323-The Value of a Novel Macrophage-Regulating Drug for Diabetic Foot Ulcers: A Cost-Effectiveness Analysis.

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Introduction

Diabetic foot ulcers (DFUs) and subsequent amputation incur enormous health and economic burdens to patients, healthcare systems, and societies. As a novel macrophage-regulating drug, ON101 is a breakthrough treatment for DFUs with proven significant efficacy among patients with DFUs in phase 3 randomized controlled trial. This study assesses the cost-effectiveness of ON101 cream added-on to general wound care (ON101+GWC) versus GWC for DFUs.

Materials and methods

Cost and health outcomes associated with the ON101+GWC and GWC strategies were estimated by a Markov state-transition simulation model over a 5-year time horizon from the Taiwanese healthcare sector perspective, discounting costs and effectiveness at 3% annually. Data were sourced from the ON101 trial and supplemented from published literature. Deterministic and probabilistic sensitivity analyses also assessed the uncertainty of input parameters and the study's generalizability. DFU-related complications, costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio are the primary outcomes and measures for assessment. The study was designed and conducted from September 1, 2020, to January 31, 2022.

Results

Simulated over 5 years from the Taiwan healthcare sector perspective, the ON101+GWC strategy versus GWC yielded additional 0.038 QALYs at an incremental cost of US$571, resulting in US$14,922 per QALY gained. Financial results were most sensitive to healing efficacy, drug cost, and health utility of the healing state. The ON101+GWC group versus the GWC group experienced more healing events, stayed healing for a longer time, and had fewer infected DFUs, gangrene, and amputations. Cost-saving results were revealed in patient subgroups with poor glycemic control, larger ulcer sizes, longer ulcer durations, and current smokers. The ON101+GWC strategy was considered cost-effective in 60%-82% of model iterations against pre-defined willingness-to-pay thresholds of US$32,787-$98,361 per QALY gained.

Conclusions

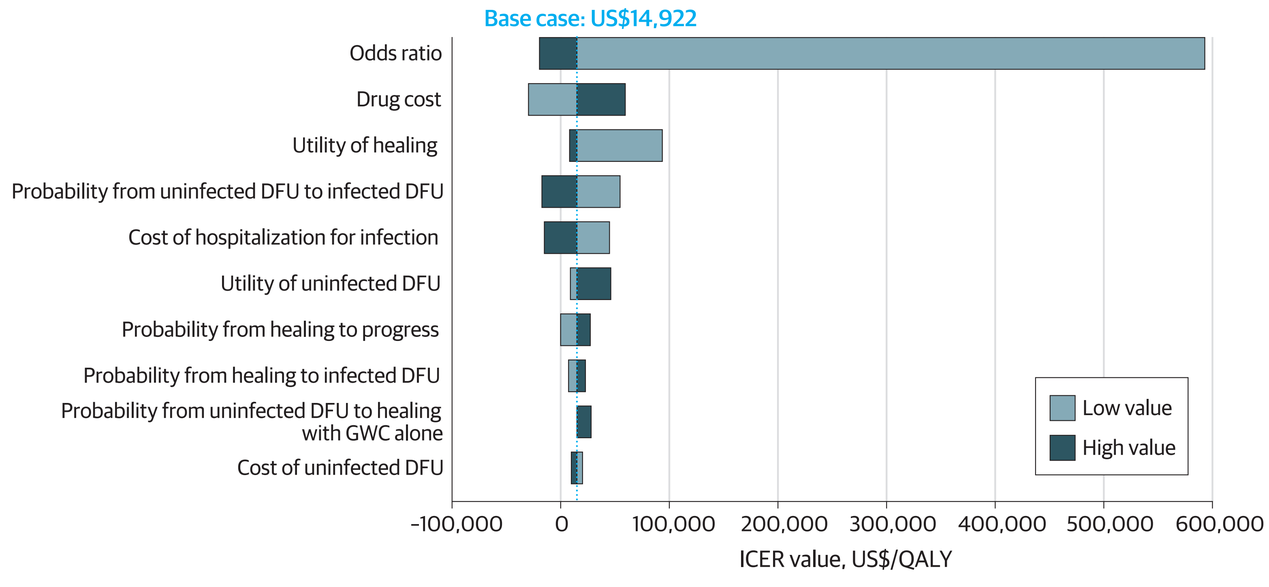
The ON101+GWC strategy represented good value for money compared with GWC for patients with DFUs and may be considered in future standard wound care as well as prioritized to those with higher risks for disease progression of DFUs.

Table 1: Base-Case Analysis Results Over a 5-Year Model Simulation

Treatment group	Total cost, 2021 US$	Incremental cost, 2021 US$	Life expectancy, y	QALY	Incremental QALY	ICER, 2021 US$/ QALY gained	Probability of cost-effectiveness, %[a]
GWC alone	9,210	NA	4.5128	3.7019	NA	NA	NA
ON101 with GWC	9,781	571	4.5135	3.7402	0.0383	14,922	82

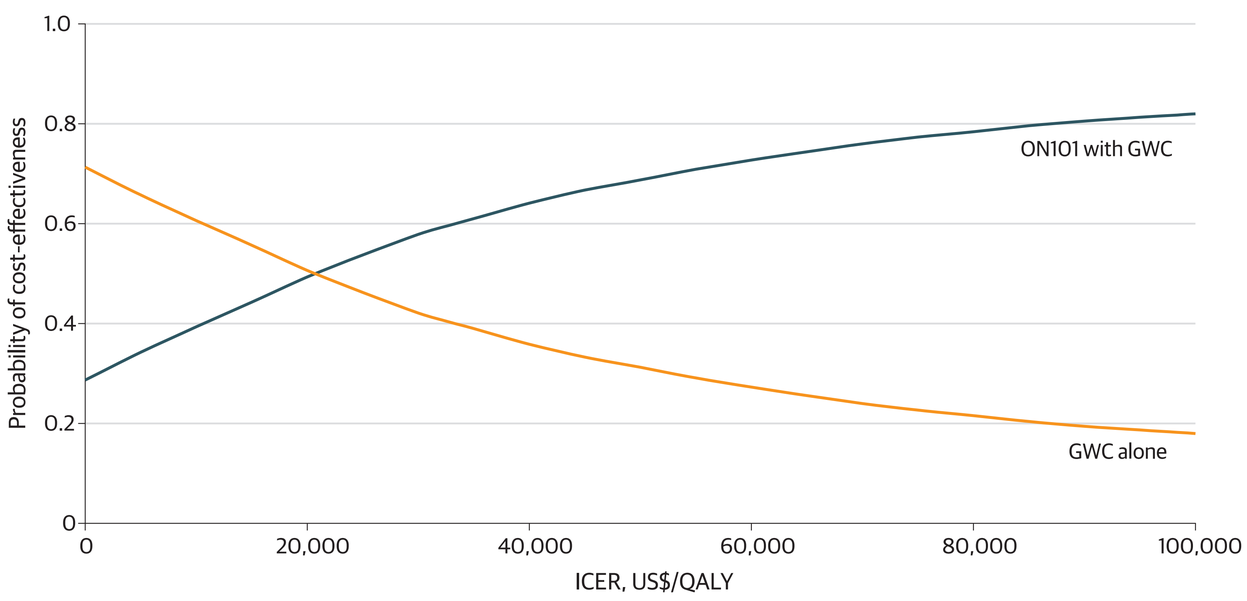
Abbreviations: GWC, general wound care; ICER, incremental cost-effectiveness ratio; NA, not applicable; QALY, quality-adjusted life-year.
[a] The probability was against the willingness-to-pay threshold of US$98,361/QALY gained.

Figure 1. Tornado Diagram for Deterministic Sensitivity Analysis Results



The figure shows the incremental cost-effectiveness ratio (ICER) of ON101 with general wound care (GWC) vs GWC alone for different model input parameters. The influential parameters whose variations yielded a base-case ICER change greater than 40% are illustrated in the figure. DFU indicates diabetic foot ulcer; QALY, quality-adjusted life-year.

Figure 2. Cost-effectiveness Acceptability Curve



The figure shows the probabilistic sensitivity analysis using Monte Carlo simulation with 10,000 iterations, in which the input parameters varied simultaneously in the plausible statistical distributions that reflected the uncertainty of the cost-effectiveness for ON101 with general wound care (GWC) vs GWC alone at different willingness to pay thresholds. ON101 with GWC had a28.7%, 59.7%, and 81.8% probability of being cost-effective against the willingness to pay thresholds of US$0, US$32,787, and US$98,361 per quality-adjusted life-year (QALY) gained, respectively. ICER indicates incremental cost-effectiveness ratio.

References:
1.Su, Hsuan-Yu, et al. "Cost-effectiveness of Novel Macrophage-Regulating Treatment for Wound Healing in Patients With Diabetic Foot Ulcers From the Taiwan Health Care Sector Perspective." JAMA Network Open 6.1 (2023): e2250639-e2250639.