Background

Leg ulcers and diabetic foot ulcers are prevalent wound types and a common cause of patients’ disability, worsening their quality of life and bringing significant costs to healthcare systems. Sucrose octasulfate dressing (SOD; Urgostart) is the only wound dressing with demonstrated superiority in wound healing speed. However, its cost-effectiveness compared to neutral dressing has not yet been assessed in the Czech Republic.

Objectives

To assess cost-effectiveness of SOD versus a control dressing (the same dressing as SOD without sucrose octasulfate; CD, UrgoStart) in patients with neuroischaemic diabetic foot ulcers (NDFU) and venous leg ulcers (VLU) in the Czech Republic. Based on randomised double-blind controlled trials (RCT; EXPLORER, CHALLENGE), we developed a one-year decision-tree model using TreeAge Pro 2018. Depending on response to treatment, the model structure consists of two mutually exclusively health states: "treatment success" and "treatment failure". Treatment success was defined as i) wound closure (in NDFU) and ii) wound area reduction (40%) in VLU. Treatment failure (the 2nd line of treatment (compression wrap therapy) is started. The 2nd line of treatment can be accompanied either by mild adverse events (AE), severe AE requiring hospitalization) or (ii) on Figure 1 (Model structure). The model reflects the patient journey through the Czech healthcare system, clinical trial design and was discussed with local key opinion leaders (KOLs).

Methods

Vacuum models with the same structure but different inputs were run for each kind of wound (NDFU, VLU) using an implicit willingness-to-pay (WTP) threshold of €47,000 per quality-adjusted life year (QALY). One-way sensitivity analysis accompanied by scenario analysis explained the impact of all important variables and assumptions on the base-case result. The summary of model settings is shown in Table 6. Transition probabilities between health states were provided by N.a. and are summarized in Table 3. Utility values for NDFU were calculated using a systematic literature review. For VLU, utilities were provided directly from RCTs (EXPLORER and CHALLENGE) and estimated using WTP value set after VLU treatment success, utilities were adjusted to general population. All utilities used in the model are summarized in Table 3. Health state resource use was based on four KOLs’ expert panel. The costs were then calculated using official Czech remuneration codes (ORHG classification codes, list of reimbursed medical procedures, list of reimbursed medicines and medical devices). In NDFU, treatment was administered for 20 weeks or until treatment success was achieved, whichever came first. In VLU, treatment was administered in 4 weeks. In both indications, the wound changing occurred on average every 3 days (RCT protocols required 2–4 days). In VLU, treatment stopped in 4 weeks and recalculated using exchange rate as of 04/2019 (i.e. 25.677 CZK per €). Czech National Bank). All costs are summarized in Table 4.

Results

From a health care payer perspective, SOD for NDFU and VLU were dominant (Table 5). Detailed decision tree results are shown in Table 6. In NDFU indication, SOD brought incremental QALYs of 0.534 (0.534 vs. 0.479) with incremental costs of €1,437 (€2,888 vs. €1,437). Thus, SOD proved to be more effective and cost-saving intervention.

Conclusions

The results of the models indicate that SOD (Urgostart) is a highly cost-effective (dominant) intervention for NDFU in the Czech Republic. Sensitivity analyses confirmed the robustness of the base-case results with one-way changes and scenarios deeply below WTP.