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COST-EFFECTIVENESS ANALYSIS OF SUCROSE OCTASULFATE (URGOSTART) DRESSING IN THE TREATMENT OF DIABETIC FOOT AND VENOUS LEG ULCERS

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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, UrgoTul) in patients with neuroischaemic diabetic foot ulcer (NDFU) and venous leg ulcers (VLU) in the Czech Republic.

Methods

Based on randomised double-blind controlled trials (RCT: EXPLORER, CHALLENGE)[1,2], we developed a one-year decision-tree model using TreeAge Pro 2018. Depending on response to treatment, the model structure consists of two mutually exclusive 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). If treatment fails, 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 no AE (**Figure 1**). The model structure reflects the patient journey through the Czech healthcare system, clinical trial design and was discussed with local key opinion leaders (KOLs).

Two parallel 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 explored the impact of all important variables and assumptions on the base-case result. The summary of models' settings is shown in **Table 1**.

Transition probabilities between health states were provided by RCTs[1,2] and are summarized in **Table 2**.

Utility values for NDFU were provided by systematic literature review.[3] For VLU, utilities were provided directly from RCT CHALLENGE and estimated using UK utility 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 reimbursement tariffs (DRG hospitalization codes, list of reimbursed medical procedures, list of reimbursed medicines and medical devices). In NDFU, treatment was administered for 20 weeks or up until treatment success (wound closure), in VLU treatment lasted 8 weeks. In both indications, the wound changing occurred on average every 3 days (RCTs protocols required 2–4 days). The costs were expressed in € 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**.

Figure 1 . Decision tree model structure

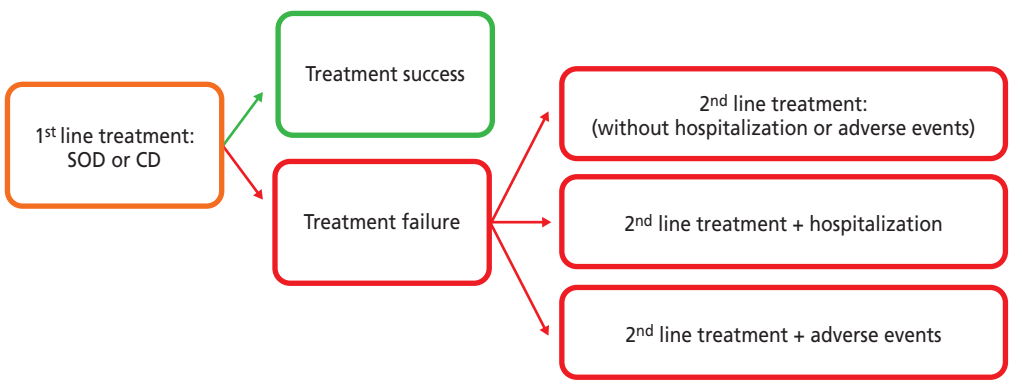

Table 1. Summary of cost-effectiveness analysis

Analysis type and model	Cost-utility; decision tree
Software	TreeAge Pro 2018
Cost perspective	Payers' (health insurance funds)
Time horizon	1 year
Assessed intervention	Sucrose octasulfate dressing (UrgoStart)
Comparator	Control dressing (UrgoTul)
Population	Patients with:
	a) Neuroischaemic diabetic foot ulcer (NDFU)
	b) Venous leg ulcers (VLU)
Treatment success definition	a) Wound closure (NDFU)
	b) Wound area reduction >40% surface area (VLU)
Efficacy data source	Clinical trials EXPLORER and CHALLENGE[1,2]
Outcomes	Quality-adjusted life-years (QALY)

Table 2. Transition probabilities used in the model (EXPLORER, CHALLENGE)[1,2]

	Sucrose octasulfate dressing (Urgostart)	Control dressing (UrgoTul)
Neuroischaemic diabetic foot ulcer		
Probability of wound closure (treatment success)	48 % (60/126)	30 % (34/114)
Median Kaplan-Meier-estimated time to closure	120 days	180 days
Probability of treatment failure	52 % (66/126)	70 % (80/114)
Of those: 2nd line treatment only	68 %	59 %
2nd line treatment + hospitalization	15 %	14 %
2nd line treatment + adverse event	17 %	27 %
Venous leg ulcers		
Probability of wound area reduction >40% (treatment success)	66 % (61/93)	45 % (42/93)
Treatment success assessment evaluation	8 weeks	8 weeks
Probability of treatment failure	34 % (32/93)	55 % (51/93)
Of those: 2nd line treatment only	69 %	70 %
2nd line treatment + hospitalization	0 %	1 %
2nd line treatment + adverse event	31 %	29 %

Table 3. Utility values

Health state	Utility value
Neuroischaemic diabetic foot ulcer (NDFU)	
Baseline utility (NDFU, before treatment)[3]	0.615*
NDFU after treatment success	0.785*
Hospitalization disutility	–0.200 (assumption)
Adverse event disutility	–0.050 (assumption)
Venous leg ulcers	
Baseline utility (before treatment)[4]	0.454
VLU after treatment success[5]	0.723
Utility while on treatment[4]	
a) on sucrose octasulfate dressing (Urgostart)	0.598
b) on control dressing (UrgoTul)	0.530
Hospitalization disutility	–0.200 (assumption)
Adverse event disutility	–0.050 (assumption)

**Beaudet et al. utility of diabetic patients without complications is equal to 0.785. If having NDFU, there was a disutility of -0.170.*

Table 4. Healthcare costs

Health state/item	Costs
Costs of dressing	
Control dressing (CD; UrgoTul) (10x10cm²)	€26.9
Sucrose octasulfate dressing (SOD; Urgostart)	€107.6*
2nd line dressing costs	€26.9†
Neuroischaemic diabetic foot ulcer	
Initial treatment (except dressing)	€311.1
Treatment success	€57.0
Treatment failure (2nd line therapy)	€1,082.8
Treatment failure (hospitalization)	€712.0
Treatment failure (adverse event)	€473.5
2nd line treatment + hospitalization	€1,794.7
2nd line treatment + adverse event	€1,556.2
Venous leg ulcers	
Initial treatment (except dressing)	€168.2
Treatment success	€24.1
Treatment failure (2nd line therapy)	€1,017.3
Treatment failure (hospitalization)	€124.2
Treatment failure (adverse event)	€285.1
2nd line treatment + hospitalization	€1,141.5
2nd line treatment + adverse event	€1,302.4

**Assumption 4-times higher than CD; At the time of our analysis, there was no official price of UrgoStart dressing.*
†Assumed to be the same as the costs of CD given jumbo cluster group of dressings in the Czech Republic.

Table 5. Cost-effectiveness analysis results (total)

	SOD (UrgoStart)	CD (UrgoTul)	Incremental
Neuroischaemic diabetic foot ulcer			
Total costs	€1,518	€1,523	€–5
Total QALYs	0.668	0.638	0.029
ICER (€/QALY)	**Dominant**		
Venous leg ulcers			
Total costs	€783	€925	–€142
Total QALYs	0.534	0.479	0.055
ICER (€/QALY)	**Dominant**		

SOD = sucrose octasulfate dressing (Urgostart); CD = control dressing (UrgoTul).

Table 6. Detailed cost-effectiveness analysis results by tree branches

	SOD (UrgoStart)	CD (UrgoTul)
Neuroischaemic diabetic foot ulcer (costs; QALYs; probability)		
Treatment success	€799; 0.73; 0.476	€530; 0.70; 0.298
2nd line treatment only	€1,986; 0.61; 0.357	€1,717; 0.61; 0.412
2nd line treatment + hospitalization	€2,699; 0.60; 0.079	€2,430; 0.60; 0.099
2nd line treatment + adverse event	€2,460; 0.61; 0.087	€2,191; 0.61; 0.191
Total weighted average	**€1,518; 0.668; n.a.**	**€1,523; 0.638; n.a.**
Venous leg ulcers (costs; QALYs; probability)		
Treatment success	€393; 0.58; 0.656	€243; 0.52; 0.394
2nd line treatment only	€1,437; 0.45; 0.237	€1,286; 0.45; 0.426
2nd line treatment + hospitalization	€1,561; 0.44; 0.000	€1,411; 0.44; 0.006
2nd line treatment + adverse event	€1,722; 0.45; 0.107	€1,572; 0.45; 0.174
Total weighted average	**€783; 0.479; n.a.**	**€925; 0.534; n.a.**

N.a.: not applicable.

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 0.029** (0.668 vs. 0.638 QALY) with **incremental costs of €–5** (€1,518 vs. €1,523). Thus, SOD proved to be more effective and cost-saving intervention.
- In VLU indication, SOD brought **incremental QALYs of 0.055** (0.534 vs. 0.479 QALY) with **incremental costs of €–142** (€783 vs. €925). Thus, SOD proved to be a more effective and cost-saving intervention.
- Detailed results (**Table 6**) clearly showed the higher probability of success in SOD arm as well as lower probability of 2nd line/hospitalization, thus offsetting slightly higher initial costs of SOD and bringing overall cost-savings.
- Sensitivity analysis confirmed the robustness of the base-case results with all one-way changes and scenarios deeply below WTP (results not shown).
  - Scenario analysis showed that even with the SOD price ten-time higher than CD, the incremental cost-effectiveness ratio (€21,777 for NDFU and €2,888 for VLU) stayed well below WTP threshold of €47,000/QALY.

Conclusions

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

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