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Cost-effectiveness analysis of fenofibrate for the prevention of diabetes complications in people suffering from Type 2 Diabetes Mellitus.

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Introduction

There are more than 4,400 diabetes-related amputations and more than 10,000 hospital admissions for diabetes-related foot ulcers in Australia. It is estimated that the cost of treating diabetic foot disease is $875 million per year. Clinical evidence from the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study demonstrated that fenofibrate can play a role in reducing the risk of diabetes-related lower limb amputations. This study sought to investigate the cost-effectiveness of using fenofibrate to prevent amputations in an Australian clinical setting.

Methods

A cost-effectiveness model was constructed to evaluate the cost and quality adjusted life years over a 20-year time horizon. Cost and quality of life inputs were sourced from government websites and the literature. Incremental cost effectiveness ratios were calculated and a standard discount rate of 3% was applied. The Australian National Diabetes Audit Report 2022 from Monash University was used as basis to simulate individual patient data. More specifically, current rates of foot ulceration, peripheral neuropathy and lower limb amputations were informed by the Australian National Diabetes Audit Report 2022 (see table 1).

Table 1. Foot complications reported among Australian T2DM patients

Foot complications	Last 12 months (%)	Prior to last 12 months (%)
Foot ulceration	6.8%	7.9%
Peripheral neuropathy	23.6%	20.4%
Lower limb amputation	2.2%	3.4%

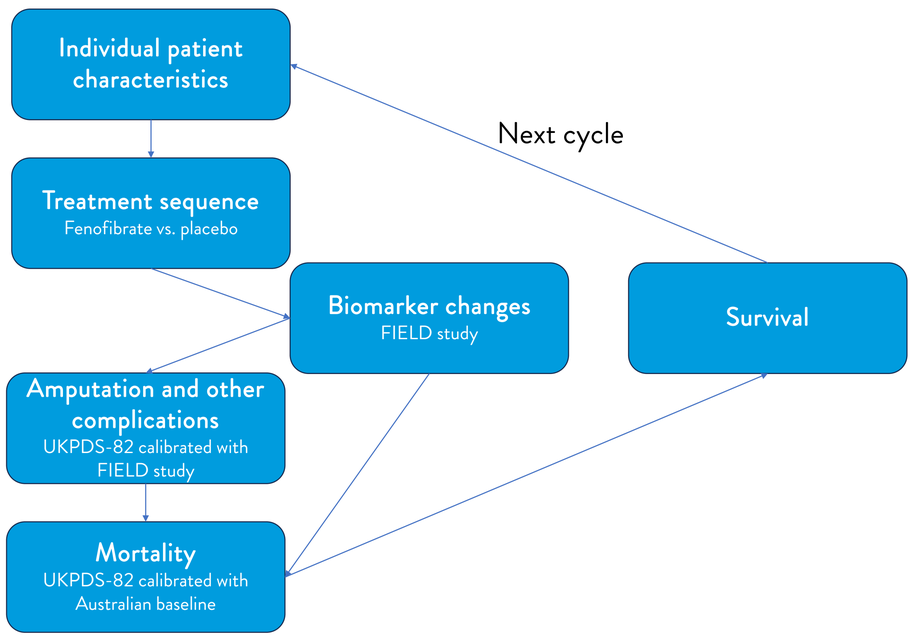
The FIELD study reported a significant reduction in risk of first amputation as well as minor amputations (see table 2).

Table 2. Effect of fenofibrate on amputation events in people with T2DM (FIELD study, 2009)

Group	Placebo (N = 4900)	Fenofibrate (N = 4895)	Hazard ratio (95% CI)	P-value
Patient with first amputation	70	45	0.64 (0.44-0.94)	0.02
Minor amputation (below the ankle)	34	18	0.53 (0.30-0.94)	0.027
Major amputation (above the ankle)	26	24	0.93 (0.53-1.62)	0.79

The number of amputations in an Australian diabetes cohort treated with fenofibrate over a 20-year time horizon was projected using the UKPDS-82 outcomes model. This is done by utilising a micro-simulation model where outcomes from individual patients are simulated displayed in figure 1.

Figure 1. Microsimulation model



Total cost of treating amputations was calculated over the 20-year time horizon. Input data was obtained from the Australian Refined-Disease Related Groups (AR-DRG) and the Australian Pharmaceutical Benefits Scheme (see table 3).

Table 3. Clinical cost inputs (in AUD)

	Cost
Lower Extremity Amputation	$47,847
Other complications	$49,895
Fenofibrate	$203.00
Metformin MR	$79.90
Gliclazide MR	$40.00
Complication free diabetes	$2,815

The outcomes part of the model was implemented in R on a Windows platform. The economic evaluation was done in MS Excel.

Results

The model predicted fewer amputations, blindness, heart failure, ischemic heart disease, myocardial infarction, renal failure and strokes for people treated with fenofibrate vs no fenofibrate (see Table 1).

Table 4. Estimated diabetes complications and final outcomes

Per 1000 people over 20 years	Fenofibrate	No fenofibrate	Difference
Diabetes complications			
Amputations	42	81	-39
Blindness	50	60	-10
Congestive Heart failure	219	233	-15
Ischemic heart disease	68	142	-74
Myocardial infarction	234	367	-133
Renal failure	131	147	-16
Stroke	162	172	-10
Final outcomes			
Death	701	743	-43
Life years (LYs)	11936	11388	548
Quality adjusted life years (QALYs)	6834	6493	341

In particular, the most significant differences in complication rates between those taking fenofibrate and those not taking fenofibrate were observed for myocardial infarction, ischaemic heart disease and amputation. This suggests a potentially significant impact of fenofibrate treatment in reducing the risk of these specific diabetes-related health problems.

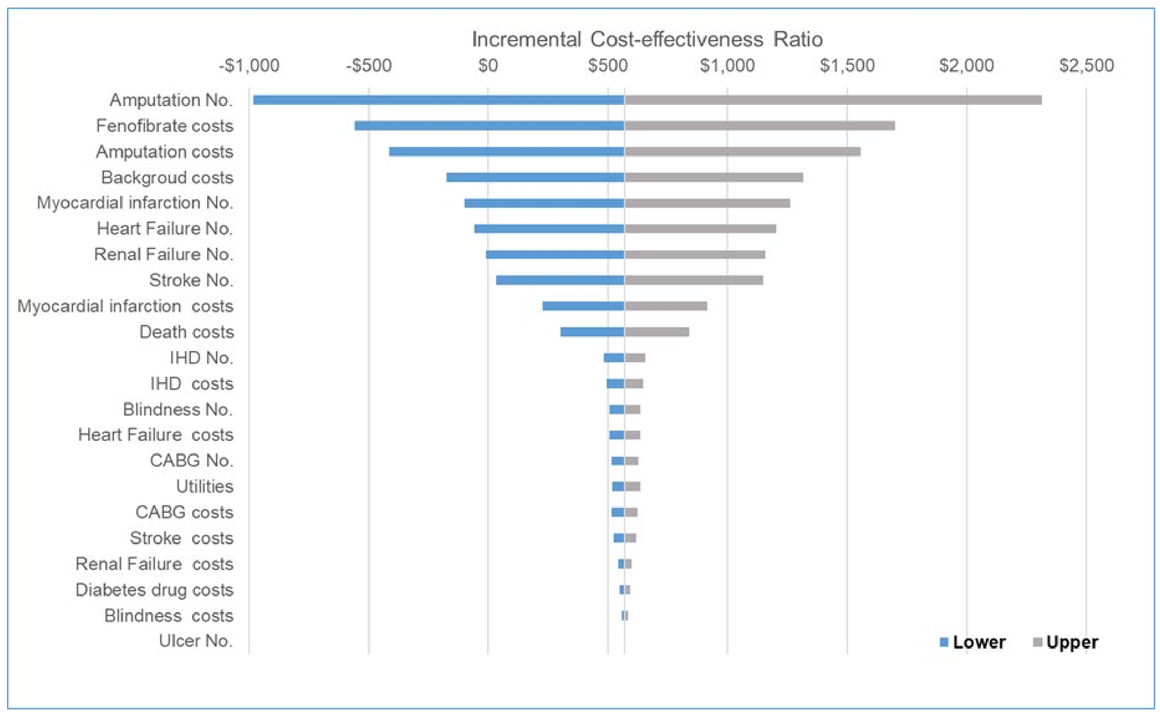
Table 5. Estimated costs

Costs	Fenofibrate	No fenofibrate	Difference
Complications	$13.05M	$17.67M	-$4.63M
Other costs (death/diabetes treatment etc)	$60.62M	$58.63M	$1.99M
Fenofibrate	$3.06M	-	$3.06M
Total	$76.72M	$76.31M	$0.41M

Cost of fenofibrate treatment was estimated to be $3.06M, and the cost of complications were estimated to be $13.05M for fenofibrate and $17.67M for people not taking fenofibrate. Thus, a cost savings $4.63M was observed for complications. The additional total cost of fenofibrate was AUD 0.41M compared to no fenofibrate. The incremental cost-effectiveness ratio is AUD0.41M/548=AUD739/LY gained and AUD0.41M/341=AUD1,189/QALY gained.

Sensitivity analysis

Figure 2. Microsimulation model



The sensitivity analysis showed that the main drivers of cost-effectiveness were number of amputations as well as the cost of fenofibrate. However, the ICER remained relatively low with no sensitivity analysis resulting in an ICER above $2,500. On the other hand, some of the sensitivity analysis actually yielded negative ICERs which indicated that fenofibrate could be dominant in some cases i.e. fenofibrate results in positive health gain at a possible health saving to the health care system.

Conclusion

Fenofibrate resulted in significant reduction of amputations by 52% presenting a cost savings $1.56M per 1000 patients. Fenofibrate is a cost-effective option for preventing of diabetic complications such as amputations in Australia. It suggests important public health implications given the medication's widespread use. Fenofibrate is a cost-effective way of preventing diabetic complications in an Australian T2DM population.

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