

# Glycosylated Hemoglobin and Hyperbaric Oxygen-related Diabetic Foot Ulcer Healing

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# Disclosures

*none*



How many have had a patient  
**denied HBO2** due to that  
patient's poor **glucose control?**  
(high A1C)



# The Problem

- The rejection of Hyperbaric Oxygen Therapy (HBO2) by Medicaid & others for **HbA1C >7%**.
- CMS National Coverage Determination for HBO2 requires **“glucose optimization” but does not define this.**

# Objectives

- **Review literature of Diabetic Foot Ulcers and HbA1c.**
- **Extract and present the actual A1C levels in those studies.**
- **Review which trials associate Diabetic Foot Ulcers with:**
  - Healing and A1C
  - No association.

# Materials/Methods

- PubMed search for:
  - “diabetic foot ulcer”
  - “glycosylated hemoglobin.”
- We filtered the results to include clinical trials.
- We also looked for papers whose purpose was to associate HbA1c with wound healing.

# Results

We scrutinized 16 peer-reviewed clinical studies found in the PubMed database.

- 12 were randomized controlled trials (RCT),
- 1 pooled analysis of 5 RCTs.
- 3 retrospective reviews (!?!)
- More than 2,000 patients are represented.

## LOW HbA1C **ASSOCIATED** WITH HEALING

Author	Year	N	Study Type	HbA1c Intervention	HbA1c Control
Christman	2011	183	<b>Retro Cohort</b>	<b>7.97</b>	
Markuson	2009	63	<b>Retro Chart</b>	<b>8.05</b>	

## LOW HbA1C **NO ASSOCIATION** WITH HEALING

Author	Year	N	Study Type	HbA1c Intervention	HbA1c Control
Bishop AJ	2012	30	<b>Retro Chart</b>	<b>7.98</b>	
Chen CE	2010	42	<b>RCT</b>	<b>9.23</b>	9.8
Londahl	2010	75	<b>RCT</b>	<b>7.8</b>	8.1
Nouvong	2009	54	<b>RCT</b>	<b>9.7</b>	9.5
Blume	2008	342	<b>RCT</b>	<b>8.3</b>	8.2
Duzgun	2008	64	<b>RCT</b>	<b>8.7</b>	8
Armstrong	2005	162	<b>RCT</b>	<b>8.2</b>	8.2
Niezgoda	2005	73	<b>RCT</b>	<b>7.9</b>	8.8
Kessler	2003	27	<b>RCT</b>	<b>9.4</b>	8.1
Hanft	2002	28	<b>RCT</b>	<b>7.95</b>	7.96
Zimny	2002	31	<b>RCT</b>	<b>8.35</b>	
Margolis	2000	561	<b>Pooled data</b>	<b>7.5</b>	
Gentzkow	1999	226	<b>RCT</b>	<b>11.3</b>	10.9
Faglia	1996	68	<b>RCT</b>	<b>9.3</b>	8.5

(RCT- Randomized Control Trial; Retro Cohort- Retrospective Cohort Study; Retro Chart- Retrospective Chart Review)



# Where's the A1C<7%?

Measure	HbA1c Intervention	HbA1c Control	Post-Intervent Group A1C
Average A1C	8.60	8.73	7.39
Median A1C	8.25	8.20	7.39
Minimum A1C	7.50	7.96	7.10
Maximum A1C	11.30	10.90	7.68

Total No. Studies = 16

Total No. Pt's = 2029

# Conclusions

- **7 of 16 studies attempted to associate HbA1c and wound healing.**
- **Low HbA1c** associated with improved healing in:
  - 1 retrospective cohort
  - 1 retrospective chart review
- **HbA1c no improvement wound healing in:**
  - **3 randomized controlled trials**
  - **1 pooled analysis of 5 randomized controlled trials**
  - 1 retrospective chart review
    - **High HbA1c + HBO2 = better wound outcomes.**

# Conclusions

- One Randomized Controlled Trial posits that healing time is **dependent on causes** of diabetic foot ulcers.
- **No Randomized Control Trial data** shows low HbA1c is associated with diabetic foot ulcer healing.
- We conclude that the practice of denying adjunctive HBO2 with HbA1c >7% for diabetic foot ulcers **has no scientific support.**

# Limitations of Chosen Studies

- Wound area only, no consistent mention of depth or grade.
- The size of wounds varied quite a bit
- Some included DFU with and without comment of vascular disease.
- No post intervention A1C in many
- No type 1 vs 2 distinction
- An “Argument from Ignorance?”

# Questions?