

Prevention and Treatment of Diabetic Foot Ulcers: A Synopsis of the Evidence

Diabetic foot ulcers are the most common complication of diabetes, affecting 4% to 10% of patients. Diabetic foot ulcers tend to be chronic and can develop into serious complications, including wound infection, osteomyelitis (infection in bone), and cellulitis (infection of the skin), and may lead to amputation (surgical removal of infected foot or toe). Early detection and treatment can improve the healing of diabetic foot ulcers and reduce the risk for amputation.

CADTH has reviewed the evidence and current practice guidelines regarding prevention and treatment approaches for diabetic foot ulcers.

In this report, you will find a summary of the evidence for:

- Screening and risk stratification for diabetic foot ulcers
- Taking pressure off the diabetic foot (off-loading devices)
- Wound care for diabetic foot ulcers (debridement procedures)
- Compression therapy
- Negative pressure wound therapy.

Screening and Risk Stratification for Diabetic Foot Ulcers

Screening and Risk Stratification for Diabetic Foot Ulcers: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines (2014)

cadth.ca/screening-and-risk-stratification-diabetic-foot-ulcers-review-clinical-effectiveness-cost

Technology: Primary care screening programs for diabetic foot ulcers in patients with diabetes may include assessment of risk factors for developing a diabetic foot ulcer (risk stratification), patient education, and referral to more specialized care. Depending on a patient's level of risk, suitable preventive measures can be undertaken.

Issue: By focusing preventive interventions based on risk, a significant reduction in diabetic foot ulcer occurrence and related complications might be expected. However, screening and risk stratification of the large population of patients with diabetes requires considerable resources.

CADTH Assessed Relevant Evidence Found in: One systematic review and eight clinical practice guidelines.

Key Messages:

- Diabetic foot ulcer screening programs and risk-appropriate preventive interventions reduce the occurrence of diabetic foot ulcers and related complications in diabetic patients (identified to be at high risk). Whether screening programs for diabetic foot ulcers in primary care for the general population with diabetes are feasible or effective is uncertain.
- Assessment of diabetic patients for diabetic foot ulcer risk factors is recommended by all evidence-based guidelines. Most of the reviewed guidelines (including the Canadian ones) recommend specialized care and/or secondary care referral for diabetic patients identified as being at high risk for foot ulceration.
- The cost-effectiveness of diabetic foot ulcer screening and risk stratification is uncertain.

Taking Pressure off the Diabetic Foot (Off-Loading Devices)

Removable Off-Loading Devices for Diabetic Foot Ulcers: A Review of Clinical and Cost-Effectiveness (2014)

cadth.ca/removable-loading-devices-diabetic-foot-ulcers-review-clinical-and-cost-effectiveness

Technology: Off-loading devices reduce the pressure to specific areas on the bottom of the foot and can be used to treat or prevent diabetic foot ulcers. Devices available include removable options such as customized footwear, cast walkers, and orthotic boots and orthoses (sometimes called orthotics), or devices that cannot be removed by patients, such as total contact casting (removal requiring a skilled technician) and instant total contact casting (making a removable walking cast permanent by wrapping it in casting material).

Issue: Off-loading devices can affect patient mobility, potentially limiting their use and effectiveness. Total contact casting may also limit wound assessment.

CADTH Assessed Relevant Evidence Found in: Three systematic reviews, six randomized controlled trials, and one economic analysis.

Key Messages:

- Non-removable off-loading devices, such as total contact casting and instant total contact casting, are more effective at healing diabetic foot ulcers than removable off-loading devices (possibly due to improved compliance and/or decreased physical activity).

- Of the removable off-loading devices, cast walkers may be the most effective in the treatment of diabetic foot ulcers (based on less conclusive evidence).
- It is uncertain which devices are most effective for diabetic foot ulcer prevention.
- Occurrence of adverse events does not differ significantly between off-loading treatments.
- Limited cost-effectiveness evidence suggests soft-heel casting may be more cost-effective than orthotic boots for diabetic foot ulcer prevention and treatment.

Wound Care for Diabetic Foot Ulcers (Debridement Procedures)

Debridement Procedures for Managing Diabetic Foot Ulcers: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines (2014)

cadth.ca/debridement-procedures-managing-diabetic-foot-ulcers-review-clinical-effectiveness-cost

Technology: Debridement is the removal of dead, damaged, infected, or callused tissue of a diabetic foot ulcer. The goal of debridement is to reduce the chance of wound infection and stimulate the healing process of the foot ulcer. Debridement methods can be surgical (sharp debridement), autolytic (hydrogels, hydrocolloids, and transparent films), chemical (antiseptics, polysaccharide beads, pastes), biological (maggots), mechanical (irrigation), or enzymatic.

CADTH Assessed Relevant Evidence Found in: One systematic review, one meta-analysis, two randomized controlled trials, one randomized controlled trial with a cost-effectiveness analysis, and seven clinical practice guidelines.

Key Messages:

- Hydrogels and enzyme preparations (clostridial collagenase ointment) appear to be more effective than standard wound care for the treatment of diabetic foot ulcers (based on evidence of limited quality).
- There is no strong evidence to support the effectiveness of sharp debridement in the treatment of diabetic foot ulcers.
- The clinical effectiveness of maggot debridement therapy is uncertain.
- No evidence was found on the effectiveness of callus debridement for the prevention and treatment of diabetic foot ulcers.
- Enzymatic debridement with clostridial collagenase ointment appears to be more cost-effective than saline moist gauze for the debridement of diabetic foot ulcers (based on evidence of limited quality).
- Canadian guidelines recommend debridement as part of a broader approach to optimal diabetic foot ulcer treatment.

Compression Therapy

Compression Therapy in Diabetic Foot Ulcer Management: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines (2014)

cadth.ca/compression-therapy-diabetic-foot-ulcer-management-review

Technology: Compression therapy devices may be used to apply controlled external pressure with the goal of improving blood circulation, reducing edema (swelling caused by excessive fluid in the foot tissue), and healing the wound. Compression bandages, specialized stockings, and inflatable garments are types of compression therapy devices. Intermittent pneumatic compression is also available, which simulates the effect of walking on the venous system by inflating and deflating sleeves to defined pressures. Compressed air massage is another method of compression therapy; it uses a stream of compressed air directly on the wound.

CADTH Assessed Relevant Evidence Found in: Two systematic reviews and one set of guidelines.

Key Messages:

- Intermittent compression therapy and compressed air massage may improve the time to heal and reduce edema of diabetic foot ulcers (based on evidence of limited quality). Patient compliance may be an obstacle to realizing the benefit of the treatment.
- The cost-effectiveness of compression therapy to treat patients with diabetic foot ulcers is unknown.
- There are no evidence-based recommendations on using compression therapy for diabetic foot ulcers; however, the identified clinical guideline suggests that foot compression in addition to standard wound care is more effective for healing infected diabetic foot ulcers than standard care alone.

Negative Pressure Wound Therapy

Negative Pressure Wound Therapy for Managing Diabetic Foot Ulcers: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines (2014)

cadth.ca/negative-pressure-wound-therapy-managing-diabetic-foot-ulcers-review

Technology: Negative pressure wound therapy applies a sub-atmospheric pressure within an airtight bandage over a diabetic foot ulcer. It may promote healing in several ways, including inhibiting bacterial growth and eliminating tissue edema.

Issue: Although negative pressure wound therapy has been widely adopted for the treatment of diabetic foot ulcers, it is costly and may result in serious adverse events. In 2011, the FDA published a warning regarding contraindications and risk factors to consider before negative pressure wound therapy use.

CADTH Assessed Relevant Evidence Found in: Three systematic reviews, one meta-analysis, one health technology assessment, one randomized controlled trial, three economic studies, and seven evidence-based guidelines.

Key Messages:

- There is evidence that negative pressure wound therapy may be a more effective treatment for diabetic foot ulcers than standard wound care, advanced moist wound care, or gauze.
- Negative pressure wound therapy does not seem to increase adverse events (based on limited evidence).

- Guidelines recommend considering the use of negative pressure wound therapy for diabetic foot ulcer treatment (varying levels of evidence). Canadian guidelines acknowledge evidence to support negative pressure wound therapy as a post-operative intervention after extensive debridement, but they cite a lack of evidence to support recommending its routine use.
- Negative pressure wound therapy seems to be more cost-effective than other treatments for diabetic foot ulcers, but this may vary by health care setting.

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October 2016