

## Kliiniline küsimus nr 9

Kas kõikidel kroonilise venoosse haavandiga patsientidel kasutada parema ravitulemuse saavutamiseks järgmisi sekkumisi vs mitte:

- lokaalse ravi kombineerimine baroteraapiaga
- füsioterapeutilised meetodid (nt magnetravi, valgusravi)

Kriitilised tulemusnäitajad: ravi tulemuslikkus, haavandi paranemine, ravisoostumus, patsiendi elukvaliteet, patsiendi rahulolu, elulemus, ravikulu.

### Süstemaatilised ülevaated

#### **Baroteraapia (*hyperbaric oxygen treatment, HBOT*)**

2015 ilmunud Cochrane süstemaatiline ülevaade, mis hindas baroteraapiat kõikide krooniliste haavandite raviks ning venoosse haavandi raviks, viitab samale RCT-le, mis 2004 aastal ning leiab, et venosete haavandite raviks HBOT soovitamiseks tõenduspõhisus puudub (Krabnke et al 2015). Venosete haavandite raviks kasutatava baroteraapia tõenduspõhisuse puudumisele viitab ka BJS 2012 ilmunud metaanalüüs (Brölmann et al 2012).

#### **Füsioterapeutilised meetodid**

##### **+ ultraheli**

2010 publitseeritud Cochrane süstemaatiline ülevaade leiab kaasates 8 uuringut, et ultraheliravi ei oma statistiliselt olulist efekti kroonilise venoosse haavandi ravil. 5 uuringut 8st näitas, et UH paranesid haavandid 7-8. nädalaks kiiremini kui ilma UH, kuid 12.nädalal erinevus paranemise osas puudus. Usaldusväärsete andmete saamiseks on vaja suuremaid RCT, senised uuringud on väga heterogeensed, ebakvaliteetsed ning väikesed. (Cullum et al 2010)

##### **+ elektromagneetiline stimulatsioon**

2015 publitseeritud Cochrane süstemaatiline ülevaade leiab toetudes kolmele RCT (kokku 94 inimest), et puuduvad kvaliteetsed andmed tõestamaks elektromagnetravi efektiivsust kroonilise venoosse haavandi raviks. (Aziz & Cullum 2015).

### Viited

| <b>Kokkuvõtte (abstract või kokkuvõtlikum info)</b>   | <b>Viide kirjandusallikale</b>   |
|---|--|
| The trials evaluating US for venous leg ulcers are small, poor-quality and heterogeneous. There is no reliable evidence that US hastens healing of venous ulcers. There is a small amount of weak evidence of increased healing with US, but this requires confirmation in larger, high-quality RCTs. There is no evidence of a benefit associated with low frequency US. | Cullum N, Al-Kurdi D, Bell-Syer SEM. Therapeutic ultrasound for venous leg ulcers. Cochrane Database of Systematic Reviews 2010, Issue 6. Art. No.: CD001180. DOI: 10.1002/14651858.CD001180.pub3. |
| <b>Objectives</b><br>To assess the effects of EMT on the healing of venous leg ulcers.<br><b>Search methods</b>   | Aziz Z, CullumN.<br>Electromagnetic therapy for treating venous leg ulcers.<br>Cochrane Database of Systematic   |

[Type text]

|   |  |
|---|--|
| <p>For this fourth update, we searched The Cochrane Wounds Group Specialised Register (searched 30 January 2015); The Cochrane Central Register of Controlled Trials (CENTRAL) (<i>The Cochrane Library</i> 2014, Issue 12).</p> <p><b>Selection criteria</b><br/>Randomised controlled trials comparing EMT with sham-EMT or other treatments.</p> <p><b>Data collection and analysis</b><br/>Standard Cochrane Collaboration methods were employed. At least two review authors independently scrutinised search results and obtained full reports of potentially eligible studies for further assessment. We extracted and summarised details of eligible studies using a data extraction sheet, and made attempts to obtain missing data by contacting study authors. A second review author checked data extraction, and we resolved disagreements after discussion between review authors.</p> <p><b>Main results</b><br/>Three randomised controlled trials (RCTs) of low or unclear risk of bias, involving 94 people, were included in the original review; subsequent updates have identified no new trials. All the trials compared the use of EMT with sham-EMT. Meta-analysis of these trials was not possible due to heterogeneity. In the two trials that reported healing rates; one small trial (44 participants) reported that significantly more ulcers healed in the EMT group than the sham-EMT group however this result was not robust to different assumptions about the outcomes of participants who were lost to follow up. The second trial that reported numbers of ulcers healed found no significant difference in healing. The third trial was also small (31 participants) and reported significantly greater reductions in ulcer size in the EMT group however this result may have been influenced by differences in the prognostic profiles of the treatment groups.</p> <p><b>Authors' conclusions</b><br/>It is not clear whether electromagnetic therapy influences the rate of healing of venous leg ulcers. Further research would be needed to answer this question.</p> | <p>Reviews 2015, Issue 7. Art. No.: CD002933.<br/>DOI:<br/>10.1002/14651858.CD002933.pub6.</p> |
| <p><b>Objectives</b><br/>To assess the benefits and harms of adjunctive HBOT</p>  | <p>Kranke P, Bennett MH, Martyn-St James M, Schnabel A, Debus SE,</p>                          |

[Type text]

for treating chronic ulcers of the lower limb.

### **Search methods**

For this second update we searched the Cochrane Wounds Group Specialised Register (searched 18 February 2015); the Cochrane Central Register of Controlled Trials (CENTRAL) (*TheCochrane Library* 2015, Issue 1); OvidMEDLINE (1946 to 17 February 2015); Ovid MEDLINE (In-Process & Other Non-Indexed Citations, 17 February 2015); Ovid EMBASE (1974 to 17 February 2015); and EBSCO CINAHL (1982 to 17 February 2015).

### **Selection criteria**

Randomised controlled trials (RCTs) comparing the effect on chronic wound healing of therapeutic regimens which include HBOT with those that exclude HBOT (with or without sham therapy).

### **Data collection and analysis**

Three review authors independently evaluated the risk of bias of the relevant trials using the Cochrane methodology and extracted the data from the included trials. We resolved any disagreement by discussion.

### **Main results**

We included twelve trials (577 participants). Ten trials (531 participants) enrolled people with a diabetic foot ulcer: pooled data of five trials with 205 participants showed an increase in the rate of ulcer healing (risk ratio (RR) 2.35, 95% confidence interval (CI) 1.19 to 4.62;  $P = 0.01$ ) with HBOT at six weeks but this benefit was not evident at longer-term follow-up at one year. There was no statistically significant difference in major amputation rate (pooled data of five trials with 312 participants, RR 0.36, 95% CI 0.11 to 1.18). One trial (16 participants) considered venous ulcers and reported data at six weeks (wound size reduction) and 18 weeks (wound size reduction and number of ulcers healed) and suggested a significant benefit of HBOT in terms of reduction in ulcer area only at six weeks (mean difference (MD) 33.00%, 95% CI 18.97 to 47.03,  $P < 0.00001$ ). We identified one trial (30 participants) which enrolled patients with non-healing diabetic ulcers as well as venous ulcers (“mixed ulcers types”) and patients were treated for 30 days. For this “mixed ulcers” there was a significant benefit of

Weibel S. Hyperbaric oxygen therapy for chronic wounds. *Cochrane Database of Systematic Reviews* 2015, Issue 6. Art. No.: CD004123. DOI: 10.1002/14651858.CD004123.pub4.

[Type text]

|   |  |
|---|--|
| <p>HBOT in terms of reduction in ulcer area at the end of treatment (30 days) (MD 61.88%, 95% CI 41.91 to 81.85, <math>P &lt; 0.00001</math>). We did not identify any trials that considered arterial and pressure ulcers.</p> <p><b>Authors' conclusions</b><br/>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.</p>  |  |
| <p>The aim of this meta-review was to compile best available evidence from systematic reviews in order to formulate conclusions to support evidence-based decisions in clinical practice.</p> <p><b>METHODS:</b><br/>All Cochrane systematic reviews (CSRs), published by the Cochrane Wounds and Peripheral Vascular Diseases Groups, and that investigated therapeutic and preventive interventions, were searched in the Cochrane Database up to June 2011. Two investigators independently categorized each intervention into five levels of evidence of effect, based on size and homogeneity, and the effect size of the outcomes.</p> <p><b>RESULTS:</b><br/>After screening 149 CSRs, 44 relevant reviews were included. These contained 109 evidence-based conclusions: 30 on venous ulcers, 30 on acute wounds, 15 on pressure ulcers, 14 on diabetic ulcers, 12 on arterial ulcers and eight on miscellaneous chronic wounds. One small trial, in which 18 venous ulcers were included with treatment failure for over 1 year, did not provide sufficient evidence on the effectiveness of hyperbaric oxygen therapy (HBOT) versus sham therapy</p> <p><b>CONCLUSION:</b><br/>For some wound care interventions, robust evidence exists upon which clinical decisions should be based.</p> | <p>Brölmann FE, Ubbink DT, Nelson EA, Munte K, van der Horst CM, Vermeulen H. (2012) Evidence-based decisions for local and systemic wound care. <i>Br J Surg.</i> 2012 Sep;99(9):1172-83.</p> |

## Ravijuhendid

### **Baroterapia (*hyperbaric oxygen treatment, HBOT*)**

SIGN ravijuhend ei soovita kasutada rutiinselt venoosete haavandite raviks baroterapiat, täpsustamata kas seda teha kombinatsioonis lokaalse raviga või eraldiseisvana (1++). Puudub piisav tõendus põhjus soovitada hüperbaarilist hapnikravi (*HBOT*). SIGN (2010)

[Type text]

ravijuhend viitab Cochrane review-le (2004), millises ühes väikeses 16 patsienti hõlmavas RCT täheldati 6 nädalase raviga, kuid 18.nädalal erinevus puudus ning ravisoostumus oli samuti madal. Samale RCT-le viitab ka AWMA (2011) ravijuhend.

### **Füsioterapeutilised meetodid**

SVS (2014) ravijuhend ei soovita rutiinselt kasutada (ehk soovitab kasutamise vastu) alajäseme venoosse haavandi puhul vaakumravi primaarse meetodina (GRADE 2C), elektrilist stimulatsiooni (GRADE 2C), ultraheliteraapiat (GRADE 2B), UV-valgusteraapiat (GRADE 2C). Soovitab kasutada balneoteraapiat naha troofika ja elukvaliteedi parandamiseks (GRADE 2B).

SIGN (2010) ravijuhend möönab, et puudub piisav tõendus põhjus alajäseme venoosse haavandi raviks elektromagnetraivil (1++), laseril ja infrapunavalgusel (1++), ultrahelil (1++).

AWMA (2011) ravijuhend jääb sisuliselt samadele seisukohtadele.

(chronic[All Fields] AND "varicose ulcer"[MeSH Terms]) AND (hyperbaric[All Fields] AND ("oxygen"[MeSH Terms] OR "oxygen"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])) AND ((Meta-Analysis[ptyp] OR systematic[sb] OR Randomized Controlled Trial[ptyp]) AND ("2005/01/01"[PDAT] : "2015/03/31"[PDAT]))

Leidus 2

(chronic[All Fields] AND "varicose ulcer"[MeSH Terms]) AND ("physical therapy modalities"[MeSH Terms] OR ("physical"[All Fields] AND "therapy"[All Fields] AND "modalities"[All Fields]) OR "physical therapy modalities"[All Fields] OR "physiotherapy"[All Fields]) AND ((Meta-Analysis[ptyp] OR systematic[sb] OR Randomized Controlled Trial[ptyp]) AND ("2005/01/01"[PDAT] : "2015/03/31"[PDAT]))

Leidus 7

(chronic[All Fields] AND "varicose ulcer"[MeSH Terms]) AND (("electromagnetic phenomena"[MeSH Terms] OR ("electromagnetic"[All Fields] AND "phenomena"[All Fields]) OR "electromagnetic phenomena"[All Fields] OR "electromagnetic"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields])) AND ((Meta-Analysis[ptyp] OR systematic[sb] OR Randomized Controlled Trial[ptyp]) AND ("2005/01/01"[PDAT] : "2015/03/31"[PDAT]))

Leidus 5