UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DIYABETIK AYAKTA HIPERBARIK OKSIJEN TEDAVISI

Akın Savaş Toklu

İ.Ü. İstanbul Tıp Fakültesi, Sualtı Hekimliği ve Hiperbarik Tıp AD

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KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

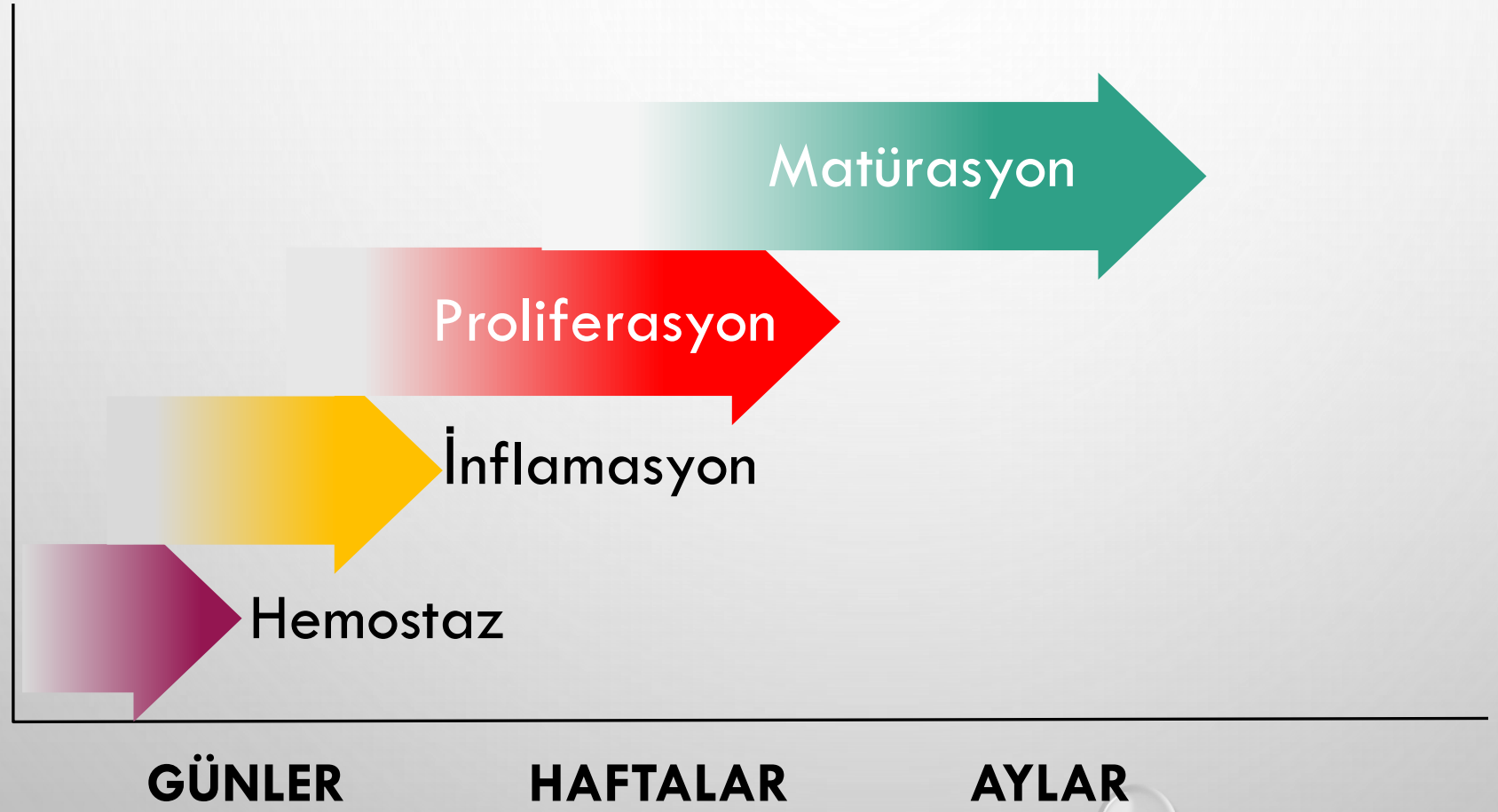
SUNUM PLANI

- Yara iyileşmesi
- Hiperbarik oksijen tedavis (HBO_2)-geçmişi
- HBO_2 'nin etki mekanizması ve uygulama şekli
- HBO_2 ve Diyabetik Ayak

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

YARA IYILEŞMESININ AŞAMALARı



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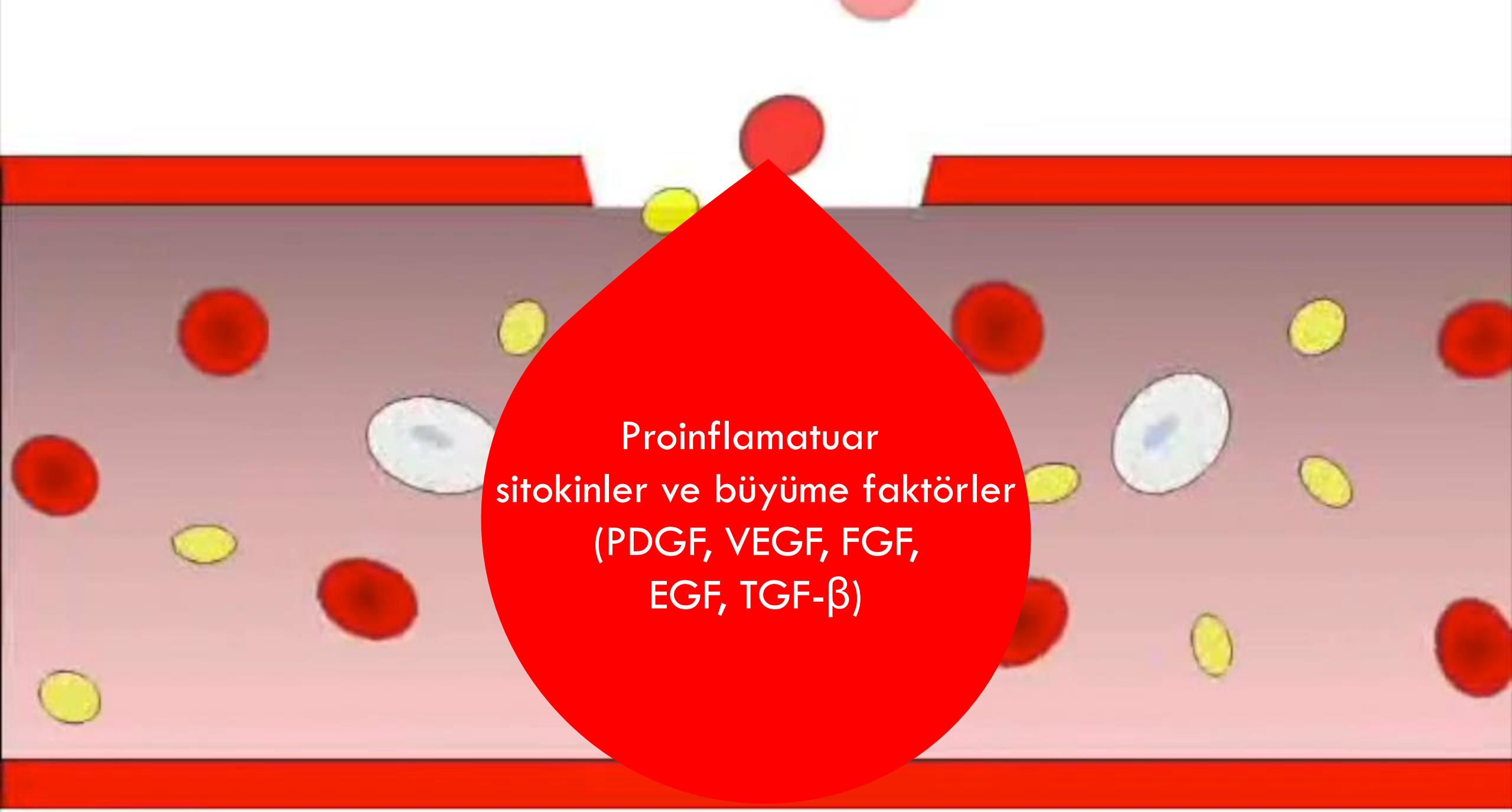
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU


Proinflamatuar
sitokinler ve büyüme faktörler
(PDGF, VEGF, FGF,
EGF, TGF-β)

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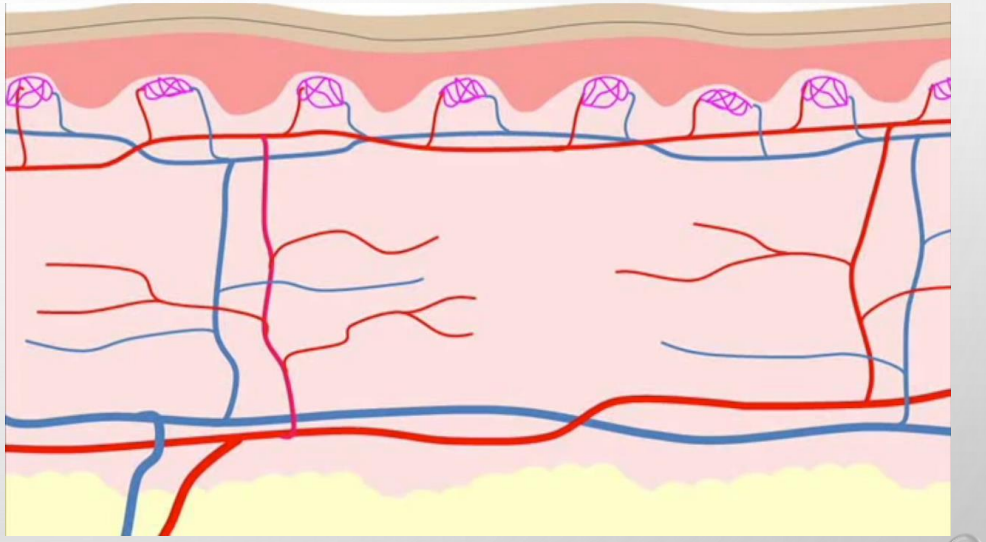
YARA İYİLEŞMESİ

- Yara
  - Derinlik
  - Genişlik
  - Tipi
  - Lokalizasyonu
- Enfeksiyon
- Konak özellikleri (sistemik hastalık, yaş)



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

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ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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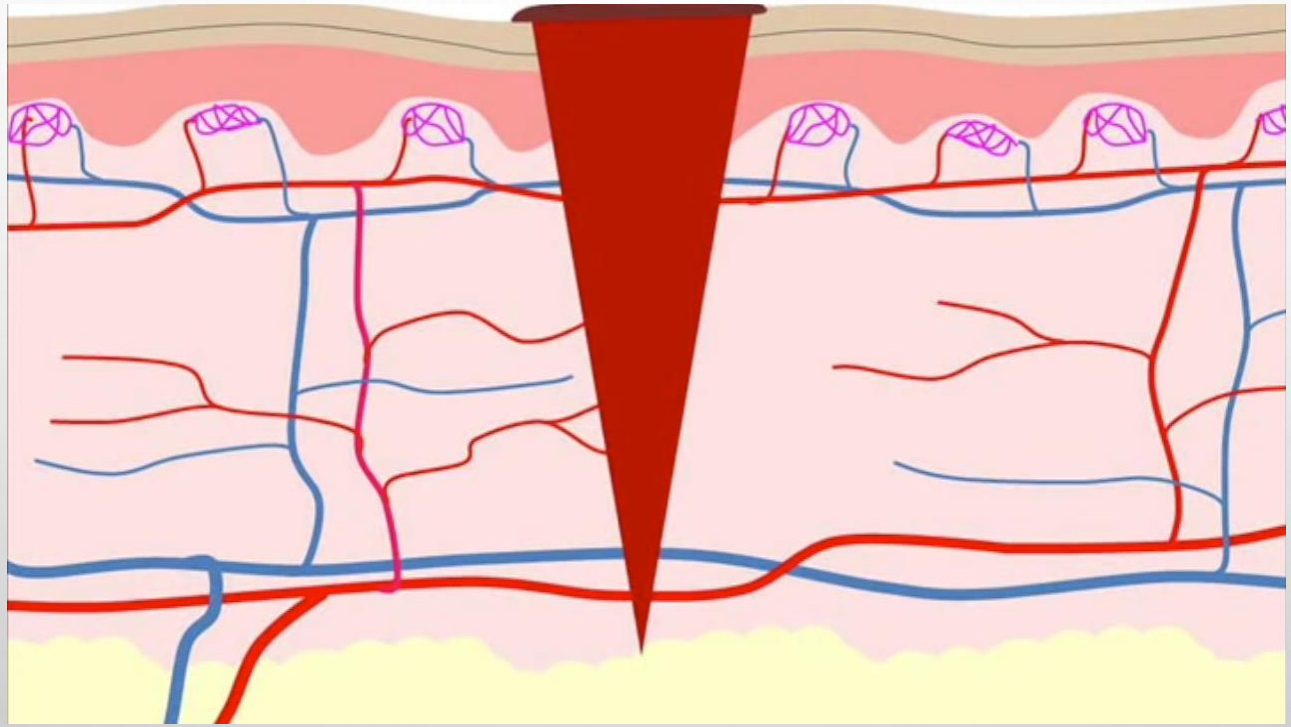

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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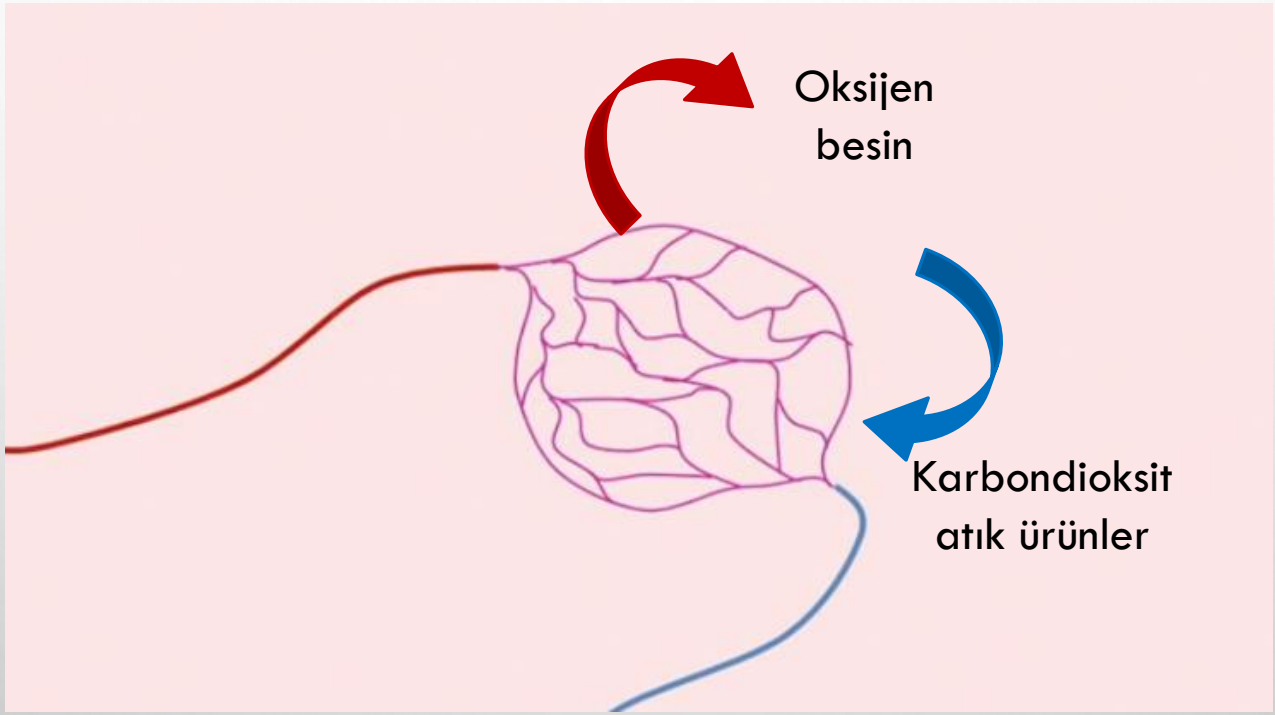

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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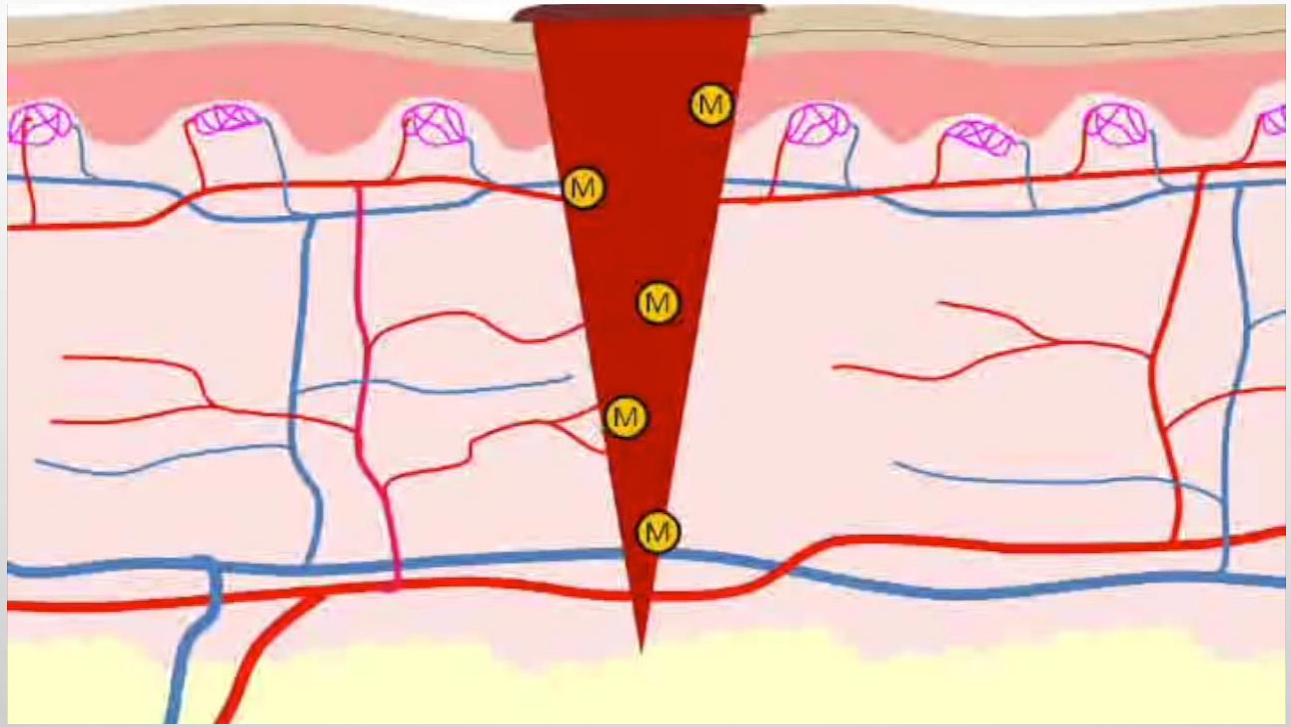

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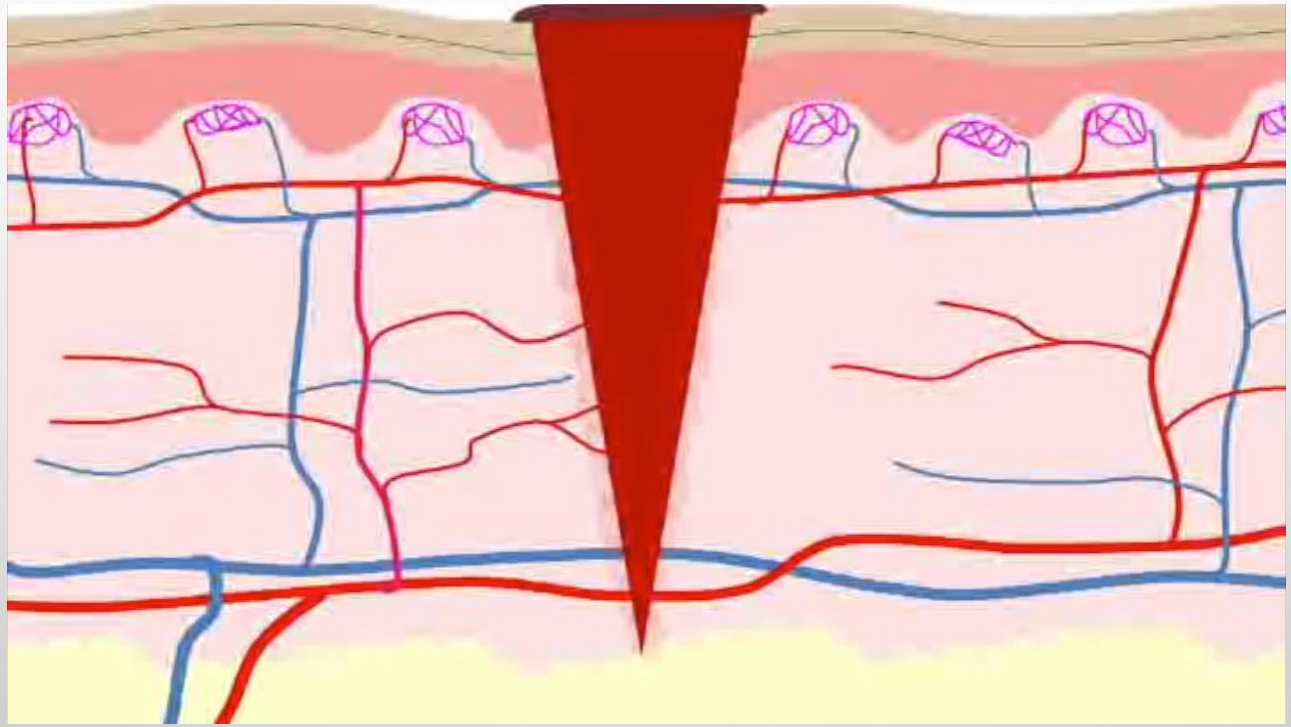
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

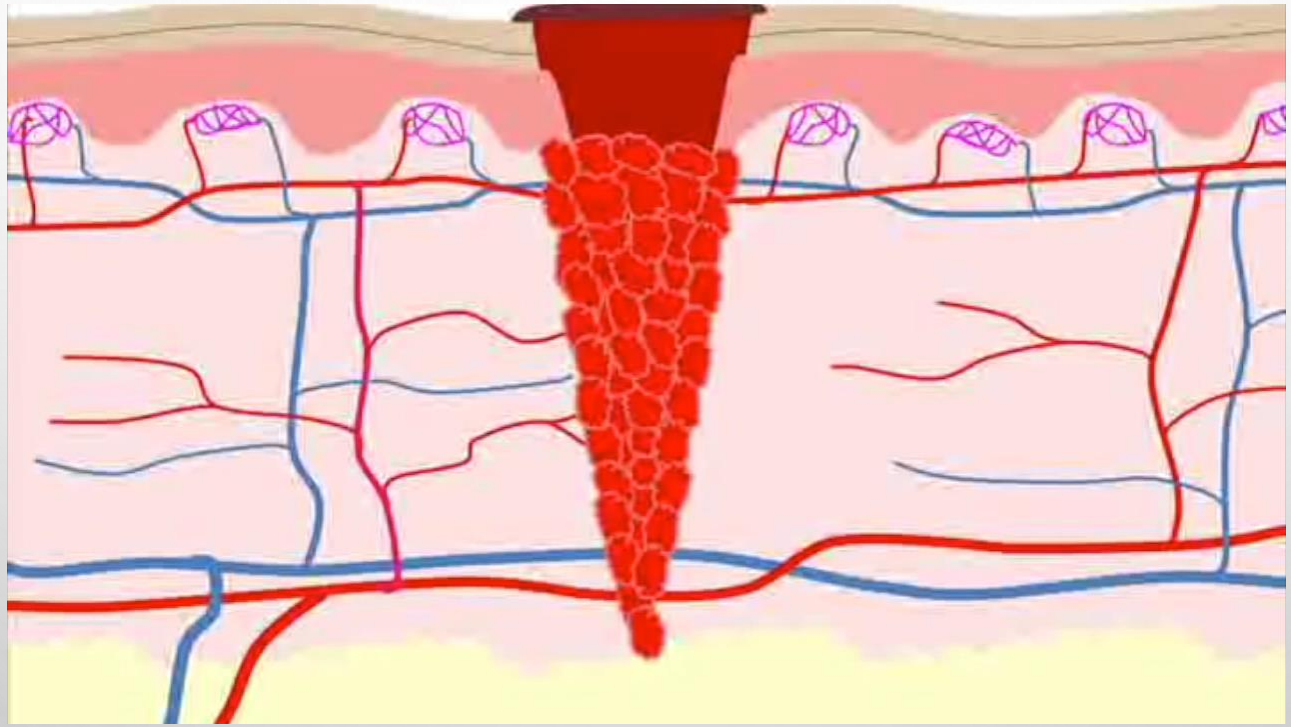
PROLIFERASYON



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

PROLIFERASYON / MATURASYON



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

YARA IYILEŞMESININ AŞAMALARı

- Fibroblastik proliferasyon
- Kollagen üretimi, salınımı ve köprüleşmesi
- Neovaskülerizasyon
- Epitelizasyon
- Osteogenez

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISI (HBO_2)

- Bir basınç odası içinde tümüyle basınç altına alınan hastaya belirli aralıklaral % 100 oksijen solutarak uygulanan bir tedavi yöntemidir.
- Tedavi basıncı genellikle 2 ATA - 3 ATA arasında ve değişik süre ile uygulanır.

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

BASINÇ ODALARI

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

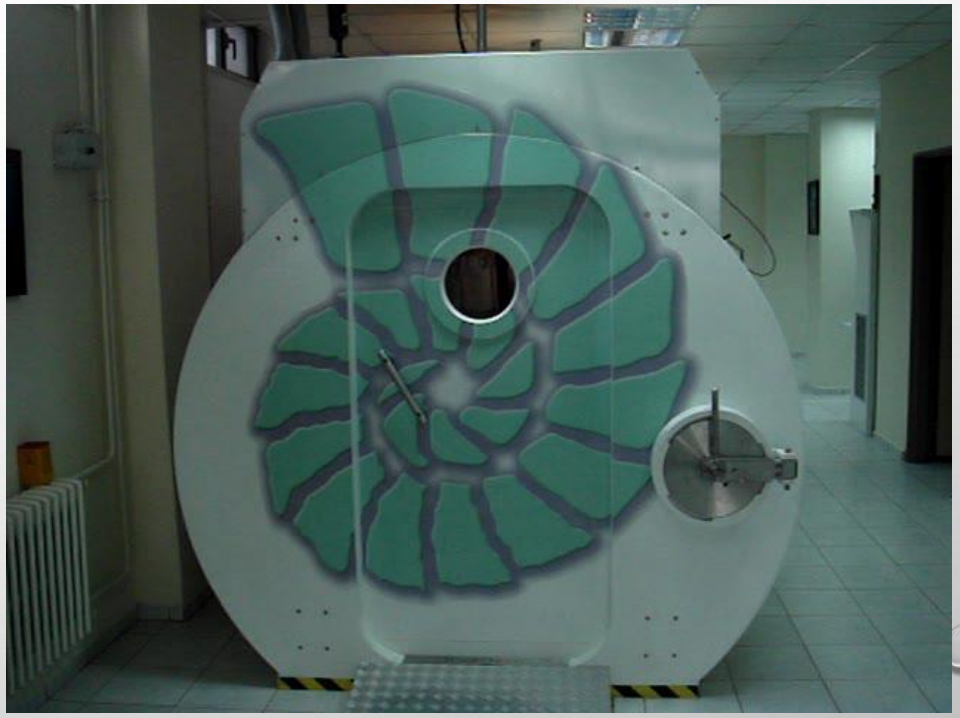
UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

BASINÇ ODALARI

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

BASINÇ ODALARI



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

% 100 O2
≥ 1 ATA

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISI

- 1 ATA'lık normal atmosfer basıncında %100 oksijen soluma ya da oksijenin topikal kullanımı HBO_2 olarak kabul edilmez.

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

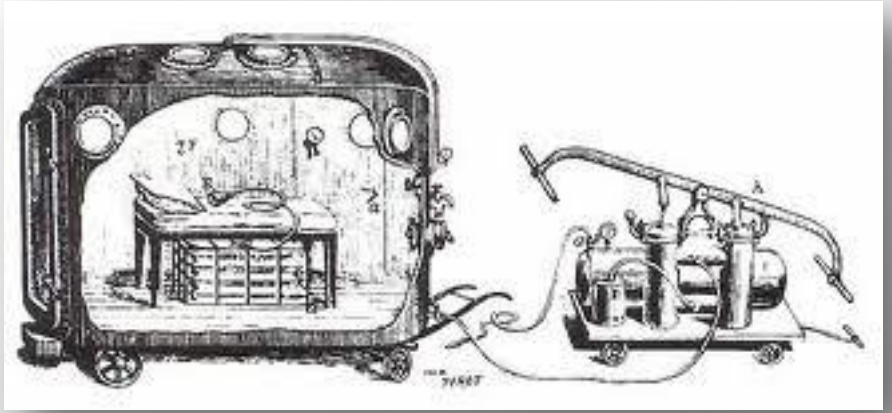
- 1650, Otto Von Guericke
- 1662, Henshaw, Domicilium "…seemed like a good idea"

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

- 1879, Fontaine,
  Seyyar basınç odası



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

- 1921, Cunningham
- 1928 “Çelik küre hastane”

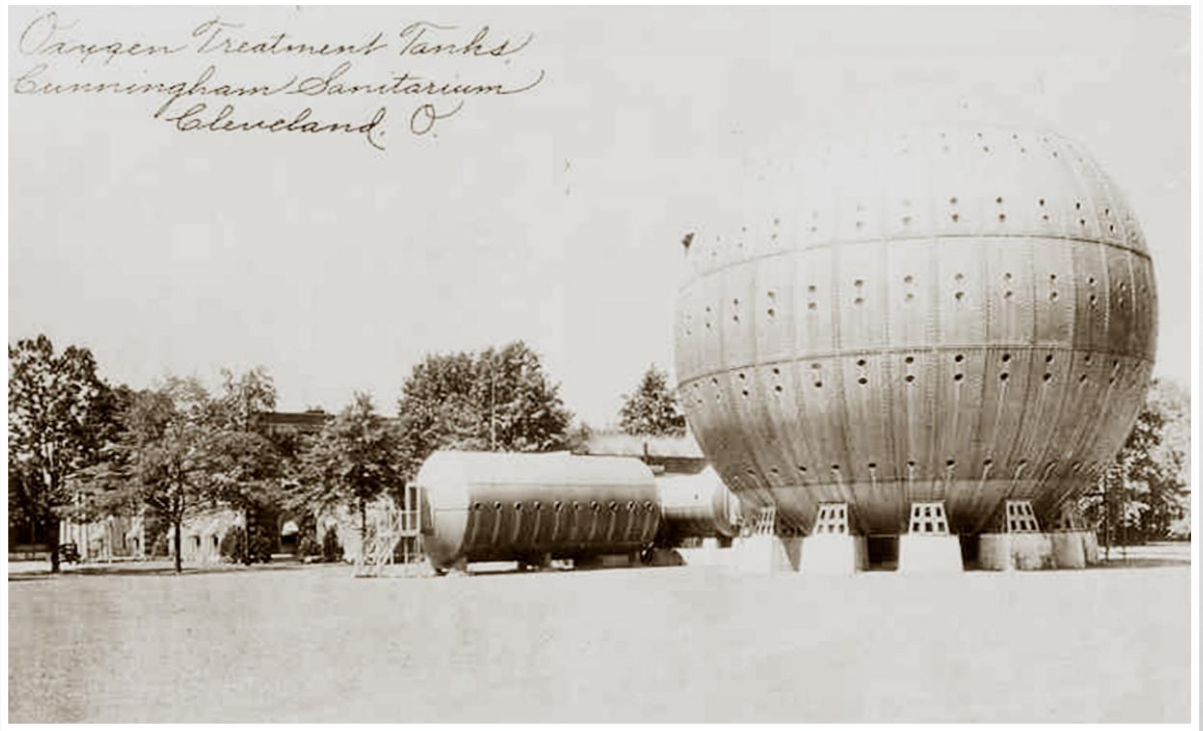
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

- 1937, Dekompresyon hastalığında HBO_2
- 1955, Churchill-Davidson, HBO_2
  - Kanser hastalarında radyoterapinin etkisini arttırmak amacıyla

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

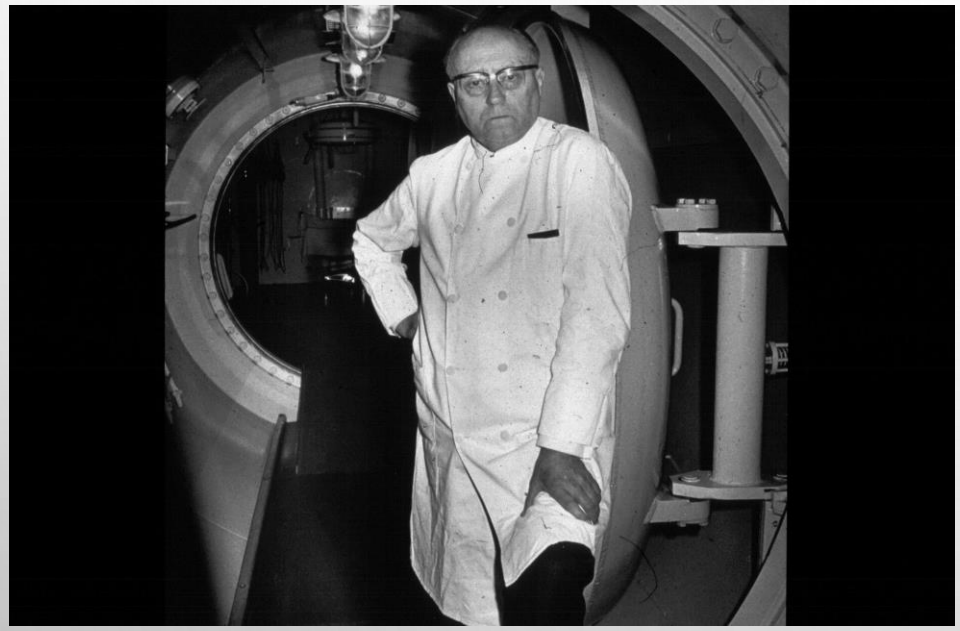
HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

- 1960, Boerama, HBO_2+Kalp cerrahisi
  - Büyük damar transpozisyonu, fallot tetralojisi, pulmoner stenoz

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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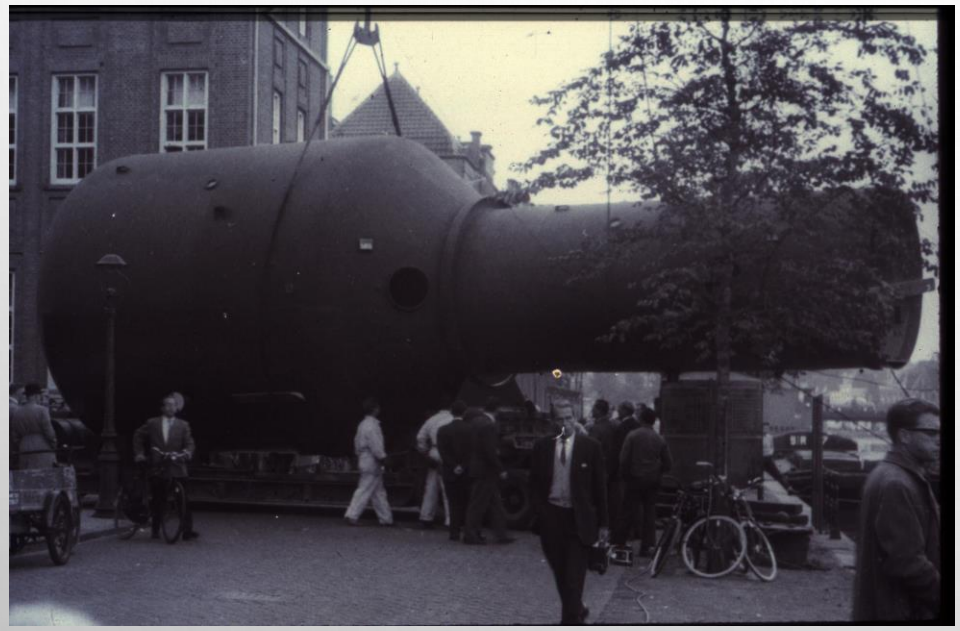
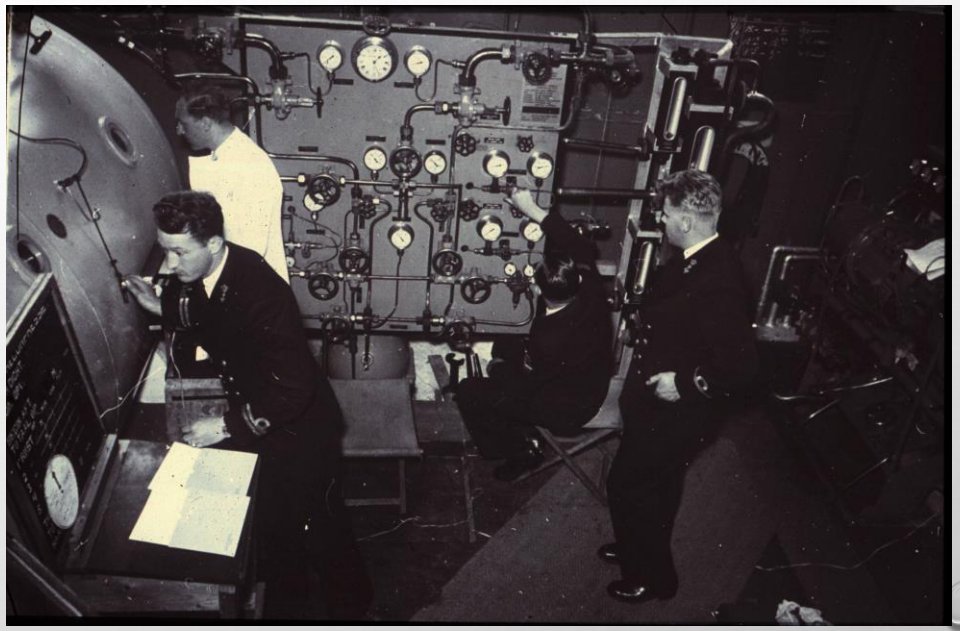
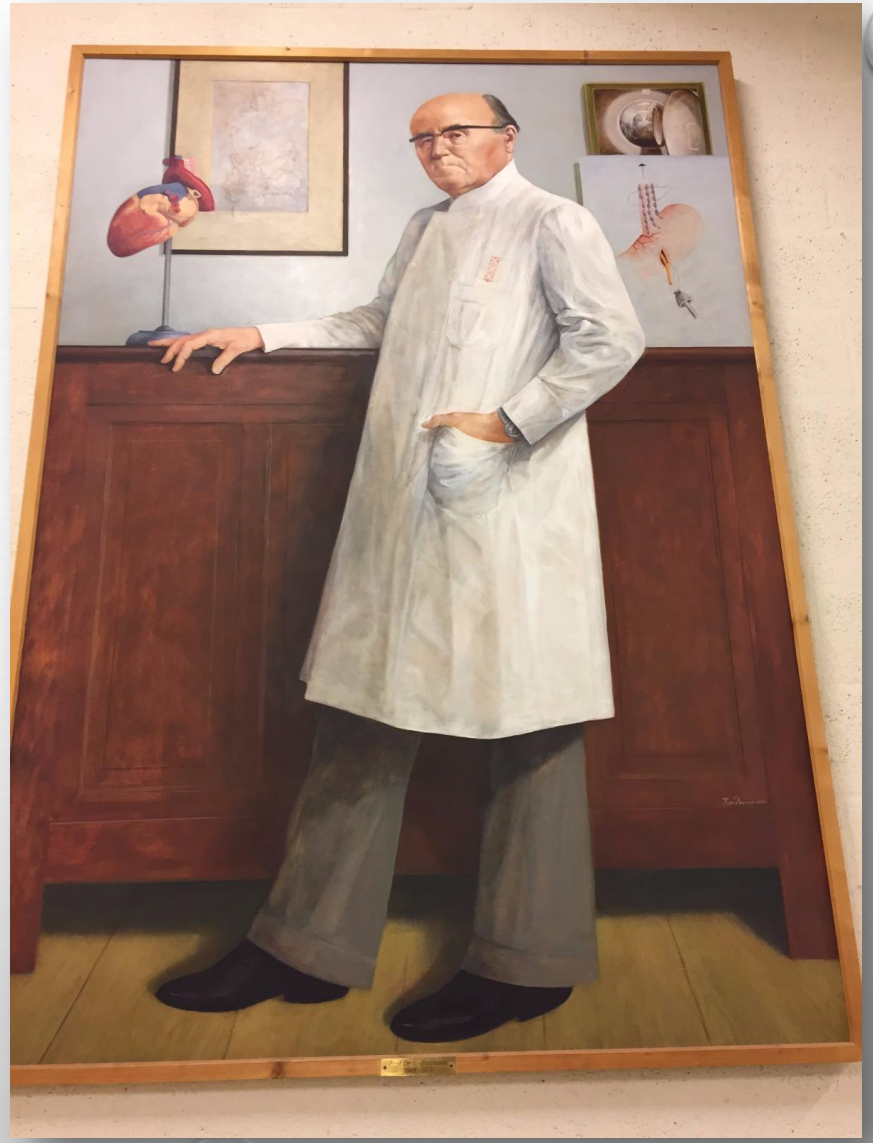




DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



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KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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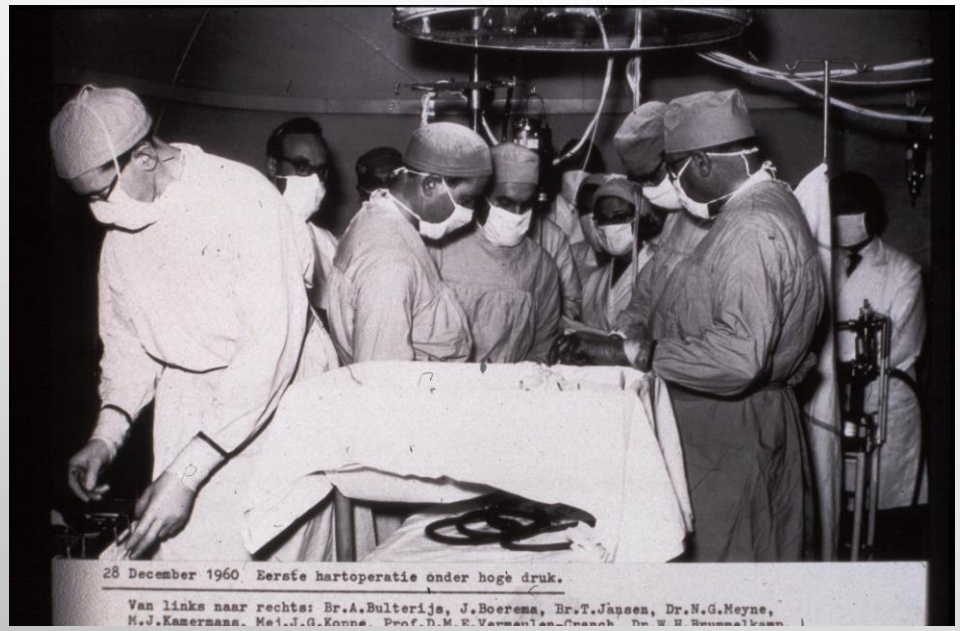
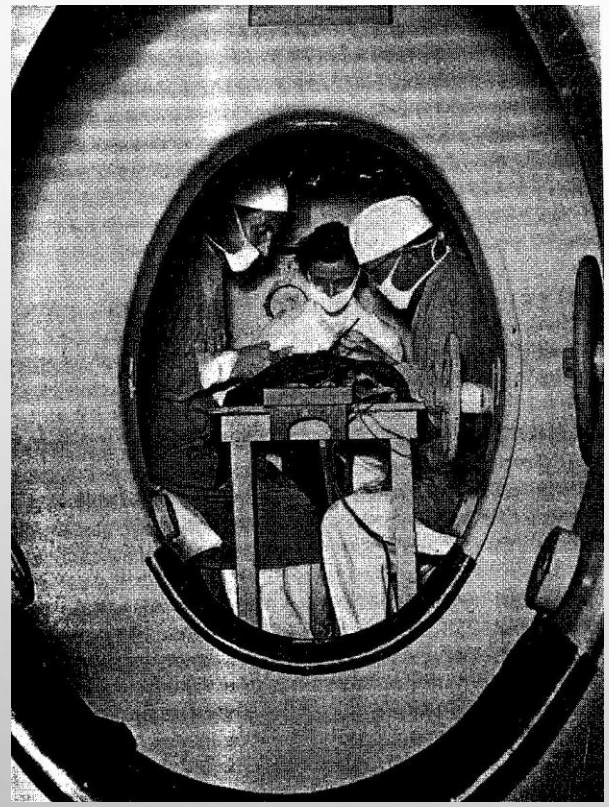


DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI



ORIGINAL PAPERS

Life without blood

(A study of the influence of high atmospheric pressure and hypothermia on dilution of the blood)

by

I. BOEREMA (*), N. G. MEYNE, W. K. BRUMMELKAMP
S. BOUMA, M. H. MENSCH, F. KAMERMANS, M. STERN HANF
and W. VAN AALDEREN
(from the Surgical Department of the University of Amsterdam)

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

Summary

The authors lowered the level of haemoglobin in young pigs to 0.4 per cent, exchanging the blood by plasma or by rheomacrodex. The animals, breathing oxygen at a pressure of 3 atmospheres in a high pressure tank, lived for 45 minutes with a level of haemoglobin not compatible with life when at normal atmospheric pressure.

During all this time the EEG showed no pathological changes, the circulation and blood pressure remained spontaneously normal.

Recovery was uneventful after re-infusion of normal blood.

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HIPERBARIK OKSIJEN TEDAVISININ GEÇMIŞI

- 1962, Simith and Sharp, karbonmonoksit zehirlenmelerinde
- Termal yanıklarda, riskli deri grefti ve flepler, iyileşmeyen problemli yaralarda HBO_2

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

Radiation necrosis, decompression sickness, gas embolism, soft tissue infection, soft tissue necrosis, bacteroides infection, compromised skin grafts, fungal infections, mucor mycosis, anemia from blood loss, carbon tetrachloride poisoning, fractures, leprosy, meningitis, radiation myelitis, cystitis and enteritis, retinal artery insufficiency, chronic brain ischemia, senility, multi-infarct dementia, infant cardiac surgery, chronic ulcers, peripheral vascular disease, diabetic neuropathy, acute endocarditis, hearing loss, cortical blindness, cellulitis, infected pacemaker, Buerger's syndrome, post-cardiac arrest, scleroderma, mycobacterium TB, abscesses, asthma, pneumomediastinum, hanging, thrombophlebitis, Lyell's syndrome, CO poisoning, gas gangrene, osteomyelitis, Crohn's DZ, Cyanide poisoning, crush injury with ischemia, Alzheimers…Thermal burns, head and spinal injury, bone grafts, frost bite, CVA's, Hydrogen sulfide poisoning, cancer therapy, Pseudomembraneous colitis, sickle cell crisis, MS, pyoderma gangrenosum, acute MI, carotid aneurysm, aortic aneurysm, anaerobic infections, post-cardiac surgery, pulmonary insufficiency, arteriosclerosis, causalgia, collagen vascular diseases, post-op confusion, traumatic amputation, pulmonary emboli, drowning, moyamoya, surgical empyema, pharyngeal fistula, brain cyst, stenotic valvular heart DZ, tetanus, intestinal obstruction, necrotizing fasciitis, post-epileptic headache, radiation pneumonia, balloon aspiration, migraine, allergic reactions, quadriplegia, dust induced bronchitis, gastroduodenal ulcer, facial neuritis, late pregnancy toxemia, liver

Basınç odaları sayısında artış

ENDİKASYON DIŞI KULLANIM

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

UNDERSEA & HYPERBARIC MEDICAL SOCIETY

European Committee for Hyperbaric Medicine

INTERNATIONAL CONGRESS HYPERBARIC MEDICINE

THE SOUTH PACIFIC UNDERWATER MEDICINE SOCIETY

SPUMS

ahdma

EUBS

European Underwater and Baromedical Society

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS

ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

DAİÇG

KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

ÜLKEMIZDE HIPERBARIK TıP

- 1976 Gölcük ve Çubuklu'da çeşitli çalışmalar
- 1976 İTF-Kurtarma Sualtı Komutanlığı protokolü
- 1981 Deniz Tababeti-Deniz ve Sualtı Hekimliği
- 1984 İTF Bilim Dalı
- 1985 GATA Anabilim Dalı
- 1989 İTF Anabilim Dalı

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

ÜLKEMIZDE HIPERBARIK TıP

- **24** Kamu kurumu
  - **5** Üniversite
  - **5** S.B. Üniversitesi
  - **14** EAH
- **1** Özel üniversite
- **21** Özel merkez
  - **10** İstanbul
  - **11** Diğer iller

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

ÜLKEMIZDE HIPERBARIK TıP

- Dekompresyon hastalığı (vurgun)
- Hava ve gaz embolisi
- Karbonmonoksit, siyanid zehirlenmesi, akut duman inhalasyonu,
- Gazlı gangren
- Yumuşak dokunun nekrotizan enfeksiyonları (derialtı, kas, fas, fasya)
- Crush yaralanmaları, kompartman sendromu ve diğer akut travmatik iskemiler.
- Yara iyileşmesinin geciktiği durumlar (diyabetik ve non-diyabetik)
- Kronik refrakter osteomiyelit
- Aşırı kan kaybı
- Radyasyon nekrozları
- Tutması şüpheli deri flepleri ve greftleri
- Termal yanıklar
- Beyin absesi
- Anoksik ensefalopati
- Ani işitme kaybı
- Retinal arter oklüzyonu
- Kafa kemikleri, sternum ve vertebraların akut osteomiyelitleri

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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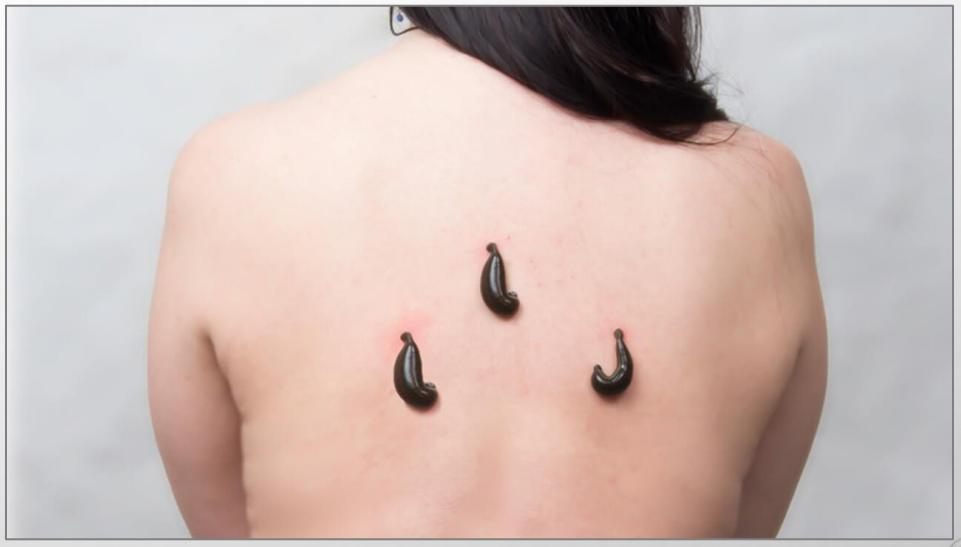
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

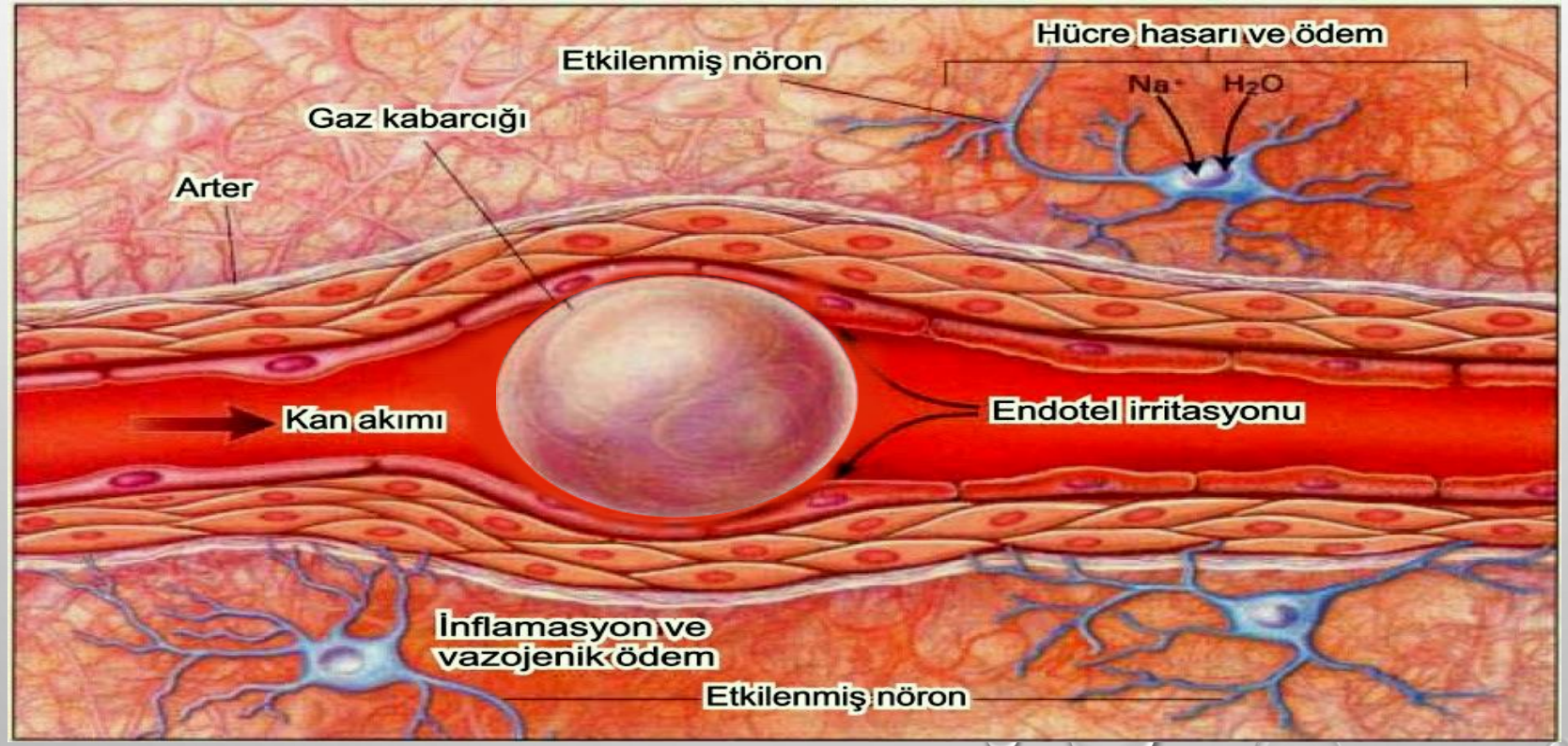


DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

- Basıncın direkt etkisi



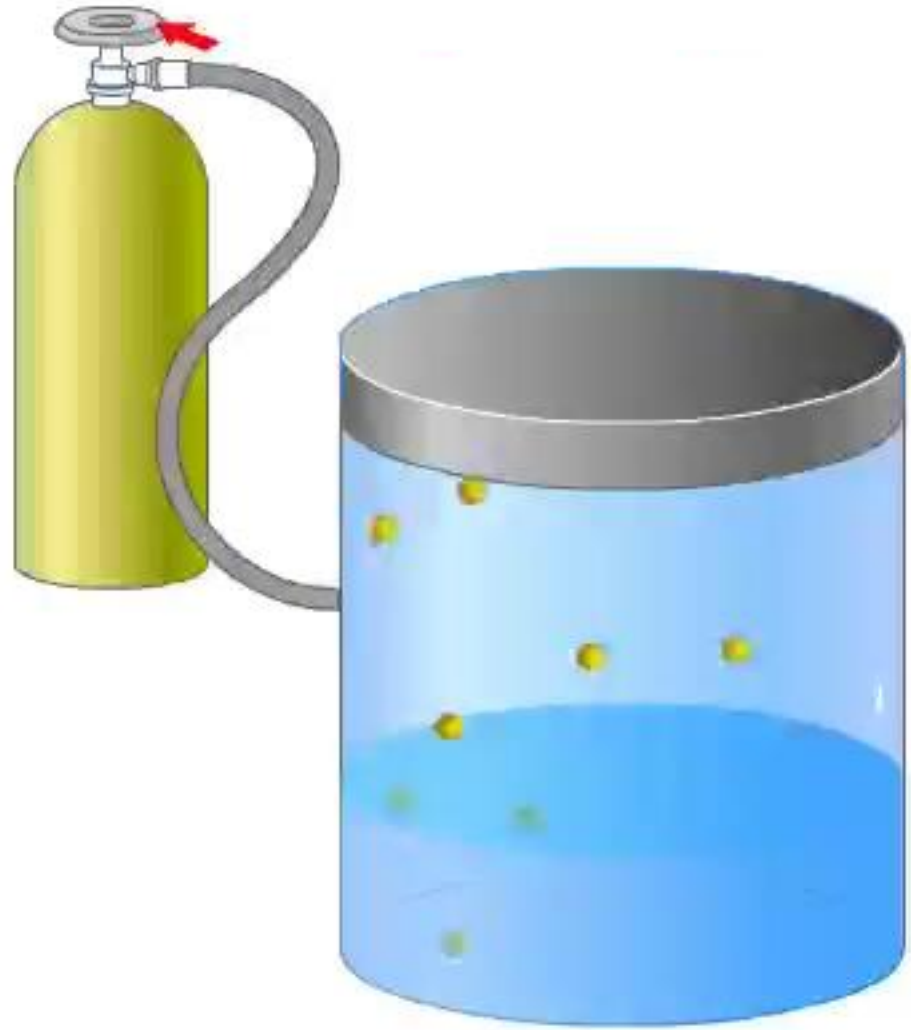
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

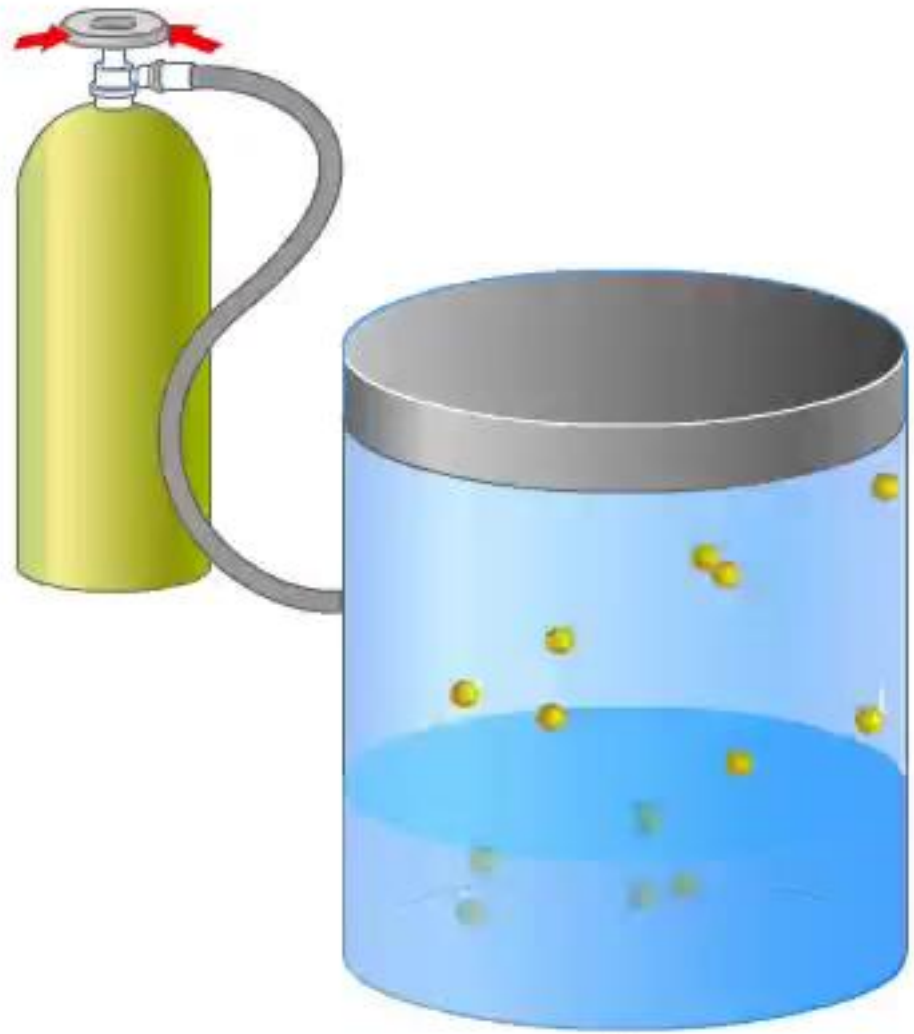
UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

- Basıncın direkt etkisi
- Çözünmüş oksijenin etkisi

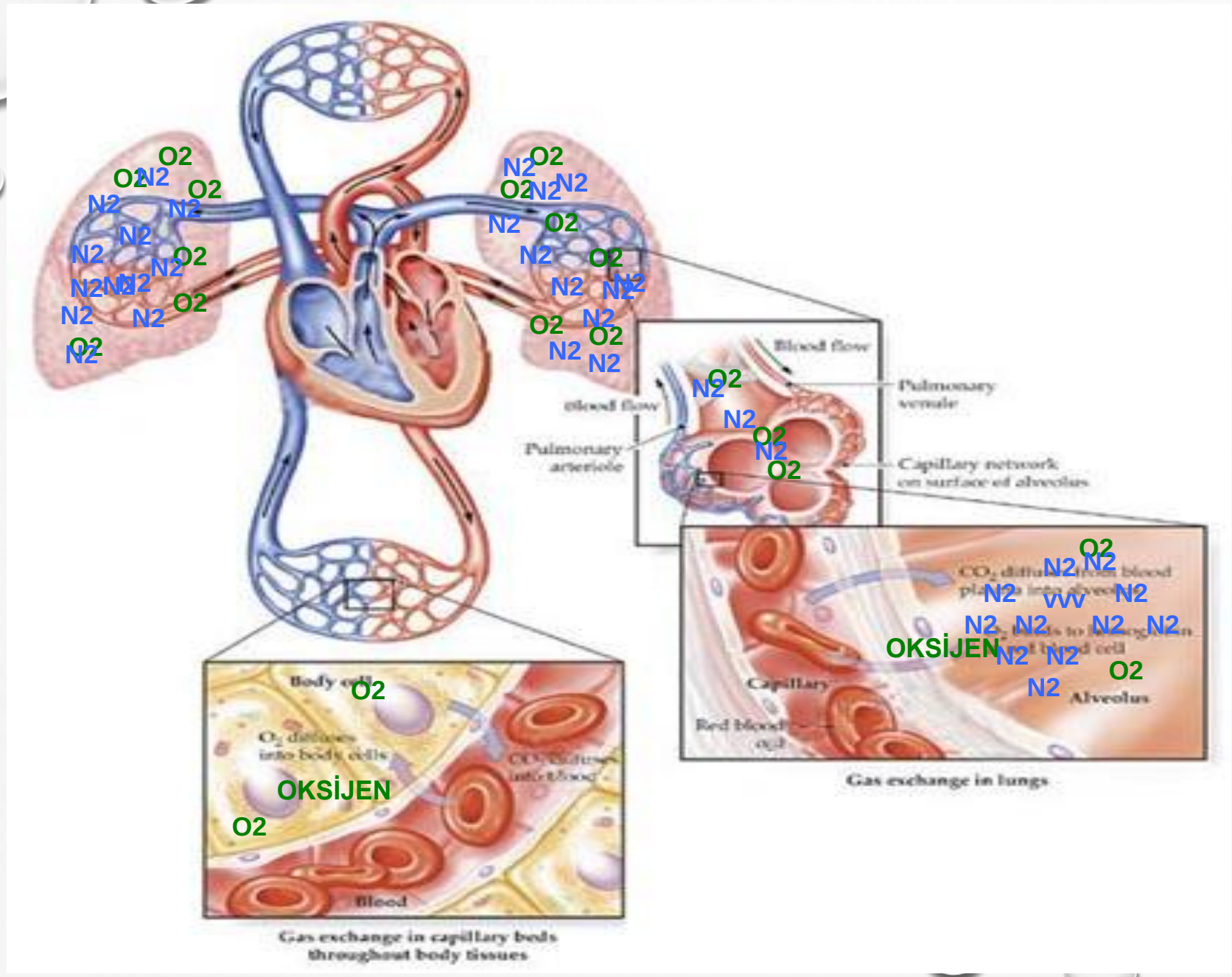
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU





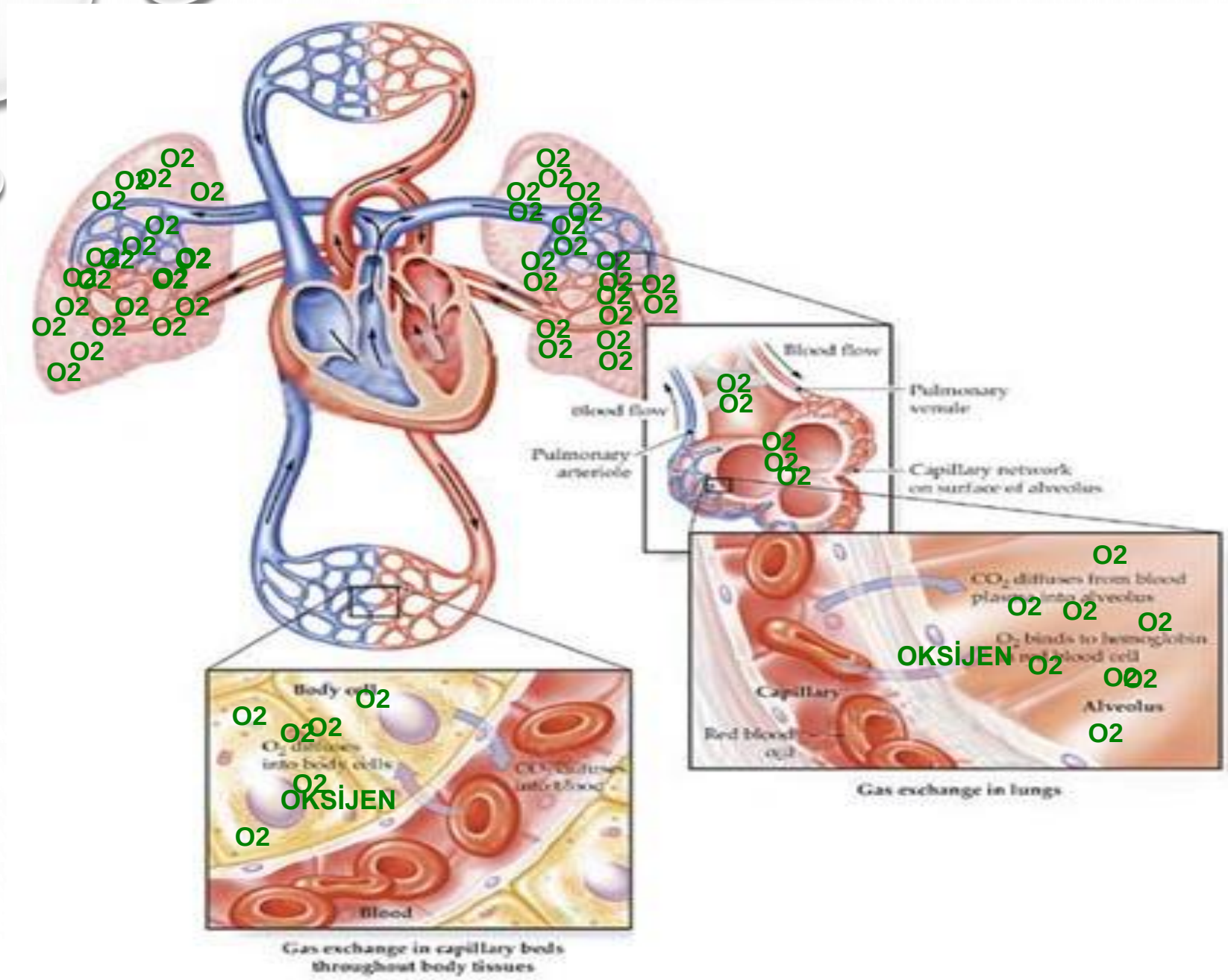
P_2

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

TOPLAM BASINÇ		PAO_2 mmHg	PAO_2 mmHg
ATA	**mmHg**	**Hava Solumu**	**O_2 Solumu**
1	760	102	673
2	1520	262	1433
2,5	1900	342	1813
3	2280	422	2193

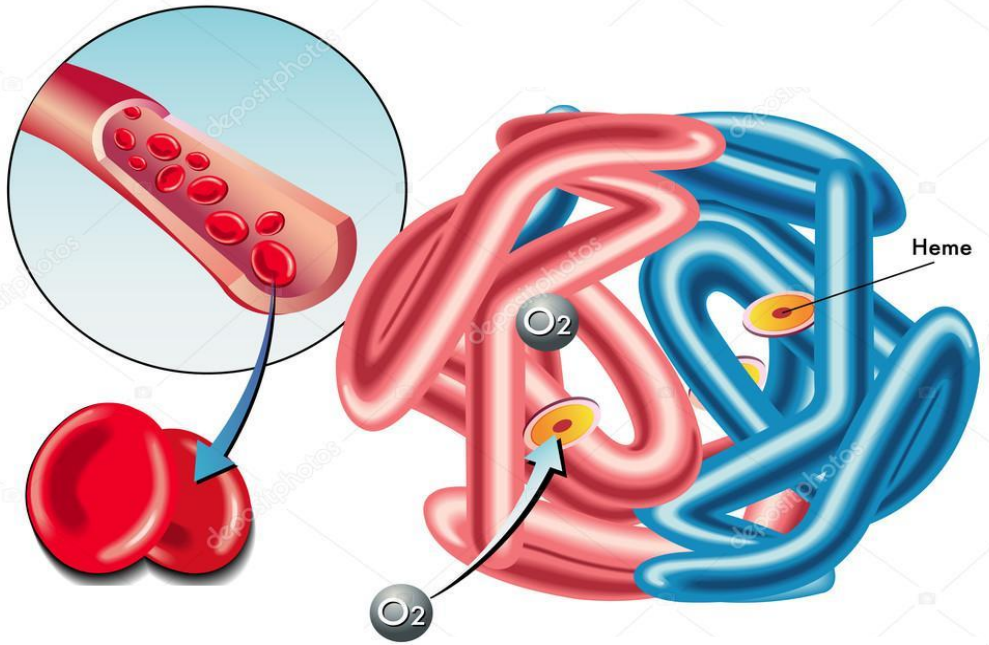
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

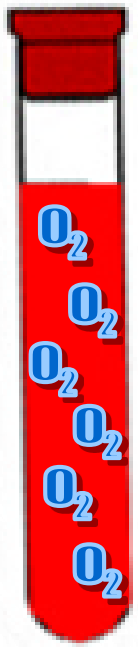
- 1 gr Hb 1,34 ml oksijen taşıyabilir.
- 100 ml kan (Hb 15 gr) 20,1 ml oksijen taşır.
- Kanın O_2 içeriği

  = (Hb x 1,34 ml x SaO_2)
  +(0,003 ml x PaO_2)

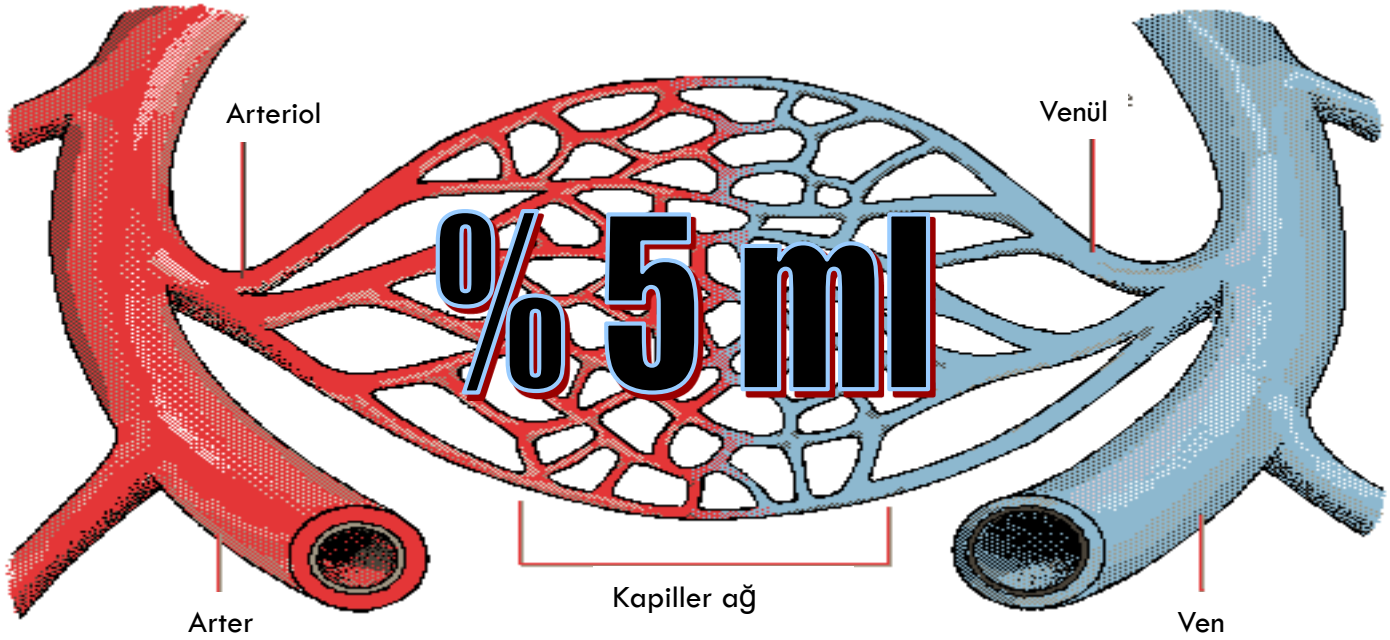


DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



% 20 ml



% 5 ml

% 15 ml

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

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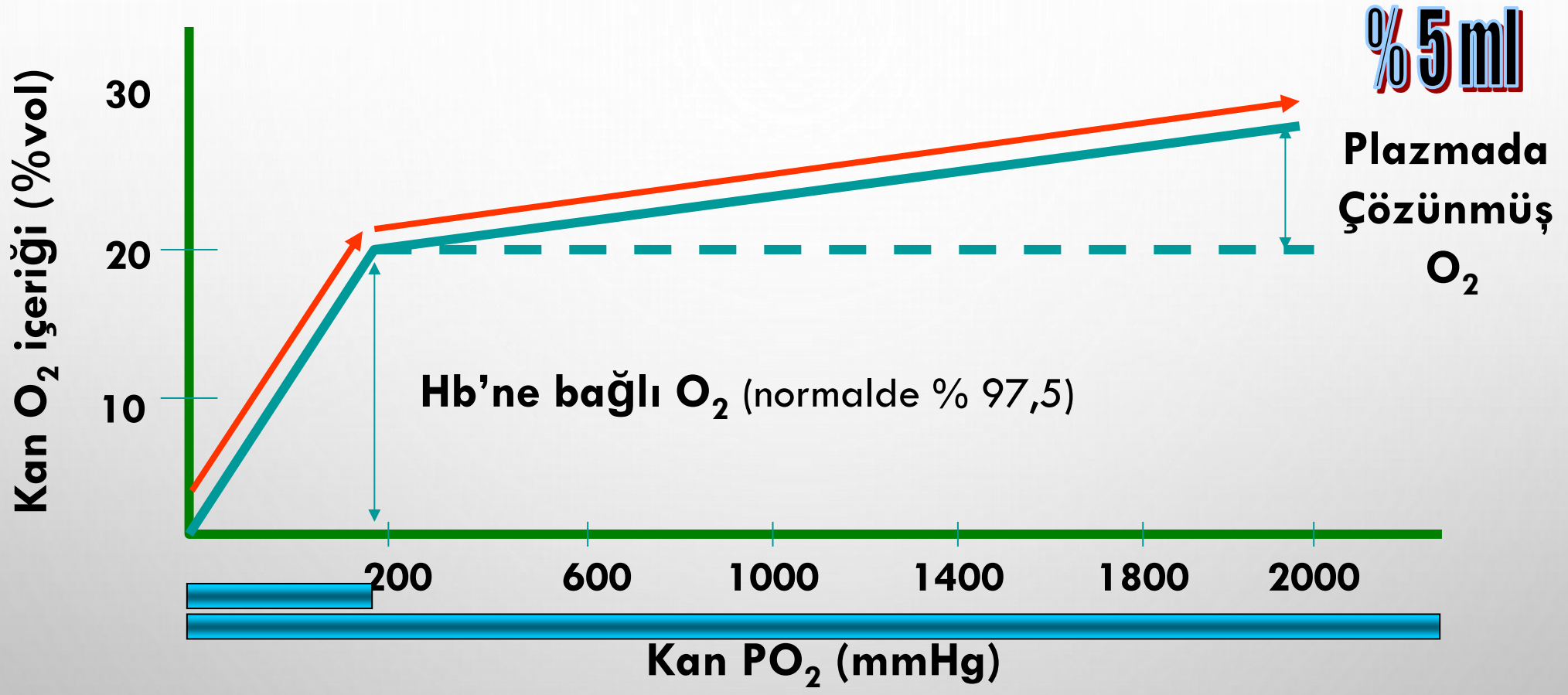
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



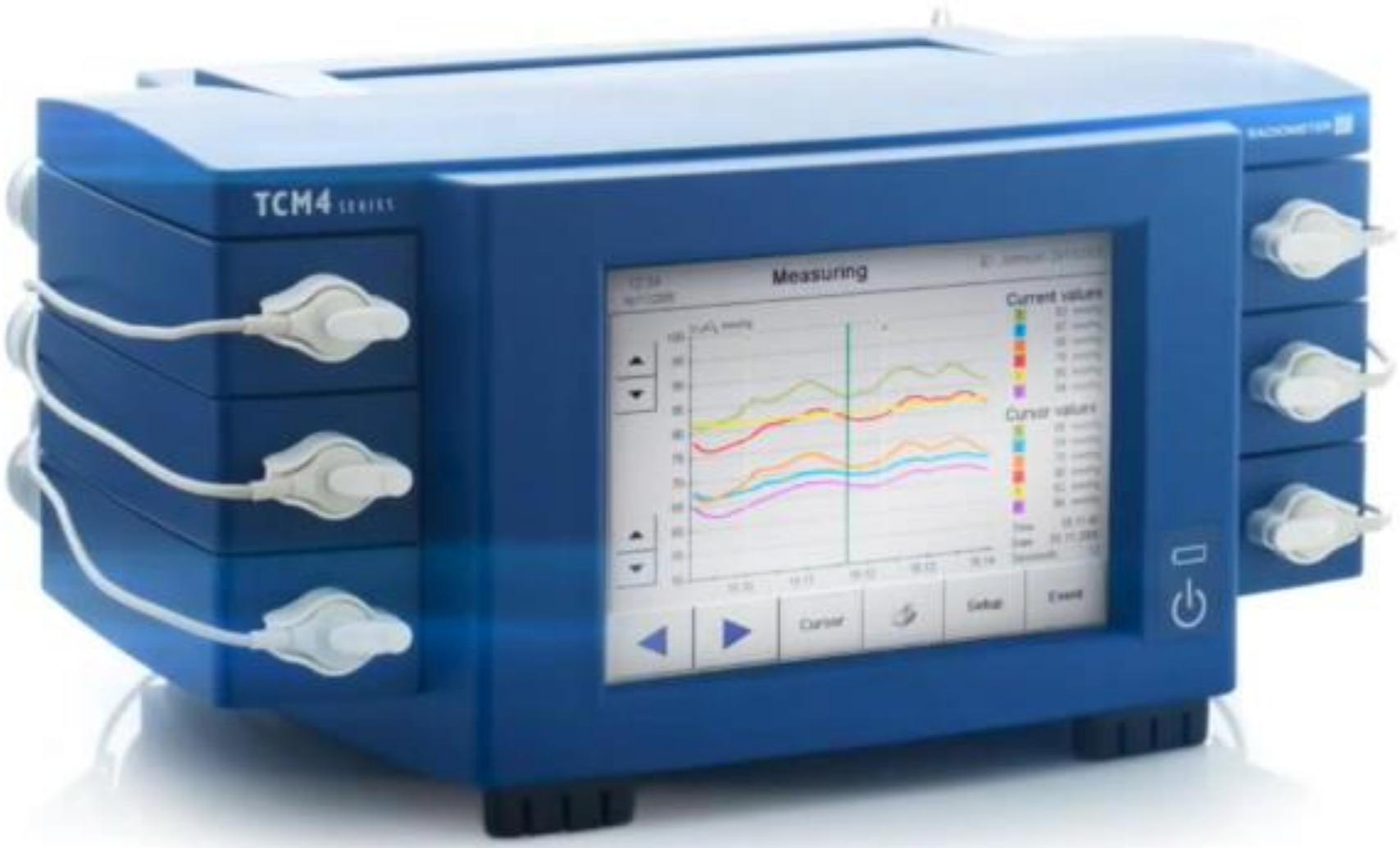
DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

TOPLAM BASINÇ		PAO_2 mmHg	PAO_2 mmHg
ATA	**mmHg**	**Hava Solumu**	**O_2 Solumu**
1	760	102	673
2	1520	262	1433
2,5	1900	342	1813
3	2280	422	2193

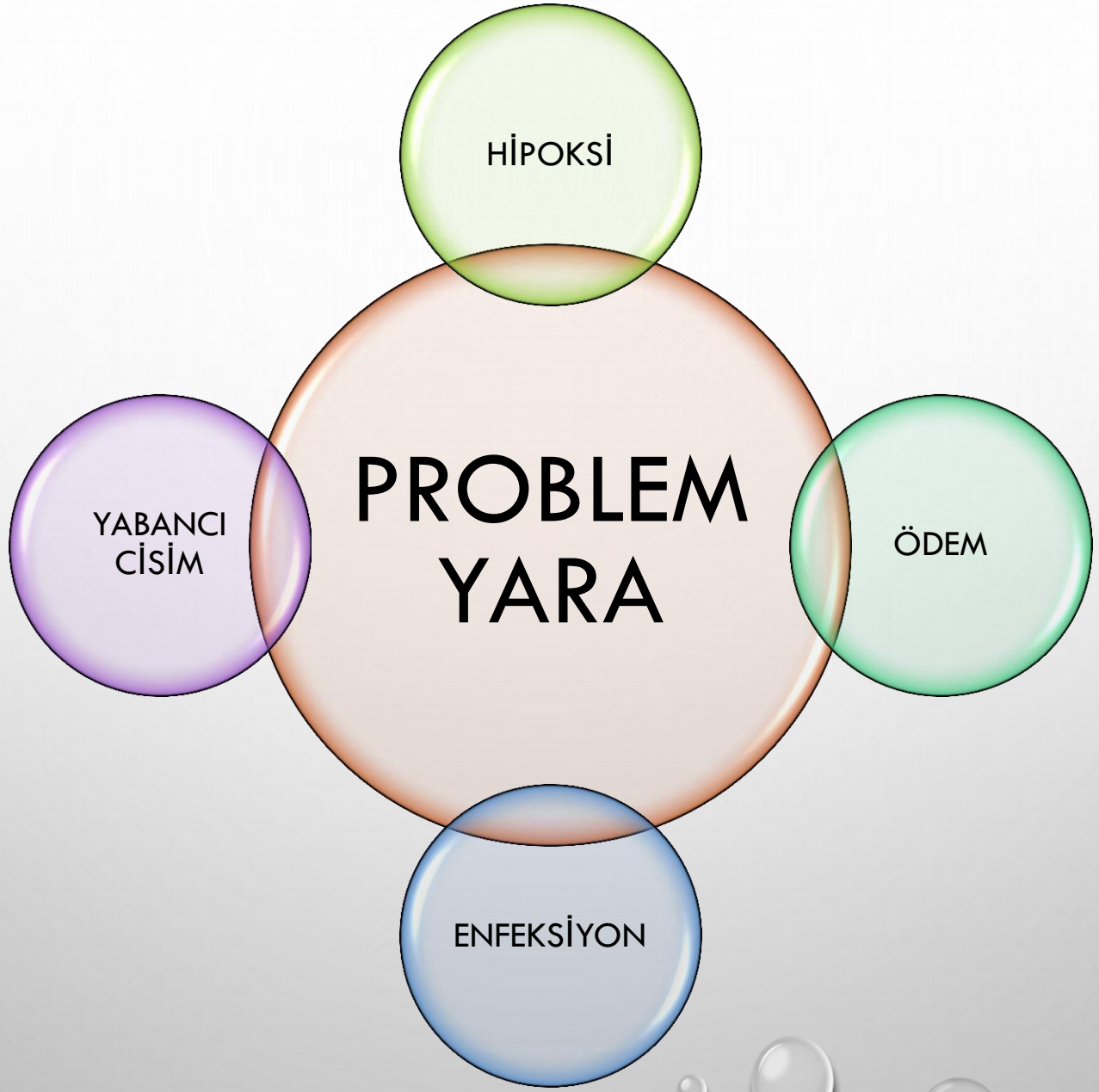
%5ml

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU


TCM4
Measuring
Current values
Cursor values
Cursor
Setup
Event

	Arteriyel pO_2	$TcpO_2$	Yara pO_2
1 ATA hava (159)	100	70-75	5-20
1 ATA O_2 (760)	600	450-550	200-400
2,5 ATA (1900)	1800	1400-1500	800-1100

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

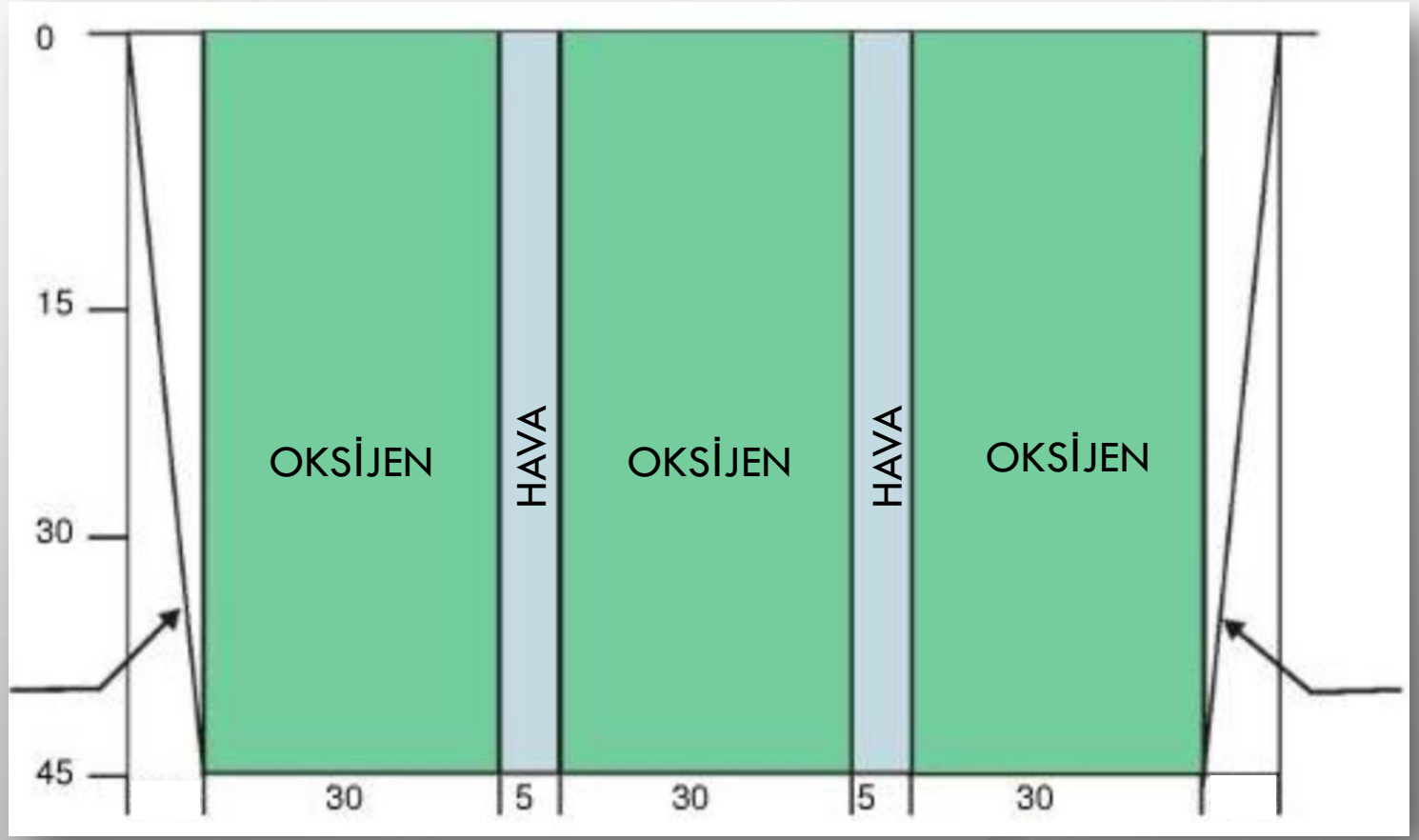
HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

- Basıncın direkt etkisi
- Çözünmüş oksijenin etkisi
  - Antihipoksik etki
  - Antiödem etki
  - Antibakteriyel etki
  - Antitoksik
  - Yara iyileşmesi üzerine etki

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI



DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2'NIN ETKI MEKANIZMASı VE UYGULAMA ŞEKLI

- 2-2,5 ATA
- Günde 1-2 seans
- Haftada 5-6 seans
- Toplam 30-60 seans

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HANGI DIYABETIK AYAKLARDA HBO_2

A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers

CPG Authors: Enoch T. Huang, Jaleh Mansouri, M. Hassan Murad, Warren S. Joseph, Michael B. Strauss, William Tettelbach, Eugene R. Worth

UHMS CPG Oversight Committee: Enoch T. Huang, John Feldmeier, Ken LeDez, Phi-Nga Jeannie Le, Jaleh Mansouri, Richard Moon, M. Hassan Murad

CORRESPONDING AUTHOR: Dr. Enoch T. Huang – *enoch.huang@mac.com*

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2 VE DIYABETIK AYAK (UHMS)

UNDERSEA & HYPERBARIC MEDICAL SOCIETY

RECOMMENDATION 1: In patients with Wagner Grade 2 or lower diabetic foot ulcers, we suggest against using hyperbaric oxygen therapy (very low-level evidence in support of HBO_2, conditional recommendation).

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (UHMS)

UNDERSEA & HYPERBARIC MEDICAL SOCIETY

RECOMMENDATION 2: In patients with Wagner Grade 3 or higher diabetic foot ulcers that have not shown significant improvement after 30 days of treatment, we suggest adding hyperbaric oxygen therapy to the standard of care to reduce the risk of major amputation and incomplete healing (moderate-level evidence, conditional recommendation).

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (UHMS)

RECOMMENDATION 3: In patients with Wagner Grade 3 or higher diabetic foot ulcers who have just had a surgical debridement of an infected foot (e.g., partial toe or ray amputation; debridement of ulcer with underlying bursa, cicatrix or bone; foot amputation; incision and drainage [I&D] of deep space abscess; or necrotizing soft tissue infection), we suggest adding acute post-operative hyperbaric oxygen therapy to the standard of care to reduce the risk of major amputation and incomplete healing (moderate-level evidence, conditional recommendation).

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (ECHM)

European Committee for Hyperbaric Medicine

2 Diving and Hyperbaric Medicine Volume 47 No. 1 March 2017

Consensus Conference

Tenth European Consensus Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment

Daniel Mathieu, Alessandro Marroni and Jacek Kot

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (ECHM)

Table 1
Consensus-based and GRADE scaling for recommendations; GRADE – Grading of Recommendations Assessment, Development and Evaluation System

Strength of recommendation (consensus-based)

Level 1 = Strong recommendation = "*We recommend…*"
The course of action is considered appropriate by the large majority of experts with no major dissension. The panel is confident that the desirable effects of adherence to the recommendation outweigh the undesirable effects.

Level 2 = Weak recommendation = "*We suggest…*"
The course of action is considered appropriate by the majority of experts but some degree of dissension exists amongst the panel. The desirable effects of adherence to the recommendation probably outweigh the undesirable effects.

Level 3 = Neutral recommendation = "*It would be reasonable…*"
The course of action could be considered appropriate in the right context.

No recommendation
No agreement was reached by the group of experts.

Level of evidence (based on GRADE system)

Grade A = High level of evidence
The true effect lies close to our estimate of the effect.

Grade B = Moderate level of evidence
The true effect is likely to be close to our estimate of the effect, but there is a possibility that it is substantially different.

Grade C = Low level of evidence
The true effect may be substantially different from our estimate of the effect.

Grade D = Very low level of evidence
Our estimate of the effect is just a guess, and it is very likely that the true effect is substantially different from our estimate of the effect.

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (ECHM)

Table 2
Recommendations on the indications accepted for HBOT (there was no Level A evidence)

Condition	Level of evidence		Agreement level
	B	C	
Type 1			
CO poisoning	X		Strong agreement
Open fractures with crush injury	X		Strong agreement
Prevention of osteoradionecrosis after dental extraction	X		Strong agreement
Osteoradionecrosis (mandible)	X		Strong agreement
Soft tissue radionecrosis (cystitis, proctitis)	X		Strong agreement
Decompression illness		X	Strong agreement
Gas embolism		X	Strong agreement
Anaerobic or mixed bacterial infections		X	Strong agreement
Sudden deafness	X		Strong agreement
Type 2			
Diabetic foot lesions	X		Strong agreement
Femoral head necrosis	X		Strong agreement
Compromised skin grafts and musculo-cutaneous flaps		X	Strong agreement
Central retinal artery occlusion (CRAO)		X	Strong agreement
Crush Injury without fracture		X	Agreement
Osteoradionecrosis (bones other than mandible)		X	Agreement
Radio-induced lesions of soft tissues (other than cystitis and proctitis)		X	Agreement

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (ECHM)

- In the diabetic patient, the use of HBOT is recommended in the presence of a chronic critical ischaemia as defined by the European Consensus Conference on Critical Ischemia (see note below), if TCOM readings under hyperbaric conditions (253 kPa, 100% oxygen) are higher than 100 mmHg (Type 1 recommendation, level A evidence).
- Note: Chronic critical ischaemia can be recognised when there is: periodic pain, persistent at rest, needing regular analgesic treatment for more than two weeks, or ulceration or gangrene of foot or toes with ankle systolic pressure < 30 mmHg in the diabetic.11
- However, despite the strong agreement on the validity of the criteria listed above to properly select patients for HBOT, the jury acknowledges the fact not all hyperbaric centres are able to perform TCOM under hyperbaric conditions (253 kPa, 100% oxygen). Therefore, owing to this limitation, we suggest HBOT in diabetic foot ulcers (grade 3 and above of Wagner classification, stage B, grade 3 and above of University of Texas classification) that have failed to respond to adequate basic wound care after four weeks (Type 2 recommendation, Level B evidence).

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBOT VE DIYABETIK AYAK (ECHM)

- Kritik iskemi
  - İstirahatte geçmeyen, iki haftadan daha uzun süre analjezik tedavi gerektiren periyodik ağrı, ayakta ülser veya gangren, ayak bileği sistolik basıncı < 30 mmHg
- 2,5 ATA da $TcPO_2$ > 100 mmHg
- 4 Haftadır standart tedaviye cevap alınamamış Wagner 3 ve üzeri

DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2 ve DA-Randomize Kontrollü Çalışmalar

1. Abidia, A., et al., *The role of hyperbaric oxygen therapy in ischaemic diabetic lower extremity ulcers: a double-blind randomised-controlled trial*. Eur J Vasc Endovasc Surg, 2003. **25**(6): p. 513-8.
2. Doctor, N., S. Pandya, and A. Supe, Hyperbaric oxygen therapy in diabetic foot. J Postgrad Med, 1992. 38(3): p. 112-4, 111.
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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

Effect of Hyperbaric Oxygen Therapy on Healing of Diabetic Foot Ulcers

Arife Polat Duzgun, MD,[1] Hakan Ziya Satır, MD,[2] Omer Ozozan, MD,[1] Barıs Saylam, MD,[1] Bahadır Kulah, MD, MS, FACS,[3] and Faruk Coskun, MD[4]

Hyperbaric oxygen therapy can be used as an adjunct to standard wound care in the treatment of diabetic patients with foot ulcers. We undertook a prospective, randomized investigation of the use of hyperbaric oxygen therapy versus standard therapy for the treatment of foot ulcers in diabetic patients. A number of demographic variables were analyzed in regard to wound healing. We noted that foot ulcers in patients in the hyperbaric oxygen therapy group were more likely to heal, and were more likely to undergo amputation distal to the metatarsophalangeal joint compared with those patients receiving standard therapy without hyperbaric oxygen. We feel that hyperbaric oxygen therapy should be considered a useful adjunct in the management of foot ulcers in diabetic patients. Level of Clinical Evidence: 2 (The Journal of Foot & Ankle Surgery 47(6):515–519, 2008)

determine appropriate antibiotic therapy. In the HBOT group, standard therapy was supplemented by hyperbaric oxygen treatments administered at a maximum working pressure of 20 atmospheres absolute (ATA), using a unichamber pressure room (Patterson Companies, Inc., St. Paul, MN) employing a volume of 10 m^3 at 2 to 3 ATA for 90 minutes. Treatment was administered as 2 sessions per day, followed by 1 session on the following day, alternating throughout the course of therapy, which typically extended for a period of 20 to 30 days.

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2 ve DA-Randomize Kontrollü Çalışmalar

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

Hyperbaric Oxygen Therapy Does Not Reduce Indications for Amputation in Patients With Diabetes With Nonhealing Ulcers of the Lower Limb: A Prospective, Double-Blind, Randomized Controlled Clinical Trial

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UDAİS
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DAİÇG
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DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
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DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

HBO_2 ve DA-Meta analiz / sistematik değerlendirme

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

Lack of Effectiveness of Hyperbaric Oxygen Therapy for the Treatment of Diabetic Foot Ulcer and the Prevention of Amputation

A cohort study

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OBJECTIVE—Hyperbaric oxygen (HBO) is a device that is used to treat foot ulcers. The study goal was to compare the effectiveness of HBO with other conventional therapies administered in a wound care network for the treatment of a diabetic foot ulcer and prevention of lower-extremity amputation.

RESEARCH DESIGN AND METHODS—This was a longitudinal observational cohort study. To address treatment selection bias, we used propensity scores to determine the "propensity" that an individual was selected to receive HBO.

RESULTS—We studied 6,259 individuals with diabetes, adequate lower limb arterial perfusion, and foot ulcer extending through the dermis, representing 767,060 person-days of wound care. In the propensity score–adjusted models, individuals receiving HBO were less likely to have healing of their foot ulcer (hazard ratio 0.68 [95% CI 0.63–0.73]) and more likely to have an amputation (2.37 [1.84–3.04]). Additional analyses, including the use of an instrumental variable, were conducted to assess the robustness of our results to unmeasured confounding. HBO was not found to improve the likelihood that a wound might heal or to decrease the likelihood of amputation in any of these analyses.

CONCLUSIONS—Use of HBO neither improved the likelihood that a wound would heal nor prevented amputation in a cohort of patients defined by Centers for Medicare and Medicaid Services eligibility criteria. The usefulness of HBO in the treatment of diabetic foot ulcers needs to be reevaluated.

Diabetes Care 36:1961–1966, 2013

Hyperbaric oxygen (HBO) therapy is used to treat foot ulcers that have not responded to initial care and thereby to prevent lower-extremity amputations (LEAs), both of which are complications of diabetes. HBO requires the exposure of a patient to 100% oxygen at a pressure two to three times greater than ambient atmospheric pressure (1). The efficacy of HBO as a treatment for lower-extremity ulcerations has been supported by several small randomized trials; its use also has been advocated by a number of review articles (2–7). However, a meta-analysis of these randomized trials did not find a long-term statistically significant improvement associated with HBO therapy and concluded that the overall quality of the reviewed studies was poor (8).

Randomized controlled studies are efficacy studies in that they estimate the likelihood that a drug or device, like HBO, will work in an ideal setting. Effectiveness studies estimate the likelihood that a drug or device will work in the "real world." Effectiveness studies can be difficult to conduct in that the design constraints of a randomized trial create a nonreal-world setting; therefore, frequently, effectiveness is assessed using cohort studies. The propensity score (PS) technique was first described ~30 years ago (9). The goal of this technique is to statistically control variables that might influence the selection of a therapy and thus to mimic the "even" distribution of variables seen in a randomized controlled study.

We compared the effectiveness of HBO with other therapies administered without HBO in a wound care network. We used PS approaches to compensate for the lack of randomized treatment assignment as well an instrumental variable analysis (Supplementary Data) to confirm our findings.

RESEARCH DESIGN AND METHODS

—Longitudinal observational data from the National Healing Corporation (NHC) were used. The study was reviewed and approved by the Institutional Review Board of the University of Pennsylvania. Our presentation is consistent with the STROBE statement for cohort studies.

Population

NHC is a company that provided comprehensive wound care management solutions to local wound care centers across the United States. NHC developed clinical pathways to guide treatment based on reviews of best practice and guidelines on

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UDAİS
ULUSAL DİYABETİK AYAK İNFEKSİYONLARI SİMPOZYUMU

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DAİÇG
KLİMİK DERNEĞİ
DİYABETİK AYAK İNFEKSİYONLARI ÇALIŞMA GRUBU

The American Diabetes Association's annual Standards of Medical Care in Diabetes provides comprehensive guidelines for clinicians caring for people with diabetes. The Standards are developed by the Professional Practice Committee (PPC), a multi-disciplinary team of 12 leading experts in the field of diabetes care. On an annual basis, the PPC conducts a comprehensive review of all areas of diabetes care, including foot and wound care. The PPC reviewed the available data on the use of hyperbaric oxygen therapy in 2016 and did not identify enough supporting data on the efficacy of this treatment to recommend its use. The PPC continues to review all treatment options available for people with diabetes with evidence-based criteria for potential inclusion the Association's Standards of Medical Care, a resource for providers and people with diabetes to guide diagnosis and treatment.

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July 19, 2017

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An open letter to the American Diabetes Association board of directors

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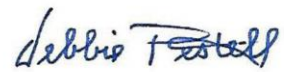
Steve Lucas, BS
Calvin Schmidt, BE, MBA
Catherine Squires, CFRE
Alan L. Yatvin, JD

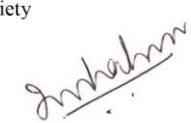
In conclusion, we request a meeting with Dr. Cefalu and the PPC to discuss our concerns about the ADA's interpretation of the literature, petition the ADA board of directors and the PPC to consider amending or revising the ADA position statement, demand a list of scientific references and/or analyses that has led the PPC to their current negative position on the use of adjunctive HBO_2 therapy for the treatment of select DFUs, and ask for a public comment period before making the ADA position final. Anything short of this demonstrates a lack of both transparency and scientific discourse.

Sincerely,

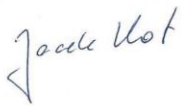
Enoch Huang, MD
President, Undersea and Hyperbaric Medical Society



Debbie Pestell, MD
President, Canadian Undersea and Hyperbaric Medical Association

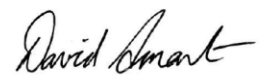


Jayesh Shah, MD
President, American College of Hyperbaric Medicine

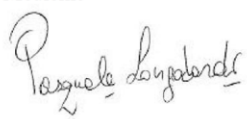


Jacek Kot, MD
President, European Undersea and Baromedical Society

Daniel Mathieu, MD
President, European Committee on Hyperbaric Medicine

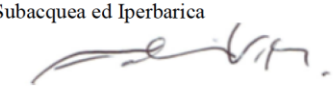


David Smart, MD
President, South Pacific Underwater Medical Society

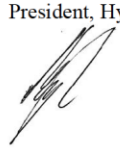


Pasquale Longobardi, MD
President, Societa Italiana di Medicina Subacquea ed Iperbarica

Tarun Sahni, MD
President, Hyperbaric Society of India



Fabrício Valandro Rech, MD
President, Sociedade Brasileira de Medicina Hiperbárica



Magnus Löndahl, MD
President, Swedish Wound Healing Society

Gregory Weir, MD
President, Southern African Underwater and Hyperbaric Medical Association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Burhan Çaçan
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