

## OBJECTIVE

ASSESS THE USEFULNESS OF CONTINUOUS DIFFUSION OF OXYGEN TO BOOST HEALING PROCESS OF SURGICALLY CLOSED WOUNDS

## INTRODUCTION

- ❖ **Significance & Impact:** Ischemic diabetic foot (IDF) encompasses a 31% conversion rate to minor amputations<sup>1</sup>. If mistreated, this procedure may lead to tissue necrosis, infection, or dehiscence<sup>2,3</sup>.
- ❖ **Premise:** Topical oxygen therapy is effective in treating non-healing open wounds<sup>4</sup>. When applied in a constant delivery fashion through continuous diffusion of oxygen (CDO), it has shown to increase wound healing compared to standard wound therapy<sup>5,6</sup>.
- ❖ **Gaps:** Our preliminary study showed moderate CDO flow (8 ml/hr) reduced wound length in IDF patients undergoing minor amputations; however adverse events accompanied<sup>7</sup>.
- ❖ **Solution:** We propose to examine effectiveness of CDO (OxyGeni®, EO2 Concepts, TX, Fig. 1) at a lower flow (4 ml/hr) to the standard of care (SOC) dressing.
- ❖ **Hypothesis:** CDO will accelerate the healing of surgically closed ischemic wounds and reduce hospital readmissions in diabetic patients undergoing minor amputations.



**Figure 1:** OxyGeni® Portable CDO System with a directed cannula to the SOC dressing (EO<sub>2</sub> Concepts, San Antonio, TX)

## MATERIALS &amp; METHODS

- ❖ **Study design:** Randomized control trial (N=15) of patients undergoing minor amputations
  - (n=14 hallux, n=1 transmetatarsal)
  - **Control Group** (n = 11): SOC
  - **Intervention Group** (n = 4): SOC + CDO (4 ml/hr)
  - Duration: 4 weeks
- ❖ **Criteria**
  - **Inclusion:** 18-85 years, diabetes mellitus type 2, presence of a surgically closed wound due to minor lower extremity amputation.
  - **Exclusion:** Charcot arthroplasty, osteomyelitis, or excessive lymphedema
- ❖ **Outcomes**
  - 30-day incidence of wound complications:
    - Necrosis, dehiscence, infection
  - 30-day hospital readmissions
- ❖ **Indications for procedures:**
  - Gangrene (n=11)
  - Infection (n=2)
  - Non-healing ulceration (n=2)

Demographics	Mean SD/ no. (%)	P value
Age, years	64.3±9.4	0.81
BMI, kg/m2	28.2±6.5	0.98
HbA1c, mmol	7.8±1.9	0.08
Previous 30-day revascularization	53.3%	0.87
Heart disease	46.7%	0.31
Chronic kidney disease	40.0%	0.09

## RESULTS &amp; FINDINGS

## CONTINUOUS DIFFUSION OF OXYGEN

## Baseline

## 4 Weeks

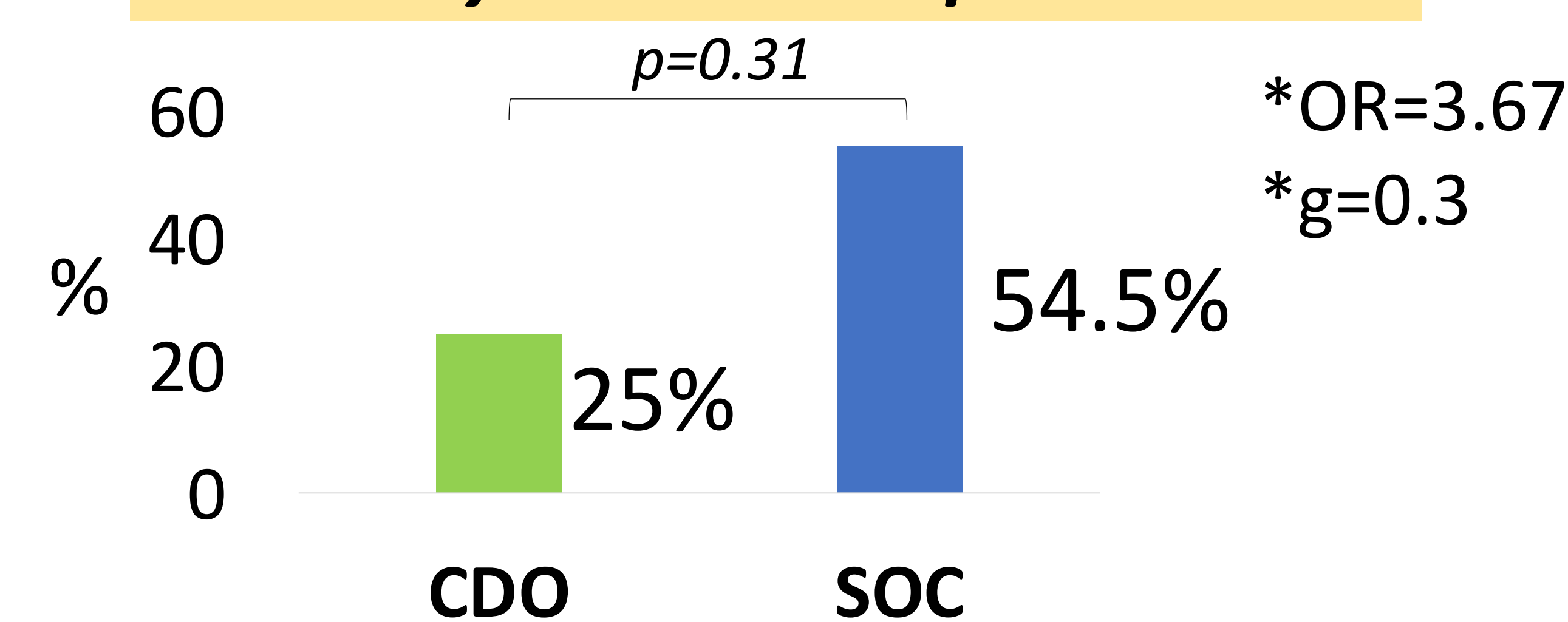
## STANDARD OF CARE

## Baseline

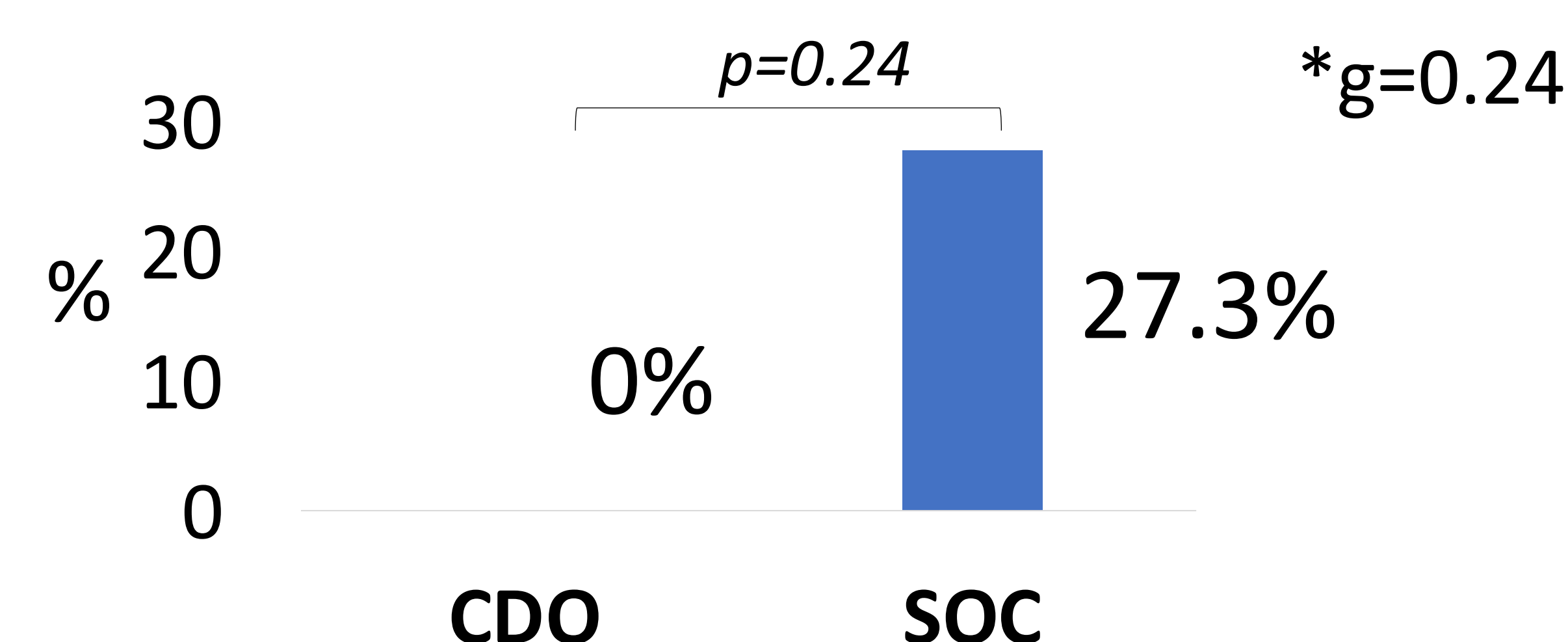
## 4 Weeks



## 30-day wound complications



## 30-day hospital readmissions



## DISCUSSION &amp; CONCLUSION

- ❖ This is the first study reporting potential effectiveness of CDO in improving surgically closed wound outcomes for IDF patients.
- ❖ A positive non-significant trend in favor of CDO may indicate potential benefit to reduce adverse outcomes and hospital readmission in diabetic patients undergoing minor amputations.
- ❖ A higher sample size is warranted to confirm this statement.

## REFERENCES

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- The study was registered in *ClinicalTrials.gov* identifier: **NCT03960463**.