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MEDICINE

# Multicenter Hyperbaric Outcomes Registry: 2023 Update



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## Summary

**Introduction/Background:** The Multicenter Hyperbaric Outcomes Registry collects a defined set of outcome measures for all 14 UHMS-approved, and for some emerging hyperbaric oxygen treatment indications. The registry is arranged as a consortium of participating centers.

**Methods:** The registry uses the same Research Electronic Data Capture (REDCap) template at all participating sites. The template defines the data elements collected for every patient. Slide 2 shows the sample REDCap screens for data entry. Drop-down menus and radio buttons are used as much as possible to minimize data entry.

**Results:** Currently, there are 5781 patient entries in the registry. Slide 3 shows the centers currently entering patient data. Slide 4 shows the case mix for the program, with delayed radiation injury as the top indication. In the last year, more cases of carbon monoxide poisoning were treated than problem wounds. Slide 5 shows the reported complications from treatment. The head and neck questionnaire is showing improvements in reported dry mouth (Slide 6).

**Summary:** An outcomes registry offers a consistent method for collecting treatment results for patients with both UHMS-approved and emerging indications. These data can be collected rapidly and will be essential for refining existing indications, developing new ones, and detecting treatment trends over time.

## Background

- Inadequate outcomes data exist to support hyperbaric oxygen indications
- Most centers are small and so only see a limited number of patients with any given indication
- With an outcomes-based registry, standardized outcomes from hyperbaric oxygen treatment can be collected across centers, allowing data to be combined
- The Multicenter Hyperbaric Outcomes Registry consortium includes 26 sites in the US, UK, and Australia

## Methods

- Sample data entry screens shown on Slide 2
- Registry built using the web-based data collection system Research Electronic Data Capture (REDCap) with a uniform data collection template across all sites
- Standardized measures entered on all patients seen in hyperbaric program
- Registry uses objective, patient-reported measures whenever possible to reduce bias
- International Registered Report Identifier for the registry is RR2-10.2196/18857

# Methods (REDCap Data Entry Screens)

Study ID: 16

**Undersea & Hyperbaric Medical Society Referral Information**

Date referral received at your center (MONTH-DAY-YEAR).  Today M-D-Y  
This is the reference date

Please re-enter YEAR you received the referral. [Important because specific dates will be scrambled during export]  
\* must provide value

Age at referral [calculated field]  View equation

Referring physician's last name

Referring physician's specialty

Referring facility

**Reason for referral**

- Acute thermal burn injury
- Air or gas embolism
- Carbon monoxide
- Central retinal artery occlusion
- Compromised grafts and flaps
- Crush injury, compartment syndrome
- Decompression sickness
- Delayed radiation injury (not compromised grafts/flaps)
- Enhancement of healing in selected problem wounds (not compromised grafts/flaps)
- Gas gangrene
- Idiopathic sudden sensorineural hearing loss
- Intracranial abscess
- Necrotizing soft tissue infections
- Osteomyelitis, refractory
- Severe anemia
- Research protocol
- Other Non UHMS Indication

Was HBOT referral urgent?

**HBOT Evaluation Information**

Formal HBOT evaluation/consult done?

Date of HBOT evaluation (MONTH-DAY-YEAR)  Today M-D-Y

HBOT evaluation done by:

**Medical History**

Has patient previously completed a course of HBO therapy?  reset

Diabetes

Smoking history

**Current HBO Indication**

Is HBO treatment indicated?

**Smoking history**

**Current HBO Indication**

Is HBO treatment indicated? Yes - Indicated

The reason for referral was Delayed radiation injury (not compromised grafts/flaps). The evaluating MD's confirmed indication for HBO is: Delayed radiation injury (not compromised gra

Radiation injury anatomic location: Bladder

Was the irradiation done because of cancer?

If not stated above, provide more details of the condition treated with radiation?   
For cancer, state site, histology etc. For non cancer condition, state diagnosis

In which year was radiation to affected region given?   
If unknown, enter 9999

Total radiation dose received (Gy)   
Dose in Gy cannot exceed 100

For the Current Indication, HBO Treatment Prescription: Number of HBO treatments PRESCRIBED

ATA

Daily frequency of HBOT PRESCRIBED

Hematuria classification scale Pre HBOT score

Date of hematuria assessment pre HBOT  Today M-D-Y

Is the patient able to complete the CYSTITIS QUESTIONNAIRE?  
\* must provide value  Yes  No, unable to complete questionnaire reset

Notes about Referral/Evaluation (optional)  Expand

Is the patient able to complete the CYSTITIS QUESTIONNAIRE?  
\* must provide value  Yes  No, unable to complete questionnaire reset

Date of Cystitis Questionnaire (MONTH-DAY-YEAR)  Today M-D-Y  
\* must provide value

1. Do you usually experience frequent urination?  Yes  No reset

2. Do you usually experience urine leakage associated with a feeling of urgency? (urgency means a strong sensation of needing to go to the bathroom)  Yes  No reset

3. Do you usually experience leakage related to coughing, sneezing, or laughing?  Yes  No reset

4. Do you experience small amounts of urine leakage (drops of urine)?  Yes  No reset

5. Do you experience difficulty emptying your bladder?  Yes  No reset

6. Do you usually experience pain or discomfort in the lower abdomen or genital region?  Yes  No reset

7. Do you ever see blood in your urine?  Yes  No reset

- Data entry screens from REDCap. Use of drop down menus and radio buttons minimize data entry. In this case, hematuria and a cystitis questionnaire are completed for a patient with radiation cystitis.

# Contributing Centers

<b>Table 1. MRHOT Contributing Sites and Locations. *Indicates part of Intermountain Health Care System.</b>
<b>Augusta Health, Fishersville, VA (AHWHC), Started 7/27/21</b>
<b>Avera McKennan Hospital, Sioux Falls, SD (AVERA), Started 11/22/19</b>
<b>Beverly Hospital, Beverly, MA, (BWHC), Started 7/6/20</b>
<b>Dartmouth-Hitchcock Medical Center, Lebanon, NH (DHMC), Started 05/28/11</b>
<b>DDRC Healthcare, Plymouth, UK (DDRC), Started 5/7/20</b>
<b>Dixie Regional Medical Center, St. George, UT (DRMC)*, Started 12/31/19</b>
<b>Duke University Medical Center, Durham, NC (DUKE), Started 12/21/19</b>
<b>East of England Hyperbaric Unit, Great Yarmouth, UK (EOE), Started 2/5/20</b>
<b>Elliot Health System, Manchester, NH (EHS), Started 05/09/18</b>
<b>Intermountain Medical Center, Salt Lake City, UT (IMC)*, Started 04/04/20</b>
<b>Latter Day Saints Hospital, Salt Lake City, UT (LDSH)*, Started 11/07/19</b>
<b>Legacy Health Group, Portland, OR (LHG), Started 03/03/18</b>
<b>Logan Regional Hospital, Logan, UT (LMRC)*, Started 01/21/20</b>

<b>Table 1. MRHOT Contributing Sites and Locations. *Indicates part of Intermountain Health Care System (continued)</b>
<b>Mayo Clinic, Rochester, MN (MAYO), Started 11/09/19</b>
<b>McKay Dee Hospital, Ogden, UT (MKD)*, Started 02/05/20</b>
<b>Prince of Wales Hospital, Randwick, NSW, Australia (PWH) Started 12/17/19</b>
<b>St. Alphonsus Hospital System, Boise, ID (SAHS), Started 12/05/18</b>
<b>St. Luke's Health System, Boise, ID (SLHS) , Started 03/19/20</b>
<b>St. Richard's Hospital, Chichester, UK, (CHI) Started 4/23/20</b>
<b>University of California at San Diego, San Diego, CA (UCSD), Started 02/16/19</b>
<b>University of Maryland Medical Center, Baltimore, MD (UMMC), Started 10/30/18</b>
<b>University of Pennsylvania Health System, Philadelphia, PA (UPENN), Started 04/07/19</b>
<b>University of Rochester Medical Center, Rochester, NY (URMC), Started 04/10/19</b>
<b>Utah Valley Hospital, Provo, UT (UVH)*, Started 01/01/20</b>
<b>The Wesley Hospital, Auchenflower, Australia, (WESL), Started 11/9/17</b>
<b>Whipps Cross University Hospital, London, UK (LHM), Started 2/5/20</b>

# Numbers of cases in the HBO Registry, by indication

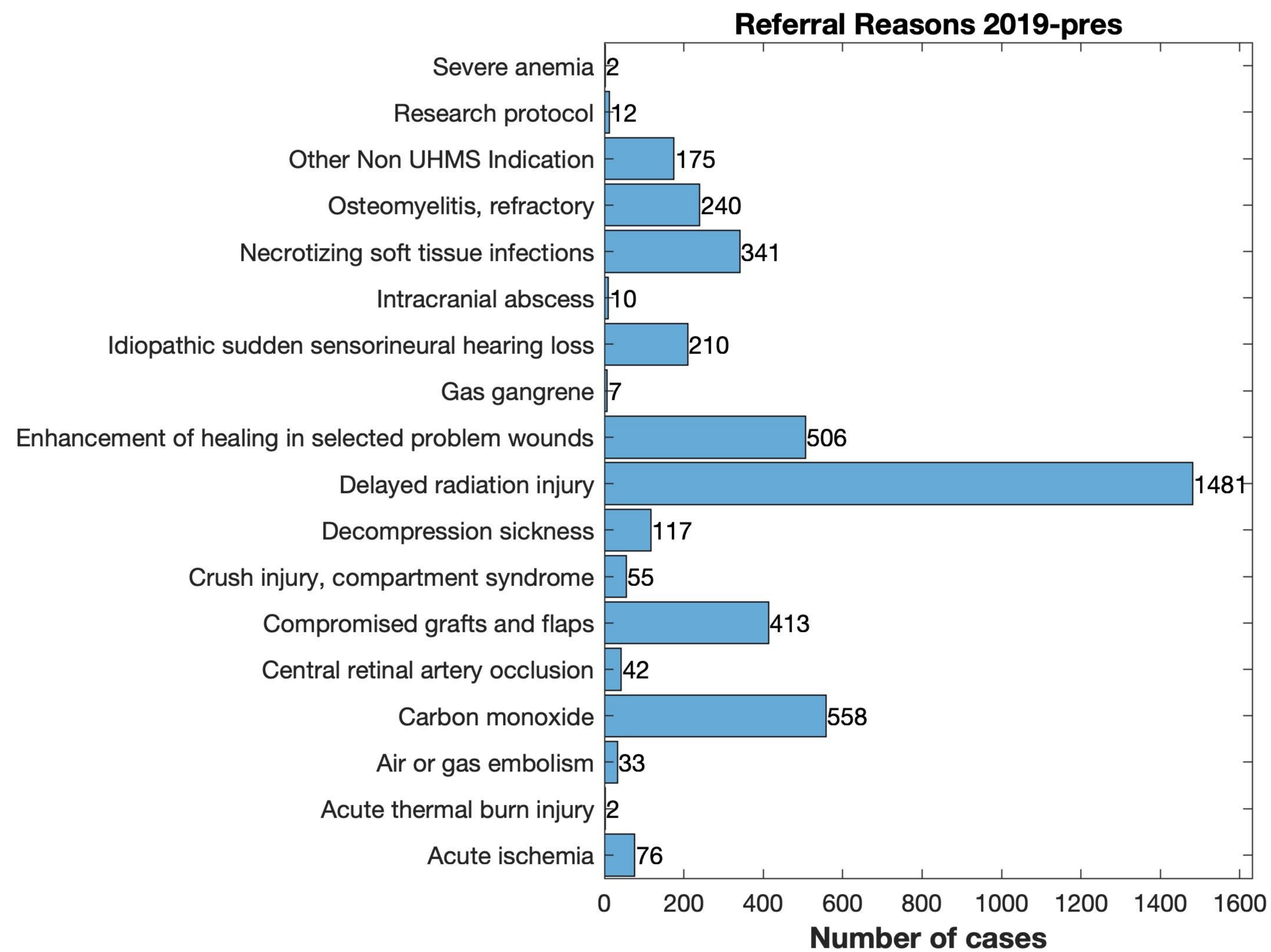


Figure 1. Overall mix of cases in the registry since 2019. Prior to 2019 enrollment was primarily from <3 centers.

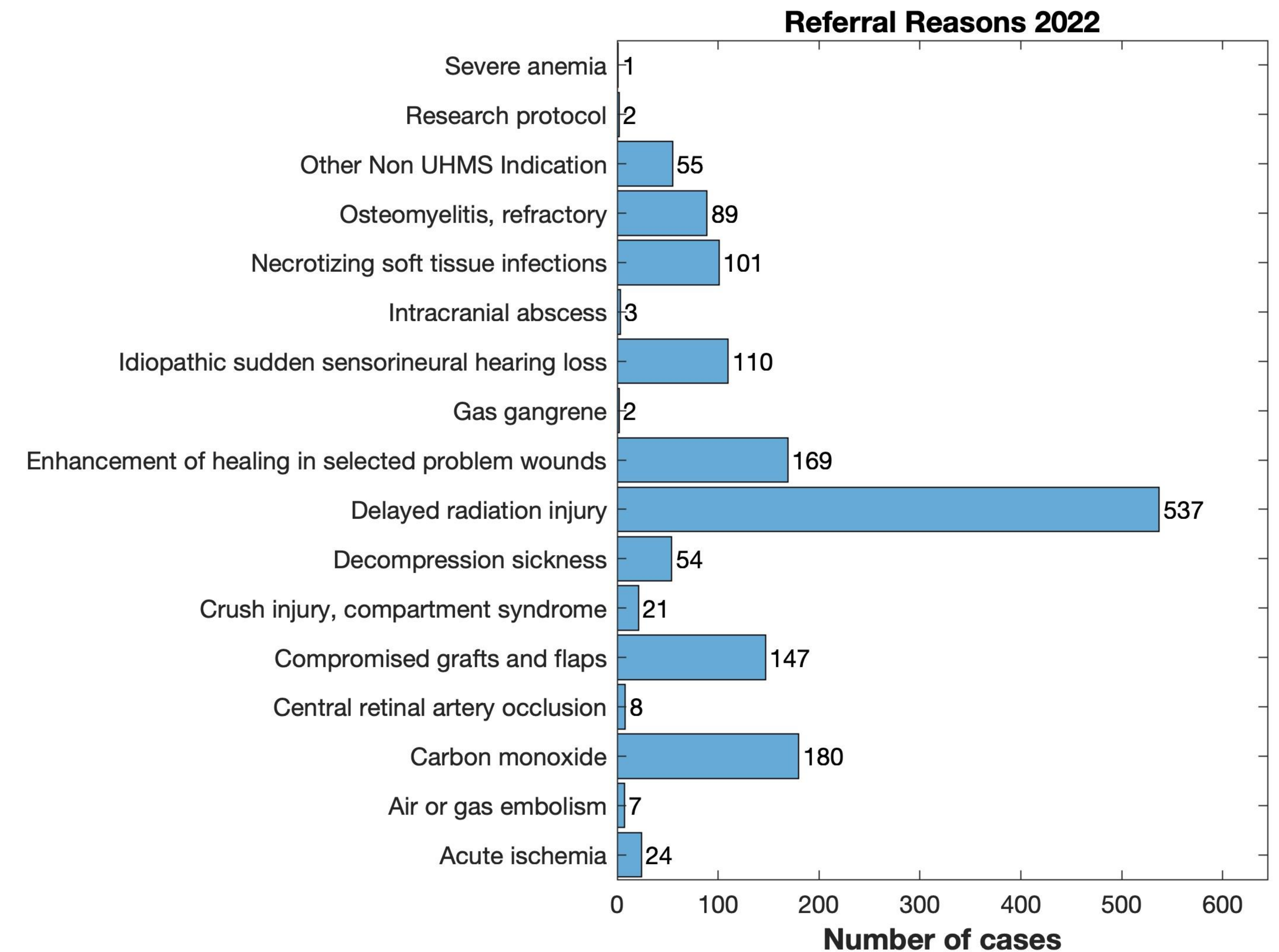
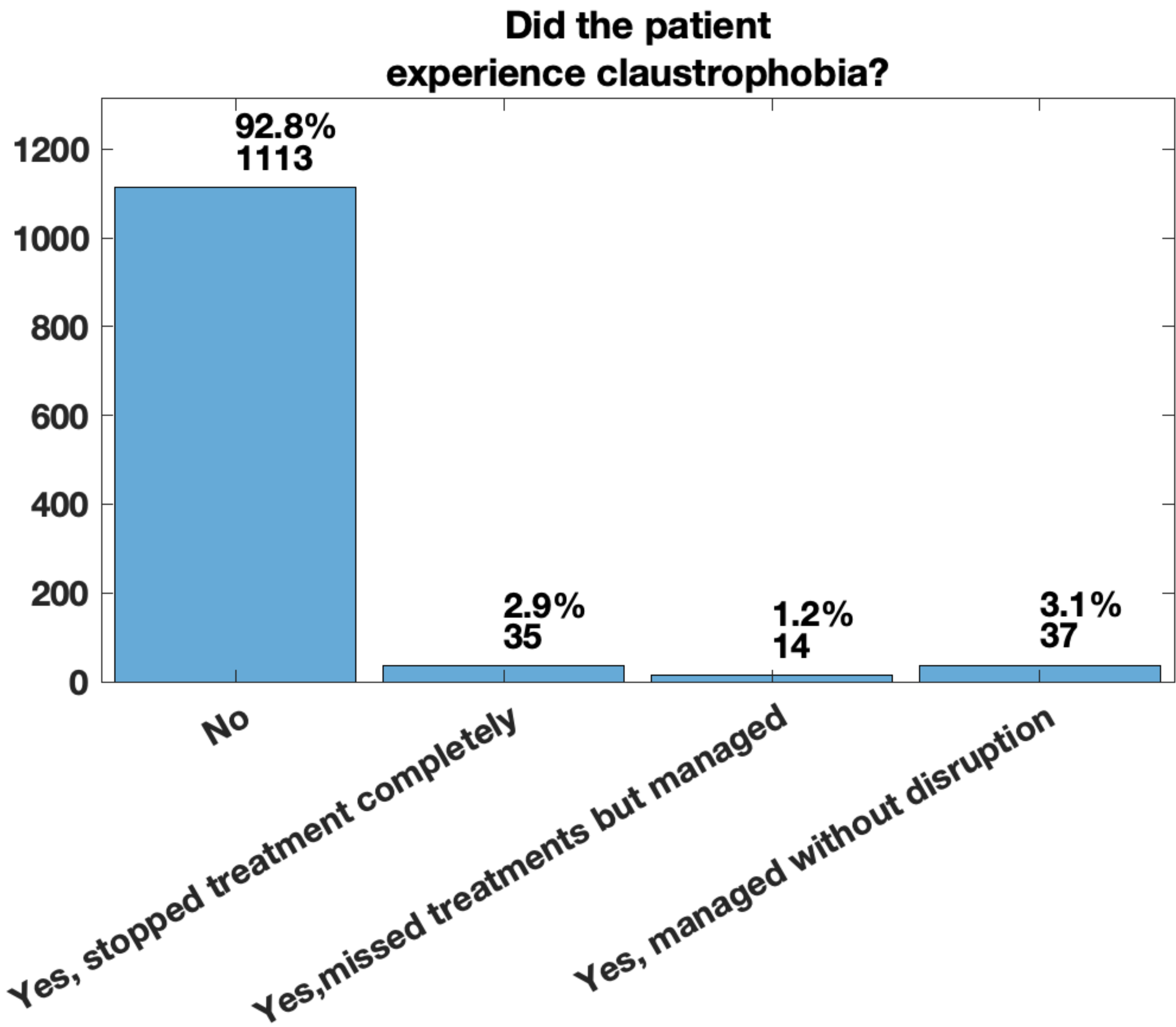
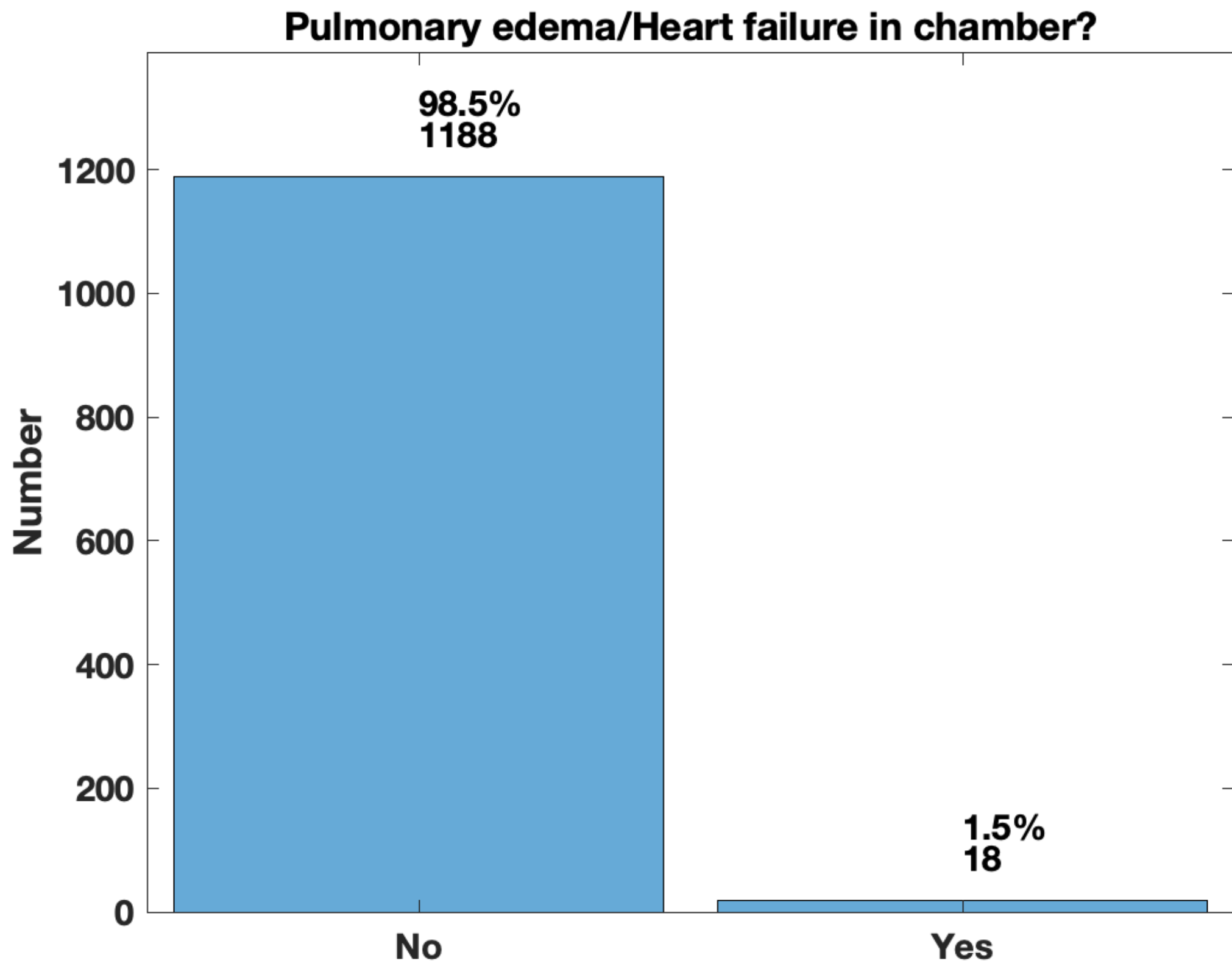
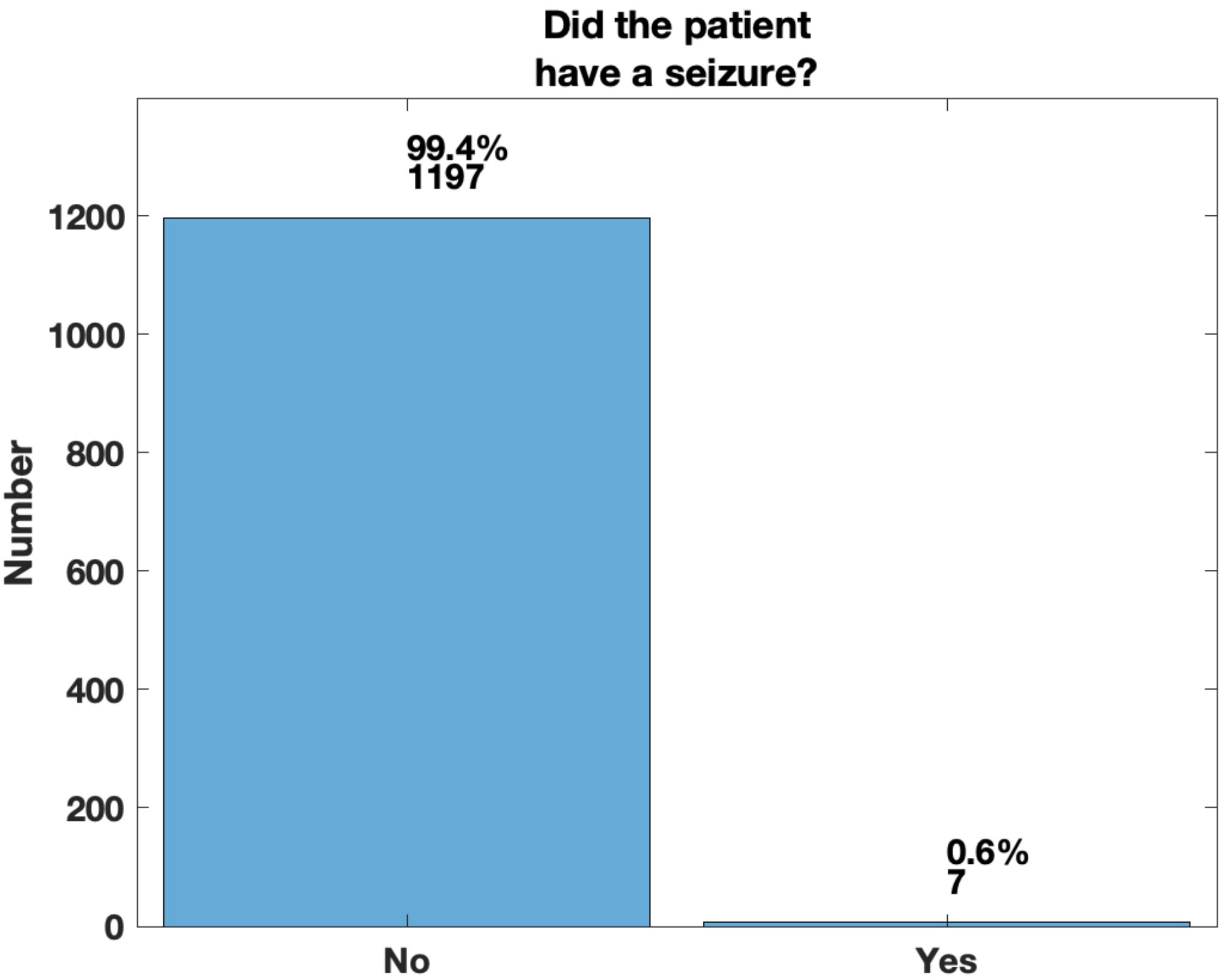


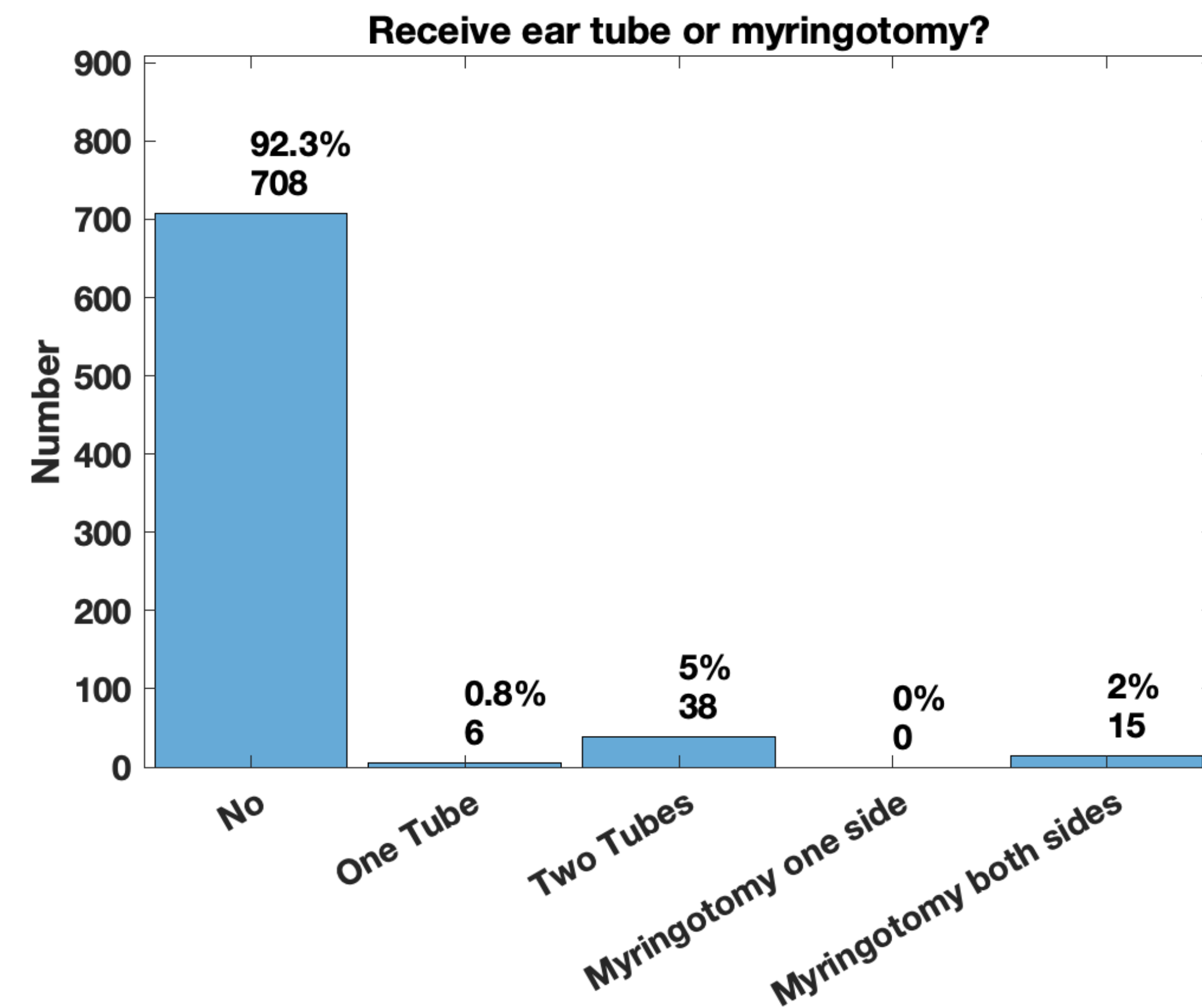
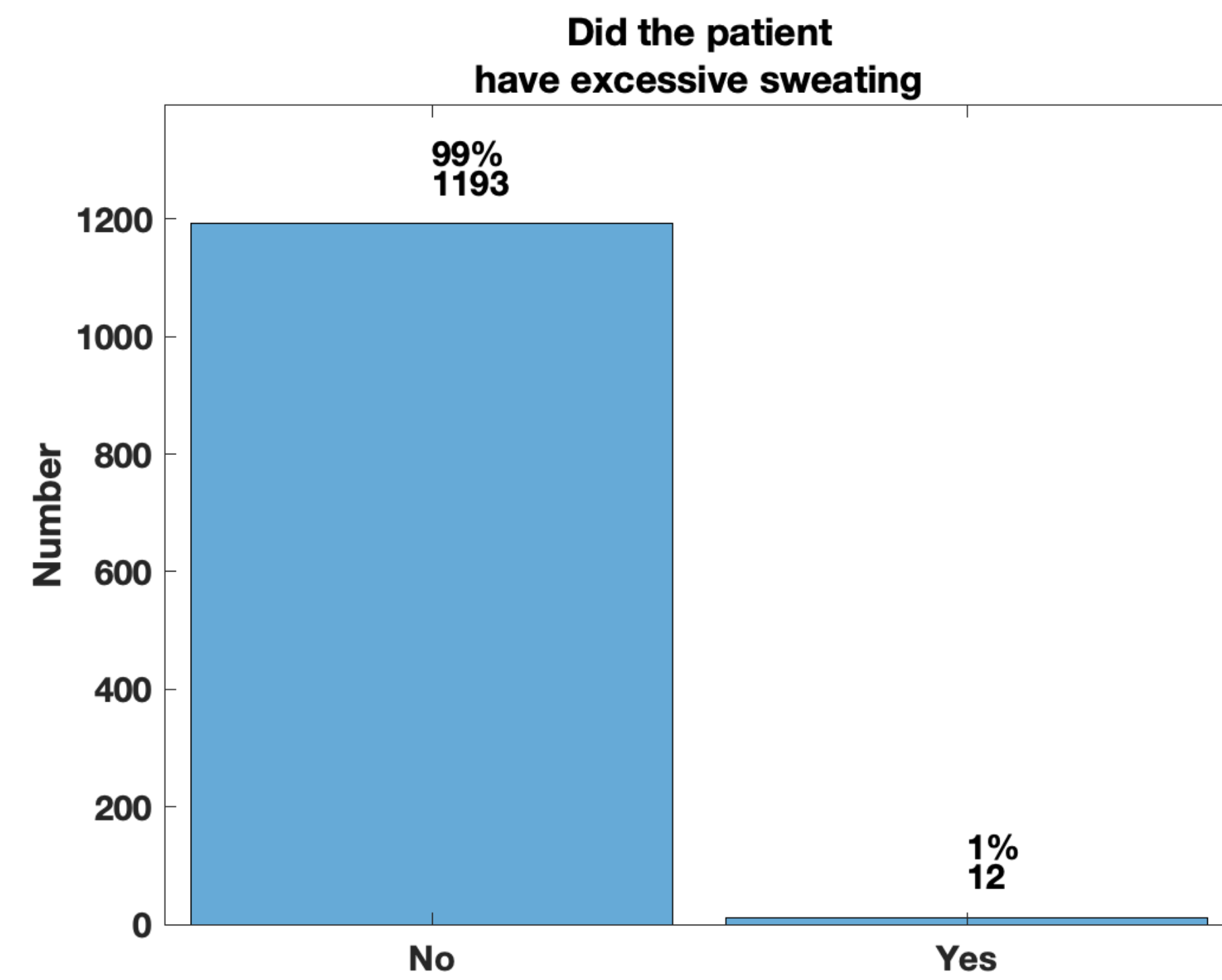
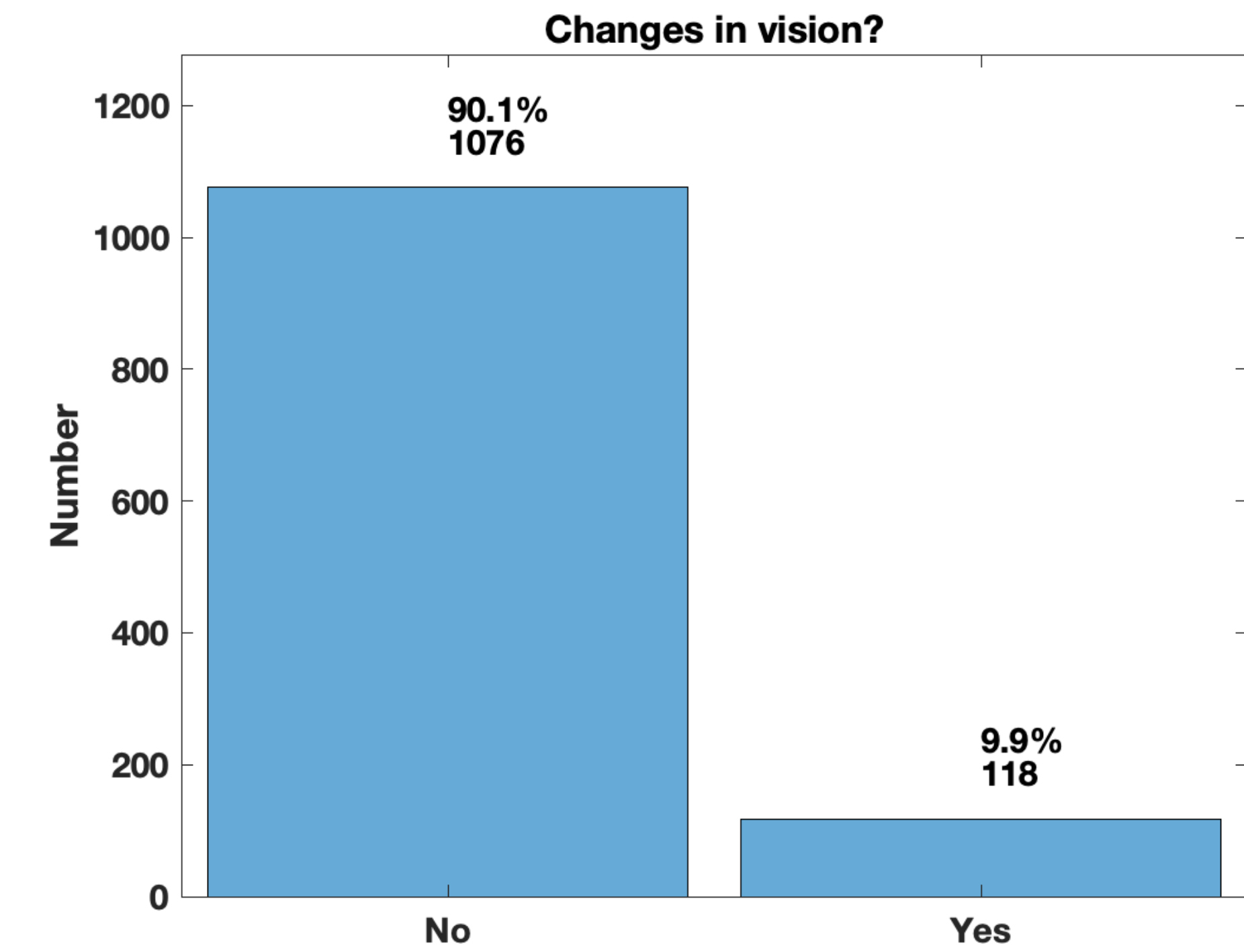
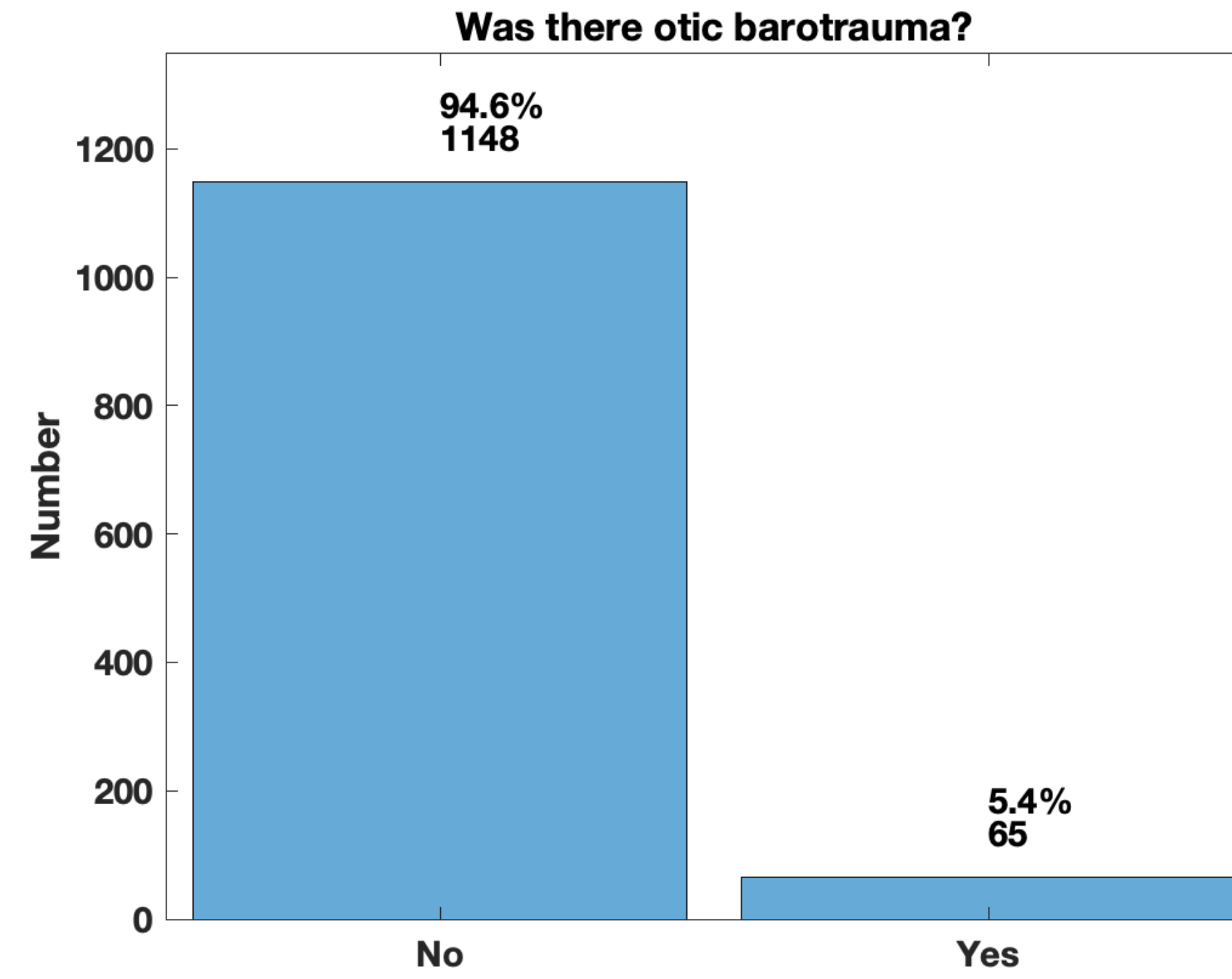
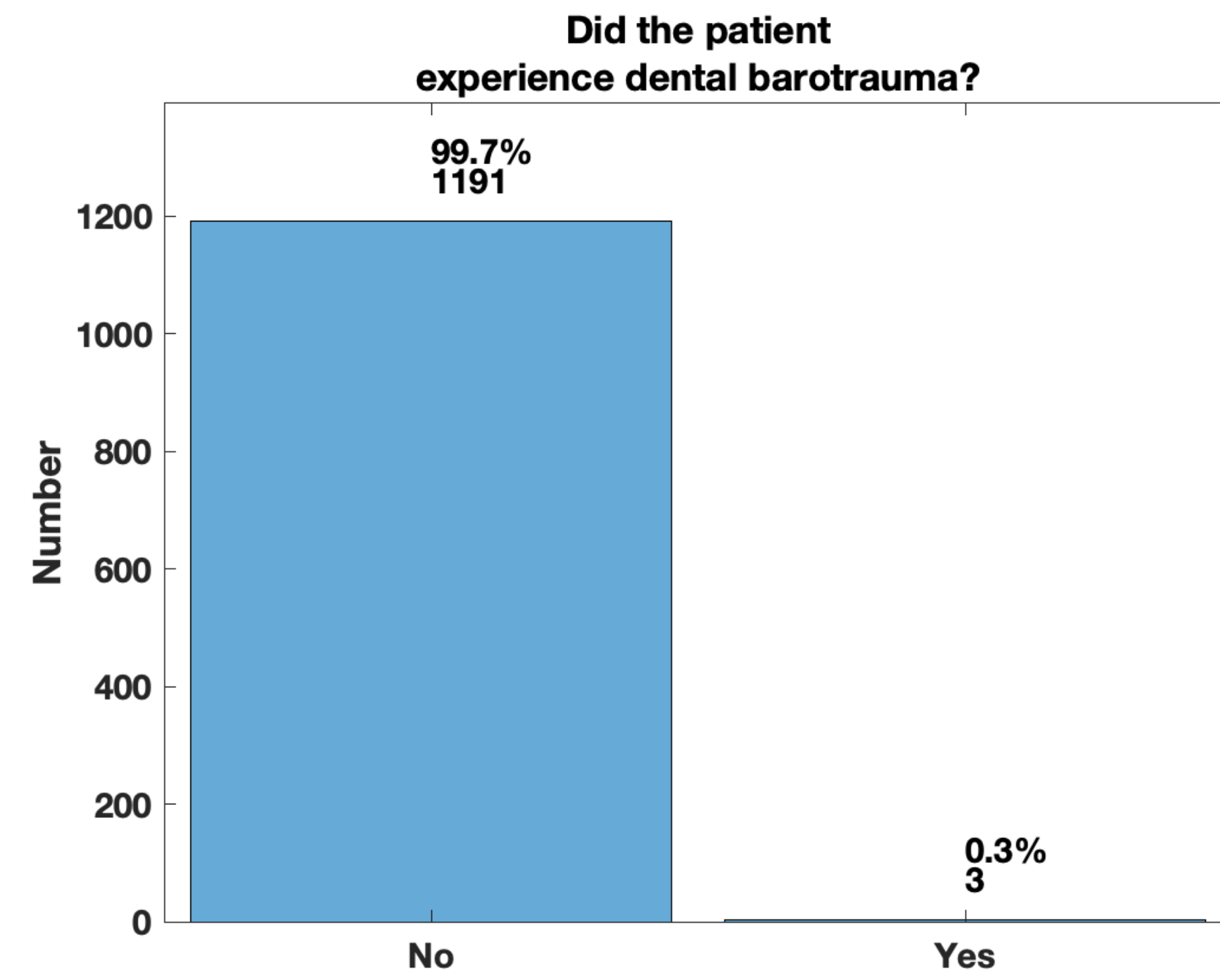
Figure 2. In 2022, delayed radiation injury was the most common reason for referral, followed by carbon monoxide poisoning and enhancement of healing in selected problem wounds. There was one referral for severe anemia in 2022.

# Complications

- Seven seizures were reported for 7 patients who started in 2022 (0.6%)
  - There was one seizure at 2.0 ATA, one at 2.4 ATA, 3 at 2.8 and two at 3.0 ATA
- Several reports of pulmonary edema/heart failure in chamber.



# Complications (continued)



# Outcome on HNDR “Dry Mouth” and HNSE “Senses” Scale from Head and Neck Questionnaire

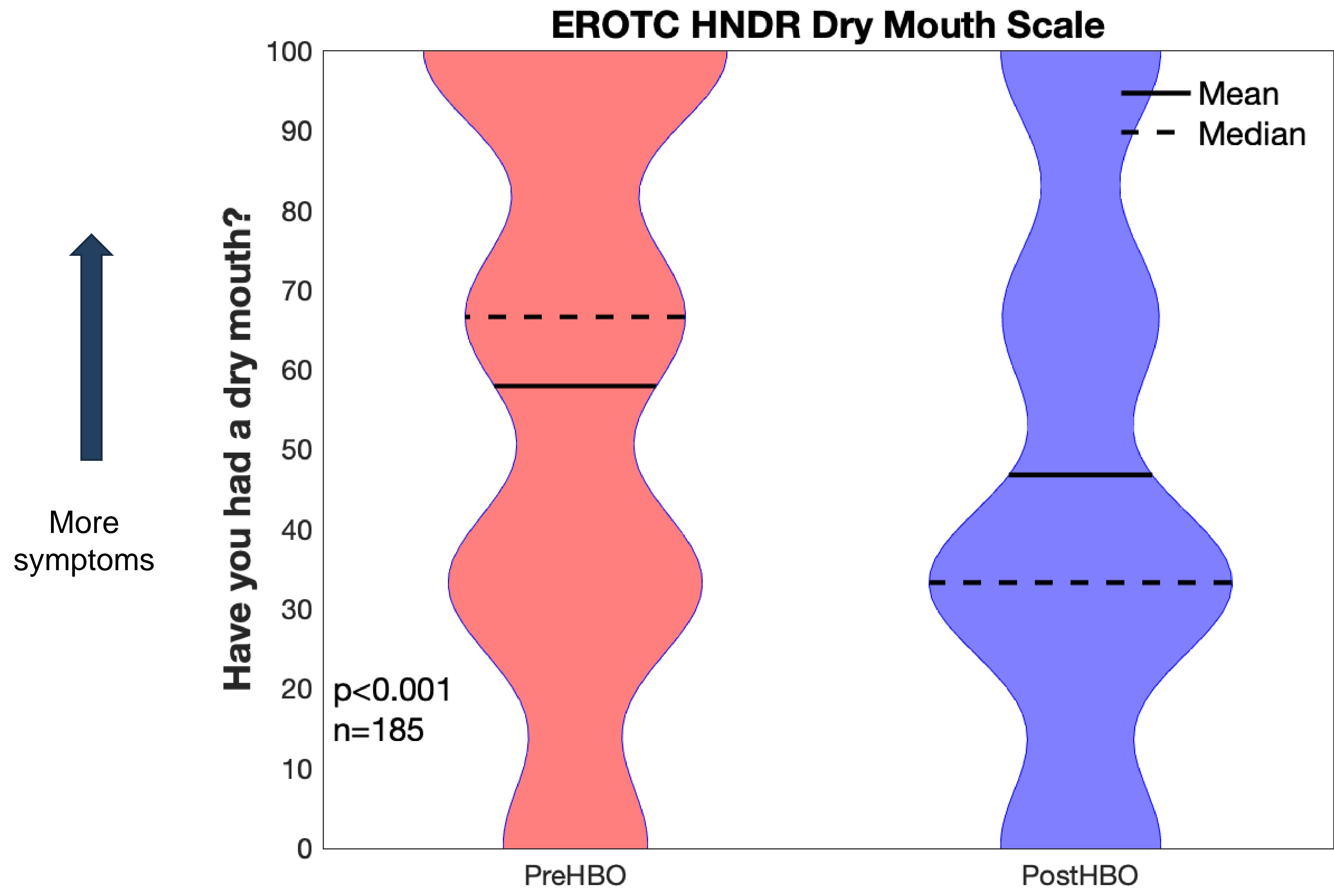


Figure 3. In patients with a history of head and neck radiation reported dry mouth decreased significantly after treatment. Higher values indicate more symptoms.

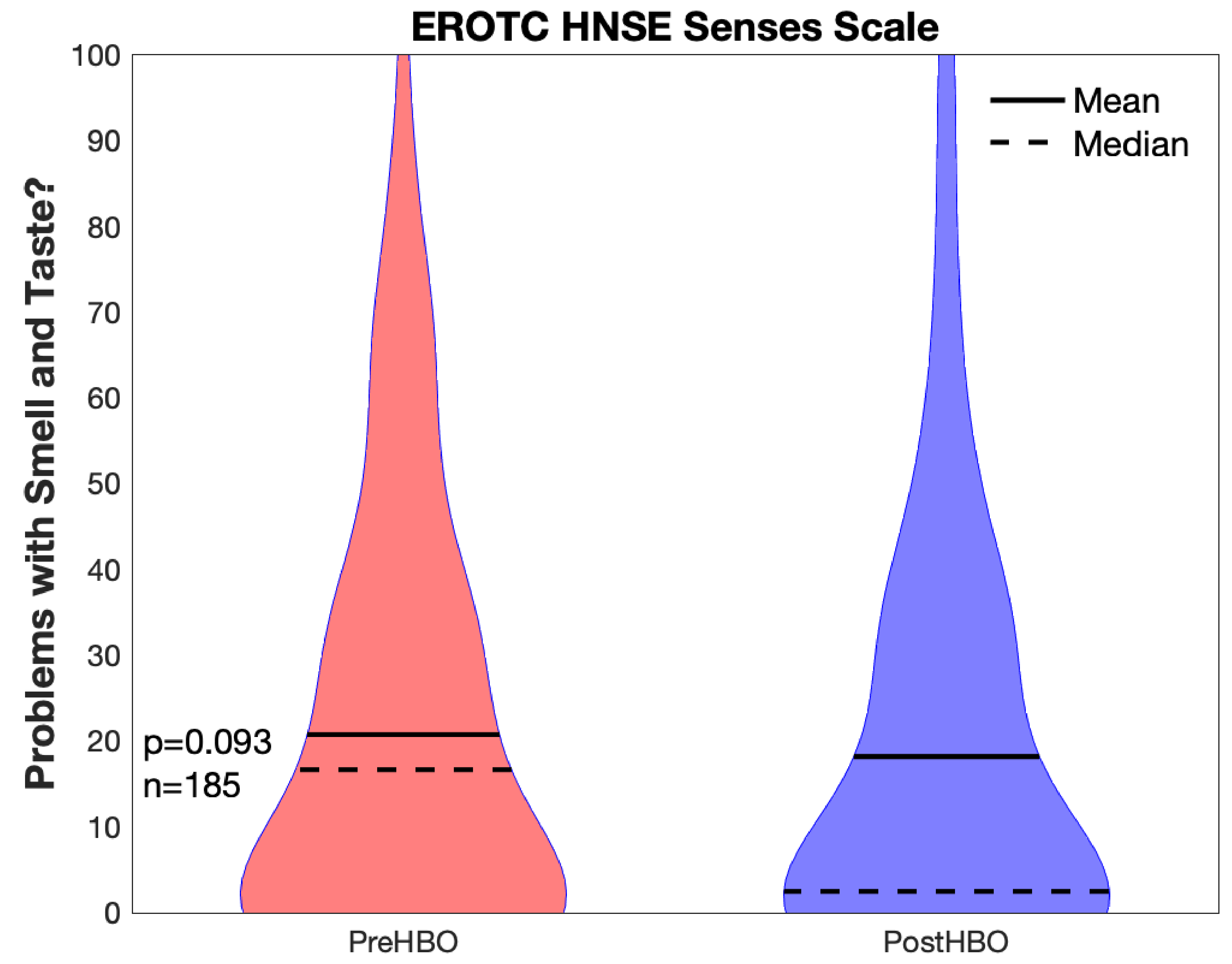


Figure 4. There was a trend for an improvement in smell and taste overall, this was significant when looking at just those who were reporting smell and test problems beforehand. Higher values indicate more symptoms.

## Challenges and Solutions for Registry

Disadvantage	Solution
Although free, REDCap requires IT support for installation, & some ongoing support	<ul style="list-style-type: none"><li>* Larger centers often have REDCap</li><li>* For others, offer de-identified data entry at DH</li><li>* In UK, King's College hosting multiple UK centers</li></ul>
REDCap is best used for relatively simple databases (not for complicated ones)	<ul style="list-style-type: none"><li>* We're focused on collecting simple data, so don't see this as a problem</li></ul>
Some validated questionnaires have big license fees	<ul style="list-style-type: none"><li>* We have chosen free questionnaires where possible; or developed new ones</li></ul>
Some centers collecting (or want to collect) different data	<ul style="list-style-type: none"><li>* Can add variables to the REDCap template that are not displayed at all sites</li></ul>
"But we don't have time to enter data!"	<ul style="list-style-type: none"><li>* You probably do! We deliberately made the database small: data entry takes only 15 minutes spread over all (often 40) patient visits</li></ul>



## Joining the Registry

1. Have your institution read the Consortium Agreement and sign a New Member Agreement
2. Obtain IRB approval (either use the Dartmouth IRB as the IRB of record or seek approval at your site)
3. Get REDCap access (either use REDCap at your site or use Dartmouth REDCap through a Data Use Agreement)

To link to the UHMS Registry Site for more information, scan:



## Contacts

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## Conclusions

- By using defined outcomes in an outcomes registry, patient results can be combined easily
- If multiple centers were to enter data using the same procedure 100's and even 1000's of patient outcomes could be combined to provide very powerful evidence on the use of hyperbaric oxygen therapy and allow for an analysis of factors that affect outcomes
- A registry approach is essential for emerging and rare indications (calciphylaxis, inflammatory bowel disease, pyoderma gangrenosum, Raynaud's) where no single center will be able to collect sufficient data for a low volume indication