2).

Costs

The primary costs to the NHS include drug, OGD, biopsy and consultation expenses. All costs were determined in British pound sterling and extracted from BNF,[25] Cambridge Bioscience,[26] and NHS tariff rates.[27] According to the BNF, lansoprazole 30 mg costs the NHS £4.92 at the time of writing.[25] Cambridge Bioscience prices vonoprazan 20 mg at £9.92, representing a 102% markup compared with lansoprazole.[26]

The unit cost of a diagnostic OGD, with (£467) or without biopsy (£396), alongside the first clinic appointment and follow-up appointments, was obtained from the 2023–2025 NHS tariff rates. All appointments were assumed to be conducted by a single medical professional; these costs were £199 and £85 for first and follow-up appointments, respectively.[27]

With all costs obtained from 2024 databases, no discounting was required.

Benefits

The primary outcomes were determined by each patient's final OGD results. As mentioned, a binary classification was assigned to the two mutually exclusive and collectively exhaustive possible outcomes.

If a patient healed and maintained their healing throughout the study period, they were assigned a value of 1. If a patient healed and did not maintain healing, or a patient did not heal at all, they were assigned a value of 0. Therefore, temporary healing was still assigned a value of 0, which is a conservative approach.

For this evaluation, only direct effects were considered, due to minimal differences in adverse effects between those who took lansoprazole and vonoprazan.[14]

RESULTS

In the healing phase, patients in the vonoprazan treatment arm accessed healthcare resources for an estimated cost of £804.88, compared with £734.88 in the lansoprazole arm. Vonoprazan demonstrated a greater efficacy of 71.6% in this phase, as compared with 65.6% for lansoprazole.

In the maintenance phase (table 1), patients in the vonoprazan treatment arm received either the 10 mg or 20 mg dose, representing estimated costs of £833.28 and £1666.56, respectively. In comparison, the estimated costs of healthcare access for patients in the lansoprazole treatment arm were £330.96. This represents a greater cost–expenditure of £502.32 and £1335.60, respectively. The efficacy of treatment in the maintenance phase varied based on disease severity. In mild disease, vonoprazan treatment yielded healing in 81.3% and 82.3% of patients in the 10 mg and 20 mg arms, while the lansoprazole treatment arm demonstrated healing in 77.1%. In cases of severe disease, vonoprazan treatment yielded healing in 74.7% and 77.2% of patients in the 10 mg and 20 mg arms, while the lansoprazole treatment arm demonstrated healing in 61.5%. Therefore, vonoprazan was more effective in treating oesophagitis in the healing and maintenance phase for both mild and severe cases.

For the healing phase, our ICER of £3421.27 showed that vonoprazan has greater efficacy but at a higher cost. When the severity of the disease was further subcategorised by LA grade, mild oesophagitis treated with vonoprazan yielded an ICER of £8045.38, while the ICER

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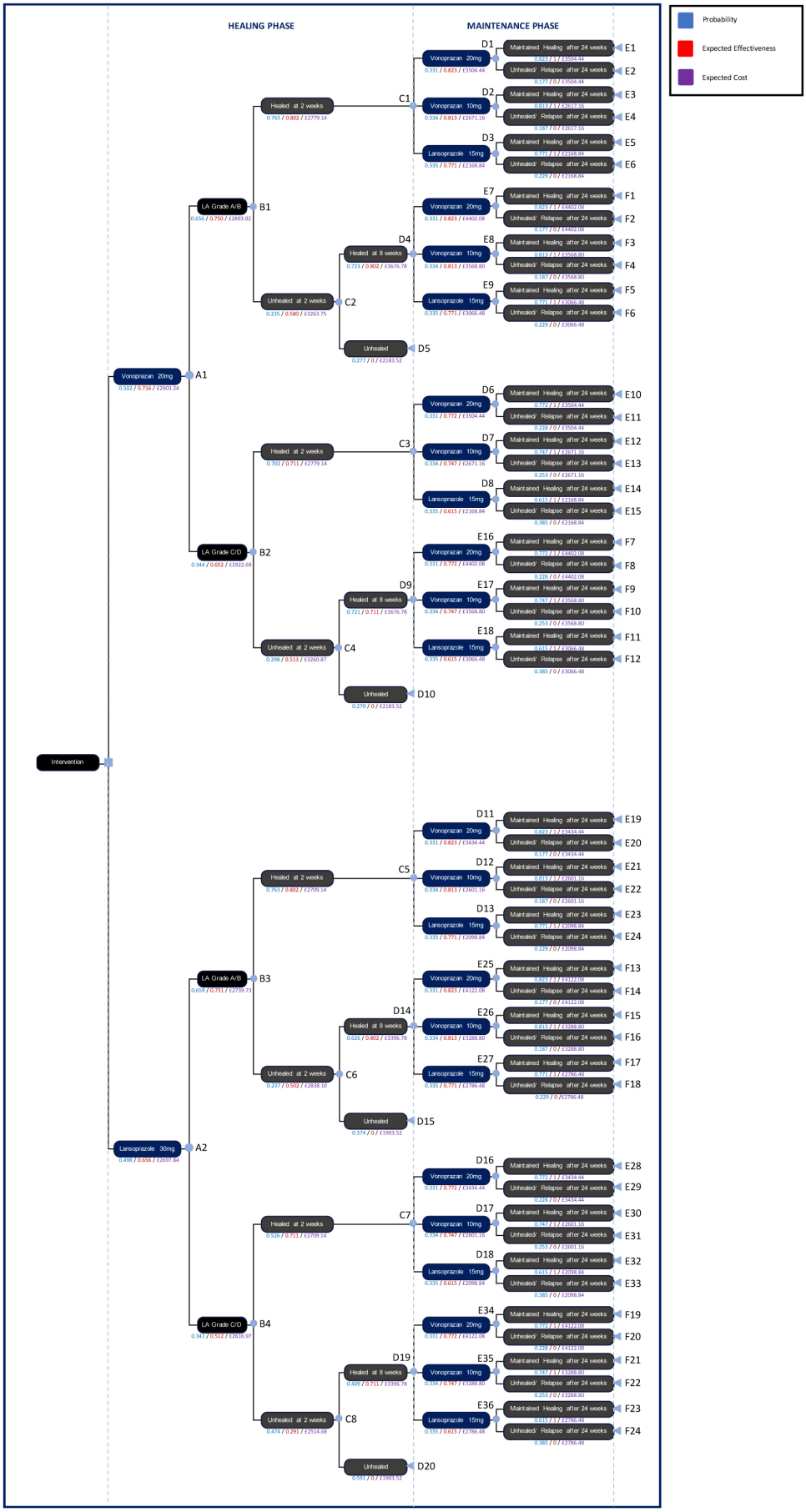


Figure 2 Decision tree modelling. LA, Los Angeles.

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Table 1 Cost and efficacy results from treatment arms during maintenance phase

Maintenance phase	Estimated cost (£)	Efficacy in mild disease (%)	Efficacy in severe disease (%)
Vonoprazan 10 mg	833.28	81.3	74.7
Vonoprazan 20 mg	1666.56	82.3	77.2
Lansoprazole 15 mg	330.96	77.1	61.5

for vonoprazan in severe oesophagitis was £2182.46 (figure 3). Using data from the REFLUX trial,[30] ICER/QALY values were calculated. The overall ICER/QALY, irrespective of oesophagitis severity, was £34 747.32 (figure 4). When further subcategorised by severity, treating severe oesophagitis with vonoprazan yielded an ICER/QALY of £22 165.56, whereas the equivalent value in mild oesophagitis was £81 710.85.

The overall cost-effectiveness in the maintenance phase was not calculated, as it was deemed inapplicable to the NHS. This is because NICE recommends 30 mg of lansoprazole as the gold-standard treatment,[3] double the dose used in the trial. Therefore, without a suitable reference for effectiveness outcomes and costs, it is difficult to make any definitive conclusions regarding vonoprazan's use in the maintenance phase in the NHS.

Sensitivity analyses

Three sensitivity analyses were performed to account for potential differences between the trial data and NICE guidelines.

Sensitivity analysis 1

The first sensitivity analysis was based on using OGD to assess the success of healing and maintenance of erosive oesophagitis. In a budget-constrained NHS, repeating OGDs to determine and monitor treatment success is financially unfeasible. A more realistic, applicable assessment of success is a symptom-free outcome after commencing medication. According to NICE guidelines,[3] OGD is only likely if maintenance of healing is unsuccessful and symptoms persist. Because this evaluation focuses on patients who have had an OGD, only the cost of the initial OGD to determine the presence and severity of erosive oesophagitis was used, alongside the cost of OGD after 24 weeks of unsuccessful maintenance therapy. ICERs were thereafter recalculated.

Having accounted for the excessive OGDs performed in the trial, all ICER/QALY values decreased, with the most significant being seen in treating severe oesophagitis, from £22 165.56 to £15 826.98. This further increases the viability of using vonoprazan as an alternative to PPIs to treat severe erosive oesophagitis in patients with an endoscopic diagnosis. For mild erosive oesophagitis, the ICER/QALY value still exceeds the NICE's QALY threshold[29] to be supported (£70 587.55).

Sensitivity analysis 2

The second analysis relates to two discrepancies between the NICE guidelines and the trial methodology.

First, NICE advises a 4–8-week course of treatment for mild erosive oesophagitis and an 8-week course for severe erosive oesophagitis.[3] However, in the trial, those who displayed healing at 2 weeks immediately entered

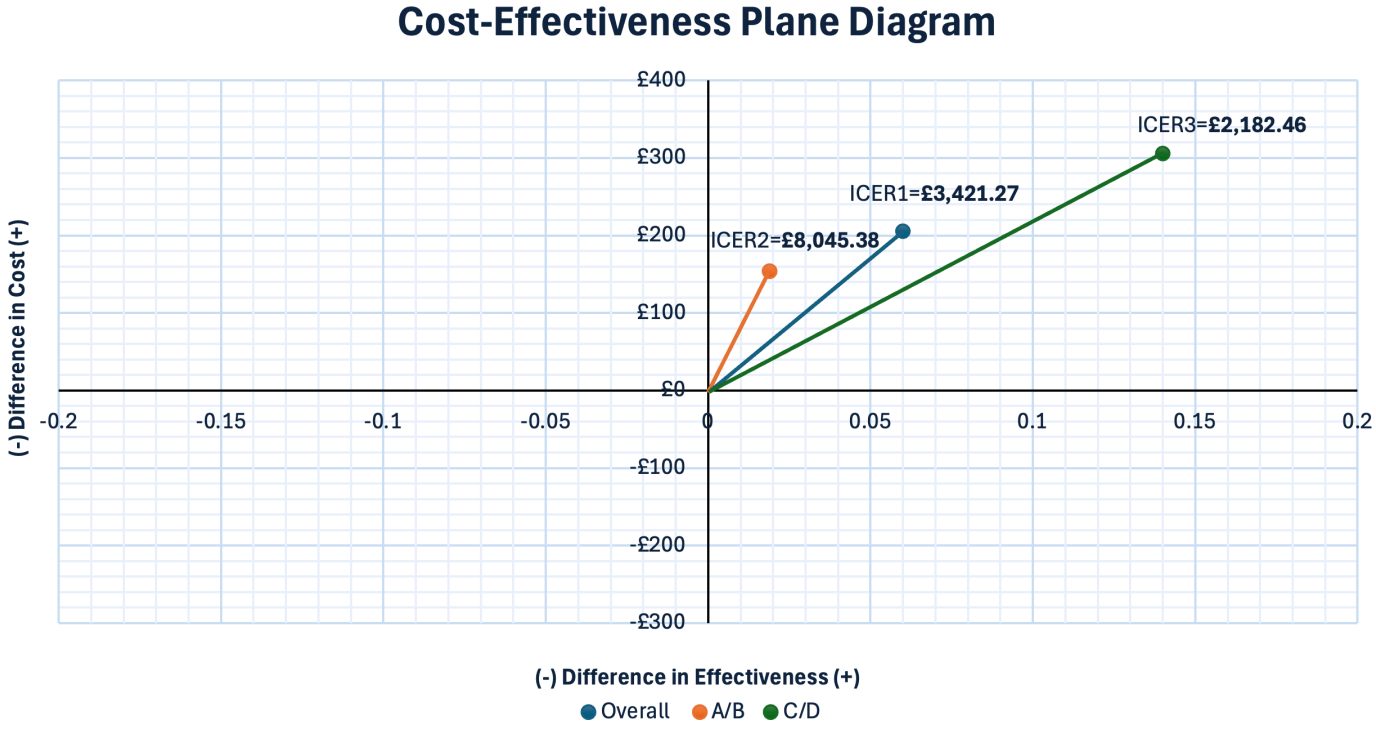


Figure 3 Cost-effectiveness plane diagram for treatment of oesophagitis, classified by severity of disease. ICER, incremental cost-effectiveness ratio.

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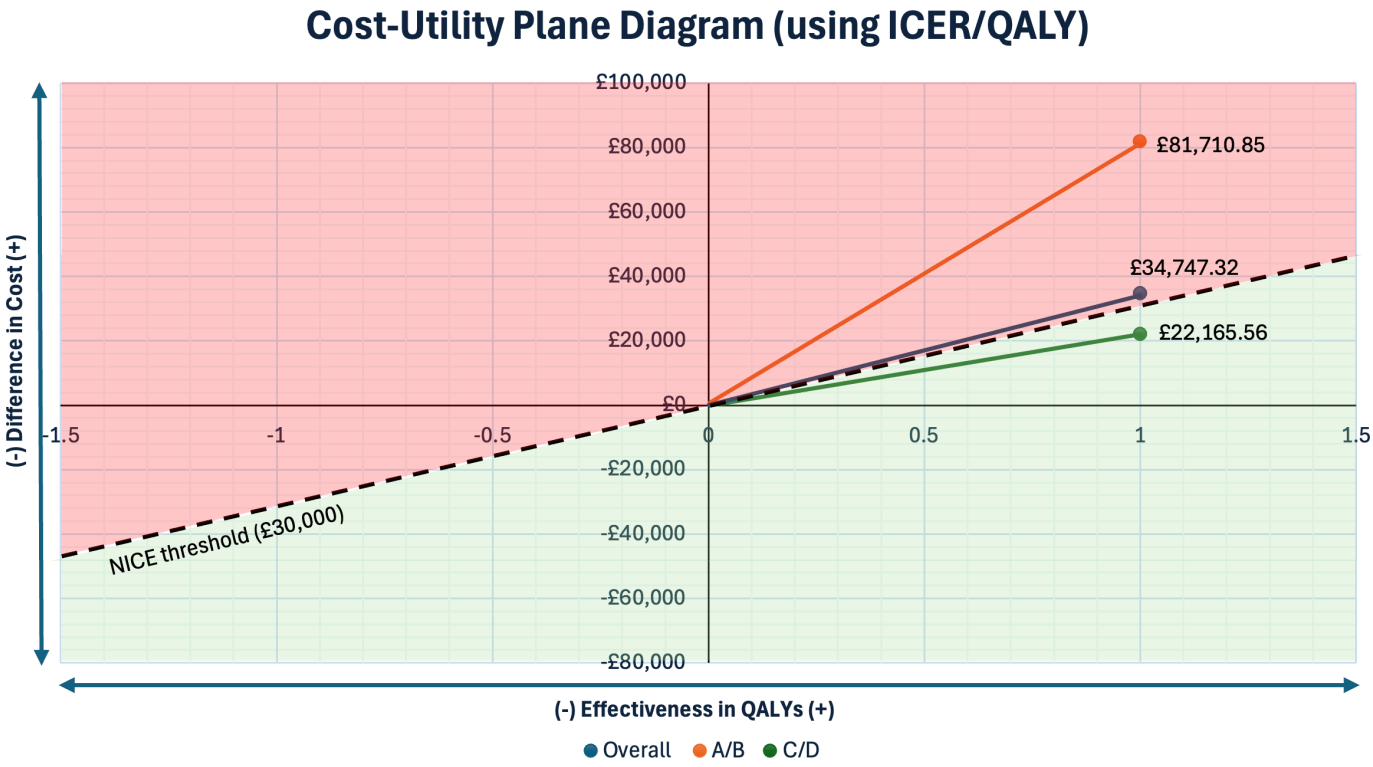


Figure 4 Cost-utility plane diagram for treatment of oesophagitis, classified by severity of disease. ICER, incremental cost-effectiveness ratio; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year.

the maintenance phase, contradicting the NICE pathway and underestimating the actual cost. Therefore, it was assumed that all participants took the drug for 8 weeks to reflect the greatest possible costs of treatments.

Second, for those with severe oesophagitis, NICE recommends 30 mg of maintenance lansoprazole,[3] double the dose used in the trial. To evaluate the worst-case scenario, in which ICER/QALY values are most likely to exceed the NICE's willingness-to-pay threshold, costings were amended to represent a 30 mg dose of maintenance lansoprazole. Additionally, a study shows non-superiority of 30 mg lansoprazole compared with a 15 mg dose[31]; therefore, efficacy was assumed to be equal between doses.

Due to the significant cost increase, the ICER/QALY of £43 998.39 for treating severe erosive oesophagitis with vonoprazan exceeds the recommended NICE's QALY threshold,[29] which suggests it is not cost-effective for use in the NHS.

However, there are two key considerations to interpret the ICER/QALY value. First, it is not routine in the NHS to confirm successful healing and maintenance via OGD,[3] nor is taking a biopsy.[32] If sensitivity analyses 1 and 2 were to be combined, the ICER/QALY value for healing severe oesophagitis would be far more comparable to the NICE threshold.[29] Second, the findings from the randomised controlled trial,[14] as well as the literature,[21] suggest that vonoprazan can achieve faster healing than lansoprazole. Therefore, this sensitivity analysis highlights the need for further studies into the optimal dosage, frequency and duration of vonoprazan, to inform NICE guidelines and achieve the greatest cost-effectiveness.

Sensitivity analysis 3

In the literature, QOL measures vary significantly depending on the method used. The final sensitivity analysis considers the highest values from a study that uses the time trade-off instrument: 0.97 for those with symptoms and 1 for those who are healed.[33] This yields far greater ICER/QALY values, with the revised figure for severe erosive oesophagitis reaching £118 216.32, rendering it not cost-effective.

However, there are two key considerations to interpret this value. First, for a patient to be investigated with an OGD, they are likely to experience persistent symptoms of GORD. Their symptom profile aligns closely with the demographics in the REFLUX trial, from where the original QOL values were derived. These patients also align more with the trial by Laine *et al* because all patients were known to healthcare institutions and identified with erosive oesophagitis (note that GORD symptoms mainly occur in those with the non-erosive subtype). Therefore, the QOL values in this sensitivity analysis are likely to be overestimated. Second, NICE prefers the EuroQol 5-Dimension instrument to assess QOL, as opposed to the time trade-off method in other studies, which tends to provide higher QOL estimates.[34] Nevertheless, this sensitivity analysis reinforces that vonoprazan should mainly be considered for patients with a more severe form of the erosive oesophagitis

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subtype of GORD, particularly those likely experiencing refractory symptoms.

DISCUSSION

From a medical perspective, Laine *et al* concluded that vonoprazan was superior to lansoprazole in the healing and maintenance phases of erosive oesophagitis. This economic evaluation considered both medical and economic perspectives to advise implementation within the NHS.

In those with severe erosive oesophagitis confirmed by OGD, vonoprazan has the potential to be a cost-effective treatment in the healing phase. This conclusion did not apply to those with mild erosive oesophagitis; the ICER/QALY was £81 710.85, exceeding the NICE's threshold of £30 000/QALY.[29] For severe oesophagitis, the ICER/QALY was dramatically lower at £22 165.56, falling below the NICE's threshold[29] and deeming it a possible alternative for lansoprazole.

In the maintenance phase, the cost-effectiveness could not be determined due to the trial's discrepancy in lansoprazole dosage compared with that of NICE. Although the second sensitivity analysis introduced assumptions for effectiveness outcomes, these cannot be used to make definitive conclusions for the maintenance phase.

Overall, the ICER/QALY values are promising and favourable towards vonoprazan in the healing phase of severe erosive oesophagitis, specifically after an endoscopic diagnosis.

The results must be considered in light of their limitations, which arise from both the trial itself and this economic analysis. In the trial by Laine *et al*, certain ethnic groups (other than Caucasians) and *Helicobacter pylori*-positive patients were not represented. This economic analysis has five main limitations.

First, our economic evaluation conclusion is based on investigation-based rather than symptom-based management, which NICE initially recommends. Therefore, our conclusion only applies to patients investigated with an OGD and diagnosed with erosive oesophagitis. Further clinical trials exploring the prescription of vonoprazan based on symptoms may help form recommendations in the initial treatment of oesophagitis as a whole.

Second, detailed data on adverse effects were unavailable. Hence, drug side effects could not be accounted for in our decision tree. However, the differences in adverse effects were reported to be minimal between those who took lansoprazole and vonoprazan, and existing literature reinforces this.[22]

Third, drug effectiveness from the trial by Laine *et al* was not measured in QALY but mapped to values from a 2008 trial,[30] combining findings from different periods. This was justified due to medical treatments being consistent over the last few decades.[1]

Fourth, to translate ICER values from an effectiveness perspective to a QALY perspective, it was assumed that all outcomes were determined after 32 weeks, regardless of whether their outcome was determined earlier. For example, those who healed at 2 weeks completed 24 weeks of maintenance and ended their involvement in the study after 26 weeks.

Finally, the dose of lansoprazole used in the maintenance phase of the trial is incongruous with the current gold-standard 30 mg dosage as per NICE guidelines.[3] Although the second sensitivity analysis aimed to address this, further studies are required to determine the superior treatment option. Moreover, the trial used a continuous daily maintenance regimen; while this is true for severe oesophagitis, 'as-needed' regimens are recommended by NICE for mild oesophagitis.[3] Further analyses are required to determine the difference in both cost and effectiveness of such regimens.

The trial by Laine *et al* can be generalised to the UK population, with comparable demographics in sex, ethnicity and age range.[35] To further increase the generality of the results, future clinical trials comparing vonoprazan with other PPIs would be highly valuable. It would also be beneficial if these trials explored the optimal dosage, frequency and length of treatment for both classes of drugs.

Given that this economic evaluation was conducted according to NICE guidelines,[3] these findings cannot be extrapolated to other healthcare systems with differing costs and management pathways. Additionally, these results cannot be extended to other gastrointestinal tract pathologies, including the treatment and complications of GORD with concurrent *H. pylori* infection.

CONCLUSION

In conclusion, vonoprazan presents itself as a potentially cost-effective treatment in the initial healing of severe erosive oesophagitis after endoscopic diagnosis. Further trials must be conducted to explore the optimal prescription of vonoprazan and to determine its cost-effectiveness in the maintenance phase. This study is the first economic analysis conducted in the West but reinforces the findings of other economic evaluations conducted in Asia.

X Laure de Preux @LauredePreux

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ORCID iDs
Saeash Jeyarajan http://orcid.org/0009-0002-4149-5620
Thejasvin K http://orcid.org/0000-0001-6648-0375
Sneha Pimpalnerkar http://orcid.org/0009-0002-5002-4409
Emily Zichu Deng http://orcid.org/0009-0004-9107-3586
Zain Ahmad http://orcid.org/0009-0000-8814-5869
Diya Banerjee http://orcid.org/0000-0001-5753-380X
Laure de Preux http://orcid.org/0000-0002-1684-9397

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