# HYPERBARIC OXYGEN THERAPY AND ULCER HEALING OF DIABETIC FOOT PATIENTS IN RANDOMIZED CONTROLLED TRIALS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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*Keywords: diabetic ulcer, healing*

**ABSTRACT**

Uncontrolled diabetes results in inadequate oxygenation of the wound bed. HBOT has been recently used to improve oxygen supply to ulcers for better healing. This study aimed to determine the effect of using HBOT on the healing of diabetic foot using RCTs from 2011-2025. Cochrane and PubMed databases were used. MeSH terms are: 1. ("diabetic foot" or "DM foot" or "wound") AND ("HBOT" or "debridement") and 2. ("amputation" or "healing") AND ("HBOT" or "debridement"). Two independent researchers filtered the studies. All relevant titles were selected and full text were analyzed based on relevant outcomes. The selected studies were evaluated for risk of bias and certainty assessment.

Of 229 studies, 7 studies were included. Study characteristics were summarized. RoB2 was used, revealing an overall risk of bias of low risk. No significant heterogeneity between studies was detected. HBOT showed no significant effect on ulcer healing compared to standard care group. A subgroup was created on studies which included minor and major amputation as an outcome. This revealed no significant effect in the amputation rate between standard care group and HBOT group. On average, 10.3 patients would have to undergo the HBOT regimen for one additional patient to have ulcer healing. For ulcer healing, evidence from seven randomized trials enrolling 392 participants suggests that HBOT may increase the likelihood of diabetic foot ulcer healing compared with standard care. This corresponds to 93 more healed ulcers per 1,000 patients treated with HBOT. For major and minor amputation, evidence from seven randomized trials enrolling 291 participants suggests that HBOT decreases the likelihood of diabetic foot amputation compared with standard care. This corresponds to 20 fewer amputations per 1,000 patients treated with HBOT.

This is the first systematic review and meta-analysis on HBOT and ulcer healing which excluded relatively old studies. Included are 7 RCTs published from 2011 to 2025. The overall HBOT effect may be uncertain but with a trend towards benefit in ulcer healing and decreasing amputation rates of DM foot patients. Careful patient selection is essential to avoid further harm to DM foot patients who may benefit more with amputation than HBOT.




**Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flowchart**



**Figure 2. Risk of bias assessment: author's judgment on the risk of bias domains for each RCT**

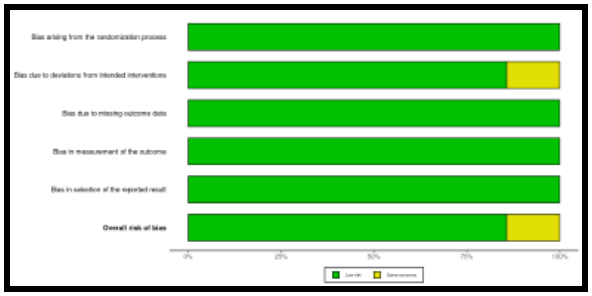


**Figure 3. Summary of risk of bias for all RCTs**

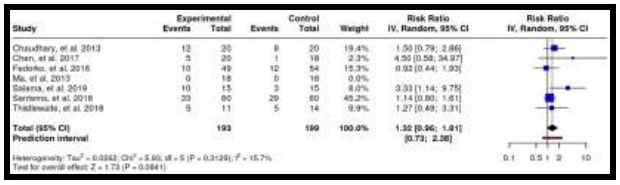


**Figure 4. Forest plot comparing SC treatment and HBOT regimen on ulcer healing**

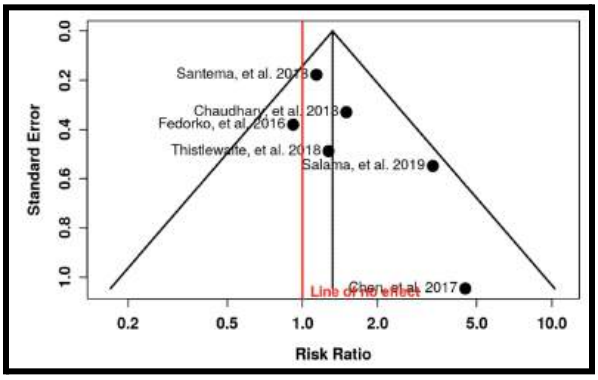



**Figure 5. Funnel plot for assessment of potential publication bias**

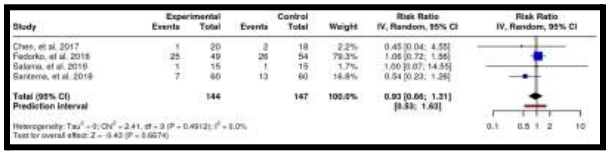


**Figure 6. Forest plot comparing SC treatment and HBOT regimen on amputation**

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Dr. Lara Montano is currently the Chief Resident of the Department of Surgery in Capitol Medical Center, Philippines. She graduated from the University of Santo Tomas Faculty of Medicine and Surgery in 2020. Some of her published, as well as locally and internationally presented papers include the following: “Metastatic Axillary Lymphadenopathy from a Triple-Negative Occult Breast Carcinoma in a Male Patient: A Case Report” and “A Path Unseen: An Incidental Cholecystoenteric Fistula in a Routine Laparoscopic Cholecystectomy.”

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# LETTER OF EXEMPTION FROM ETHICAL REVIEW FORM

26 January 2026

**DR. LARA VERONICA LOUISE G. MONTANO**
Principal Investigator
Capitol Medical Center, Inc.,
Quezon Avenue corner Scout Magbanua St. Q.C.

**Re:** **2026-002-Montano**
**Title:** "HYPERBARIC OXYGEN THERAPY AND ULCER HEALING OF DIABETIC FOOT PATIENTS IN RANDOMIZED CONTROLLED TRIALS: A SYSTEMATIC REVIEW AND META-ANALYSIS"

**Subject: Letter of Exemption from Review**

**Dear DR. MONTANO:**

This is to acknowledge submission of the following documents:

- Research Protocol
- Approved Technical Review
- Request Form for Waiver of Informed Consent

After a preliminary review of the above documents, the CMCI Research Ethics Board deemed it appropriate that the above proposal be EXEMPTED FROM ETHICAL REVIEW.

This means that the study may be implemented without undergoing an expedited or full review. Neither will the proponents be required to submit further documents to the committee as long as there is no amendment nor alteration in the protocol that will change the nature of the study, nor the level of risk involved. The Primary Investigator is required to submit the **Final Report** at the end of the study.

Thank you.

Very truly yours,

**DR. ROGER S. DE VENECIA**
Chairman, Research Ethics Board
Capitol Medical Center Inc.