



Evidence of diabetic foot treatments

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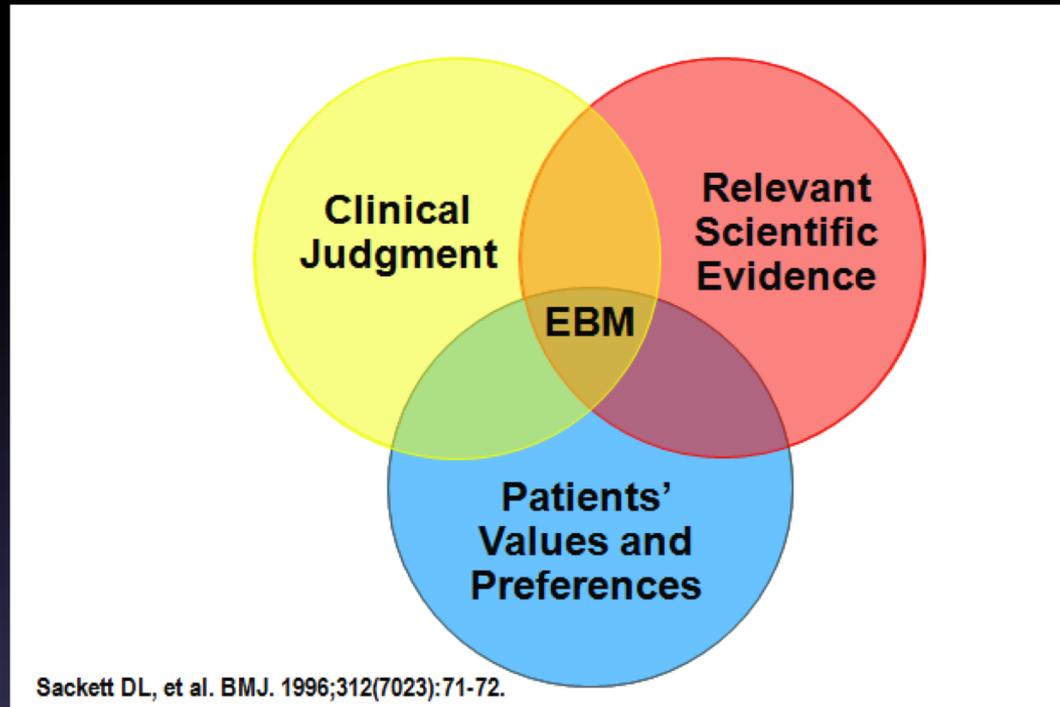
Helsinki Hospital Ltd.

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6-7th November, Helsinki



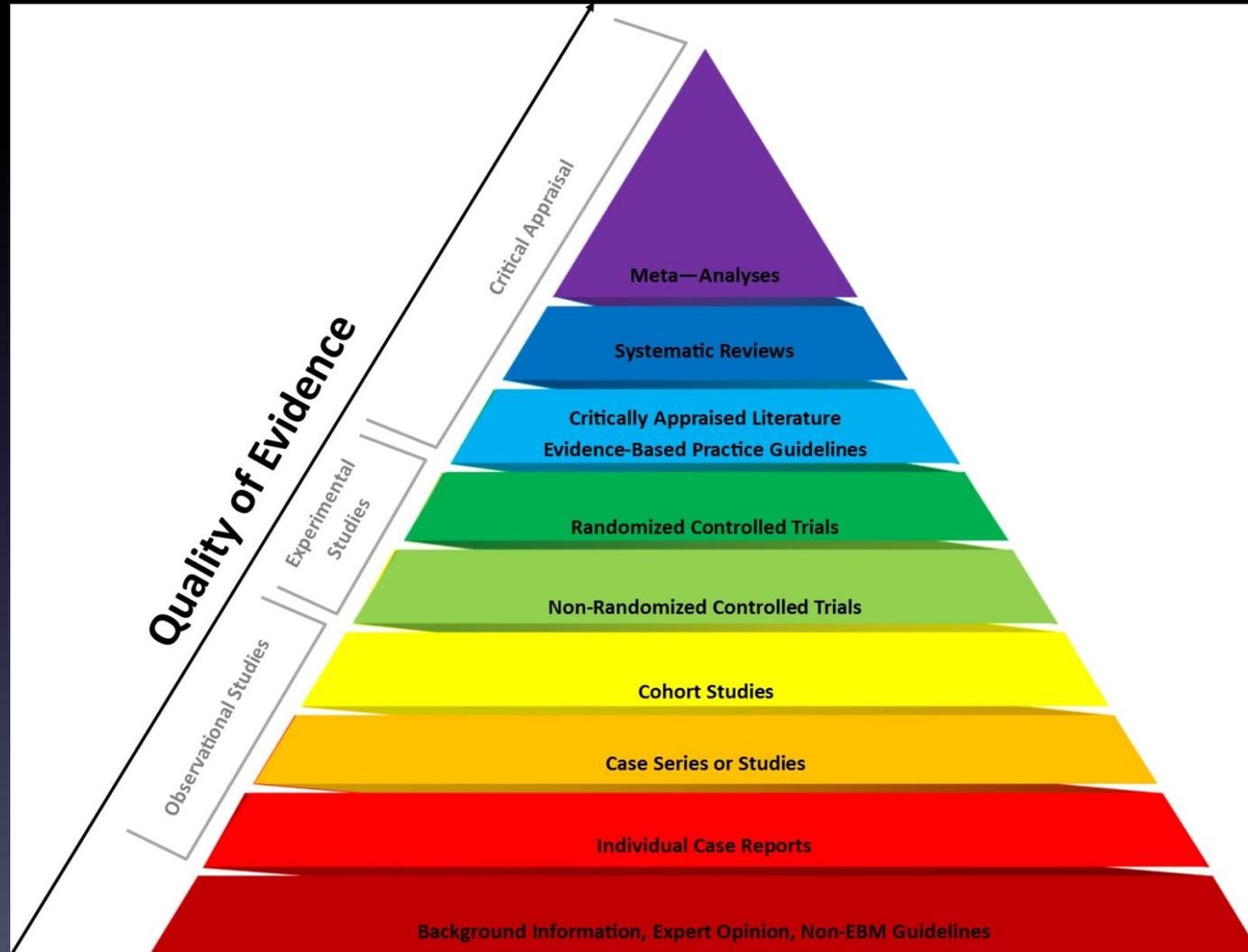
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Evidence Based Medicine (EBM)



Integration of **clinical expertise**, **patient values**, and the **best research evidence** into the decision making process for patient care.

Levels of evidence



Cochrane systematic reviews

“Cochrane Reviews base their findings on the results of studies that meet certain **quality criteria**, since the most reliable studies will provide the **best evidence for making decisions** about health care.”

The screenshot shows the Cochrane Library website interface. At the top, the Cochrane Library logo is on the left, with the tagline 'Trusted evidence. Informed decisions. Better health.' to its right. A search bar is in the top right corner. Below the header is a purple navigation bar with 'Cochrane Reviews', 'Trials', and 'More Resources' dropdown menus. The main content area is titled 'Browse by Topic' and includes the subtitle 'Browse the Cochrane Database of Systematic Reviews by Topic...'. The topics are organized into three columns, each starting with a letter from A to O. The 'Wounds' topic under the 'W' column is circled in red.

A	G	P
Allergy & intolerance	Gastroenterology & hepatology	Pain & anaesthesia
B	Genetic disorders	Pregnancy & childbirth
Blood disorders	Gynaecology	Public health
C	H	R
Cancer	Health & safety at work	Rheumatology
Child health	Heart & circulation	S
Complementary & alternative medicine	I	Skin disorders
Consumer & communication strategies	Infectious disease	T
D	K	Tobacco, drugs & alcohol
Dentistry & oral health	Kidney disease	U
Developmental, psychosocial & learning problems	L	Urology
Diagnosis	Lungs & airways	W
E	M	Wounds
Ear, nose & throat	Mental health	
Effective practice & health systems	Methodology	
Endocrine & metabolic	N	
Eyes & vision	Neonatal care	
	Neurology	
	O	
	Orthopaedics & trauma	

Cochrane Wounds systematic reviews

By subtopic:

- ▷ CHRONIC WOUNDS (1)
- ▷ PRESSURE ULCERS (42)
- ▷ VENOUS ULCERS (40)
- ▷ DIABETIC FOOT ULCERS (33)
- ▷ RHEUMATOID ULCERS (1)
- ▷ BURNS (23)
- ▷ BITES (3)
- ▷ LACERATIONS / TRAUMATIC WOUNDS (12)
- ▷ GUNSHOT WOUNDS (1)
- ▷ MALIGNANT WOUNDS (2)
- ▷ SURGICAL WOUNDS (64)
- ▷ SKIN ABCESSSES (7)
- ▷ OTHER REVIEWS (23)
- ▷ ACUTE WOUNDS (3)

255 reviews

**In wound care
most treatment methods
and technologies are not
evidence based!**



**Cochrane
Library**

Cochrane Database of Systematic Reviews

- ▽ DIABETIC FOOT ULCERS (33)
 - ▽ Prevention (4)
 - ▽ Complex interventions (2)
 - ▽ Education (1)
 - ▽ Local skin care (1)
 - ▽ Pressure reduction and relief (0)
 - ▽ Treatment (29)
 - ▽ Local wound care (16)
 - ▽ Organisation of care (2)
 - ▽ Nutrition (2)
 - ▽ Physical therapies (3)
 - ▽ Pressure reduction and relief (1)
 - ▽ Skin replacements (2)
 - ▽ Systemic drug therapy (3)

Best evidence in wound care for clinical decision making?

Cochrane

- Systematic review of adequate RCTs, meta-analyses

Clinical guidelines

- All levels of evidence, not only level-I
- Expert opinion in situations, where evidence is weak

International Working Group on the Diabetic Foot (IWGDF)



The 2015 IWGDF Guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus

Prepared by the IWGDF Editorial Board

1. Prevention of foot ulcers
2. Footwear and offloading
3. Peripheral artery disease
4. Foot infections
5. Interventions to enhance wound healing

GRADE in IWGDF guidance documents

GRADE: The Grading of Recommendations Assessment, Development and Evaluation

Quality of Evidence

- High
- Moderate
- Low

Strength of Recommendation

- Strong
- Weak

Debridement of diabetic foot ulcers. 2010



Cochrane
Library

2010

Cochrane Database of Systematic Reviews

Search methods

For this fourth update we searched The Cochrane Wounds Group Specialised Register (searched 21 April 2011); The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2011, Issue 2); Ovid MEDLINE (2009 to April Week 2 2011); Ovid MEDLINE (In-Process & Other Non-Indexed Citations, April 20, 2011); Ovid EMBASE (2009 to 2011 Week 15); and EBSCO CINAHL (2009 to 15 April 2011).

Selection criteria

Randomised controlled trials (RCTs) evaluating any method of debriding diabetic foot ulcers and measuring complete healing or rate of healing. There was no restriction on articles/trials based on language or publication status.

Main results

Six RCTs of debridement were identified: four assessed hydrogels, with an additional study evaluating larval therapy against hydrogel and one evaluated surgical debridement. Pooling the three RCTs which compared hydrogel with gauze or standard care suggested that hydrogels are significantly more effective in healing diabetic foot ulcers (Relative Risk 1.84, 95% Confidence Interval (CI) 1.3 to 2.61). Surgical debridement showed no significant benefit over standard treatment. One small trial, available in abstract form only, suggested that larvae resulted in a greater reduction in wound area compared with hydrogel, but this evidence has not been confirmed by publication of full trial results. Other debridement methods such as enzyme preparations or polysaccharide beads have not been evaluated in diabetic foot ulcers.

...Debridement of diabetic foot ulcers

Authors' conclusions

There is evidence to suggest that hydrogel increases the healing rate of diabetic foot ulcers compared with gauze dressings or standard care.

More research is needed to evaluate the effects of a range of widely used debridement methods and of debridement per se.



Debridement, IWGDF Guidelines

Recommendations and Rationale

What is the best way of debriding a diabetic foot ulcer?

Recommendation 1:

Clean ulcers regularly with clean water or saline, debride them when possible in order to remove debris from the wound surface and dress them with a sterile, inert dressing in order to control excessive exudate and maintain a warm, moist environment in order to promote healing. (GRADE strength of recommendation: Strong; Quality of Evidence: Low)

Recommendation 2:

In general remove slough, necrotic tissue and surrounding callus with sharp debridement in preference to other methods, taking relative contra-indications such as severe ischemia into account. (Strong; Low)



IWGDF Guidance on the diagnosis and management of foot infections in persons with diabetes

Prepared by the IWGDF Working Group on Foot Infections

Antimicrobial therapy

19. While virtually all clinically infected diabetic foot wounds require antimicrobial therapy do not treat clinically uninfected wounds with antimicrobial therapy (Strong; Low)
20. Select specific antibiotic agents for treatment based on the likely or proven causative pathogens, their antibiotic susceptibilities, the clinical severity of the infection, evidence of efficacy of the agent for DFI and costs (Strong; Moderate)
21. A course of antibiotic therapy of 1-2 weeks is usually adequate for most mild and moderate infections (Strong; High)
22. Administer parenteral therapy initially for most severe infections and some moderate infections, with a switch to oral therapy when the infection is responding (Strong; Low)
23. Do not select a specific type of dressing for a diabetic foot infection with the aim of preventing an infection or improving its outcome (Strong; High)
24. For diabetic foot osteomyelitis we recommend 6 weeks of antibiotic therapy for patients who do not undergo resection of infected bone and no more than a week of antibiotic treatment if all infected bone is resected. (Strong; Moderate)
25. We suggest not using any adjunctive treatments for diabetic foot infection. (Weak; Low)
26. When treating a diabetic foot infection, assess for use of traditional remedies, previous antibiotic use, and consider local bacterial pathogens and their susceptibility profile. (Strong; Low)



IWGDF Guidance on the diagnosis and management of foot infections in persons with diabetes

Prepared by the IWGDF Working Group on Foot Infections

Surgical treatment

- 16.** Consult a surgical specialist in selected cases of moderate, and all cases of severe, DFI (Weak; Low)
- 17.** Perform urgent surgical interventions in cases of deep abscesses, compartment syndrome and virtually all necrotizing soft tissue infections (Strong; Low)
- 18.** Consider surgical intervention in cases of osteomyelitis accompanied by: spreading soft tissue infection; destroyed soft tissue envelope; progressive bone destruction on X-ray, or bone protruding through the ulcer (Strong; Low)

Topical silver for treating infected wounds



Cochrane
Library

2007

Cochrane Database of Systematic Reviews

- Randomised controlled trials (RCTs) assessing the effectiveness of topical silver in the treatment of contaminated and infected acute or chronic wounds.
- Three RCTs were identified, a total of 847 participants.
- **Authors' conclusions:** Only three trials with a short follow-up duration were found. **There is insufficient evidence to recommend the use of silver-containing dressings or topical agents for treatment of infected or contaminated chronic wounds.**

Topical antimicrobial agents for treating diabetic foot ulcers



Cochrane
Library

2017

Cochrane Database of Systematic Reviews

- “Use of an antimicrobial dressing instead of a non-antimicrobial dressing **may increase the number of diabetic foot ulcers healed** over a medium-term follow-up period (low-certainty evidence)”.

Hyperbaric oxygen therapy for treating chronic wounds



Cochrane
Library

2015

Cochrane Database of Systematic Reviews

Authors' conclusions:

In people with foot ulcers due to diabetes, HBOT significantly improved the ulcers healed in the short term but not the long term and the trials had various flaws in design and/or reporting that means we are not confident in the results. More trials are needed to properly evaluate HBOT in people with chronic wounds; these trials must be adequately powered and designed to minimise all kinds of bias.

HBOT, IWGDF

IWGDF Guidance on use of interventions to enhance the healing of chronic ulcers of the foot in diabetes

Prepared by the IWGDF Working Group on Wound Healing

Consider the use of systemic hyperbaric oxygen therapy, even though further blinded and randomised trials are required to confirm its cost-effectiveness, as well as to identify the population most likely to benefit from its use (**GRADE strength of recommendation: Strong; Quality of Evidence: Low**)

Negative pressure wound therapy



Cochrane
Library

2018

Cochrane Database of Systematic Reviews

- There is **low-certainty evidence** to suggest that NPWT may be effective in healing postoperative foot wounds and ulcers of the foot in people with diabetes compared with wound dressings
- We cannot be certain whether NPWT is effective for treating foot wounds in people with diabetes.

NPWT, IWGDF

- Topical negative pressure wound therapy **may be considered** in post-operative wounds even though the effectiveness and cost-effectiveness of the approach remains to be established (GRADE strength of recommendation: Strong; Quality of Evidence: Low)

Offloading



Cochrane
Library

2013

Cochrane Database of Systematic Reviews

Authors' conclusions:

Non-removable, pressure-relieving casts are more effective in healing diabetes related plantar foot ulcers than removable casts, or dressings alone. Non-removable devices, when combined with Achilles tendon lengthening were more successful in one forefoot ulcer study than the use of a non-removable cast alone.



IWGDF Guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes

Prepared by the IWGDF Working Group on Footwear and Offloading

Recommendations

Casting and prefabricated healing devices

1. To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface. (GRADE recommendation: strong, Quality of evidence: high)

5. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis. (Strong; Low)

Not recommended in normal clinical practice (IWGDF guidelines):

- Antimicrobial dressings
- Larval therapy
- Growth factors, bioengineered skin
- Electricity, magnetism, ultrasound, lasers and shockwaves

Challenges in wound study

- **P**atients
- **I**ntervention
- **C**omparator/Control
- **O**utcome

Ethical issues in human wound research



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

BMJ 2003, bmj.com

Diabetic foot, deep infection



EWMA 2010



Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management

JOURNAL OF WOUND CARE VOL 19, NO 6, JUNE 2010

EWMA-IWGDF

Report of study standards

Reporting standards of studies and papers on the prevention and management of foot ulcers in diabetes: required details and markers of good quality

William J Jeffcoate, Sicco A Bus, Frances L Game, Robert J Hinchliffe, Patricia E Price, Nicolaas C Schaper, on behalf of the International Working Group on the Diabetic Foot and the European Wound Management Association

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Summary

- In diabetic foot care most treatment methods are not based on high quality evidence.
- Cochrane reviews are not enough for clinical decision making
- Clinical decision making integrates **clinical expertise, patient values,** and the **best available research evidence.**
- There is a huge need for high quality comparative trials in wound care