

Multicenter Hyperbaric Outcomes Registry: 2020 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 non-approved, hyperbaric oxygen treatment indications. We have now accumulated sufficient patient encounters for some indications to show statistically significant changes in signs and symptoms before and after treatment.

Methods: 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 934 patient entries in the registry. Slide 3 shows the case mix for the program, with delayed radiation injury and enhancement of healing in selected problem wounds as the top two indications. The top non-UHMS indication currently is ulcerative colitis (Slide 3). Major findings include: a) Significant increase in self-reported quality of life on the EQ-5D-5L (Slide 4) b) Significant decrease in hematuria score for radiation cystitis (Slide 5) c) Significant decrease in patient reported dry mouth in those with head and neck radiation along with a significant improvement in overall head and neck symptoms (Slide 6) d) In patients with diabetic foot wounds the median percentage reduction in wound length was 53% and the average percentage reduction in width was 50% (Slide 7) e) Significant improvement in audiometry in patients treated for idiopathic sudden sensorineural hearing loss (Slide 7)

Summary

An outcomes registry offers a consistent method for collecting treatment results for patients with both UHMS-approved and emerging indications. Other centers have begun entering into this registry and once enrolled will periodically pool their de-identified data to provide larger datasets on outcomes. 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 amount of patients with any particular 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 is currently underway at 11 sites in the US and the UK

Methods

- Sample data entry screens shown on Slide 2.
- Registry built using the web-based data collection system REDCap.
- Standardized measures entered on all patients seen in hyperbaric program.
- Registry uses objective, patient-reported measures whenever possible to reduce bias.



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)
* must provide value Today M-D-Y

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

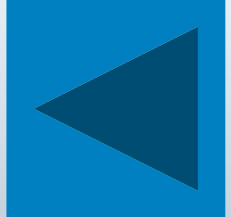
4. Do you experience small amounts of urine leakage (drops of urine)? Yes No reset

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

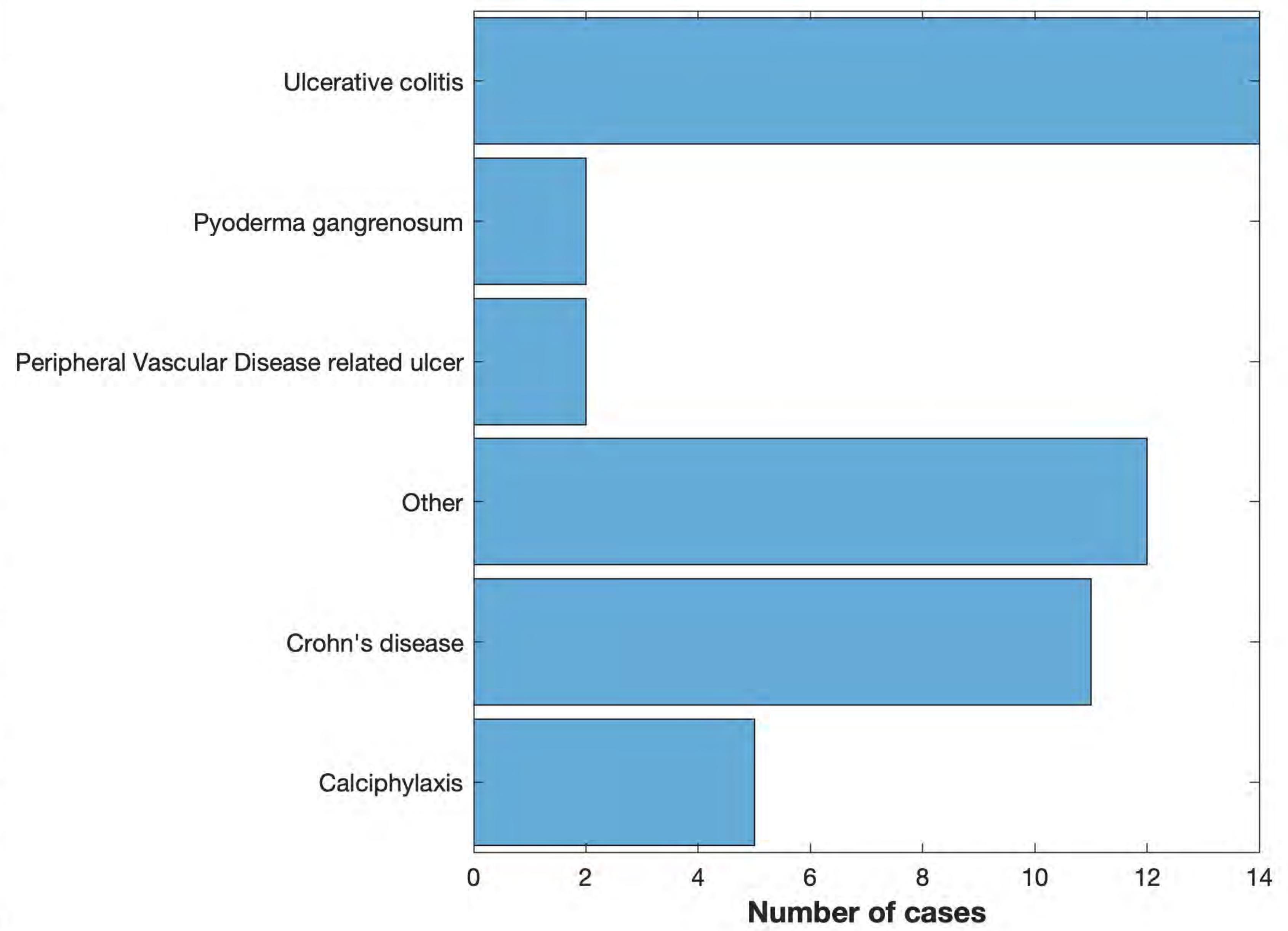
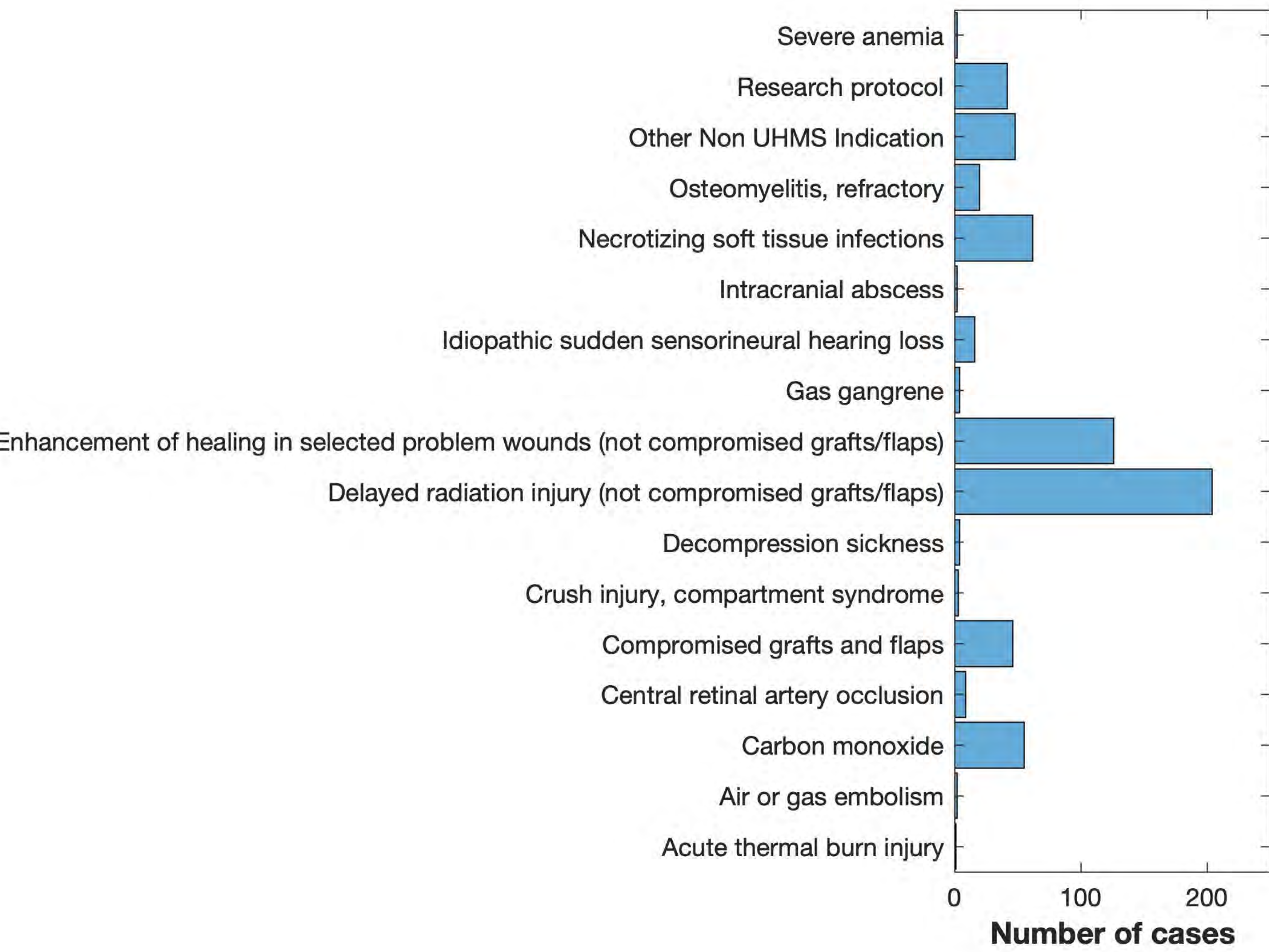
6. Do you usually experience pain or discomfort in the lower abdomen or genital region? Yes No reset

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.

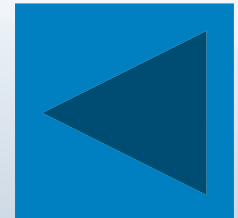


Numbers of cases in the HBO Registry, by indication

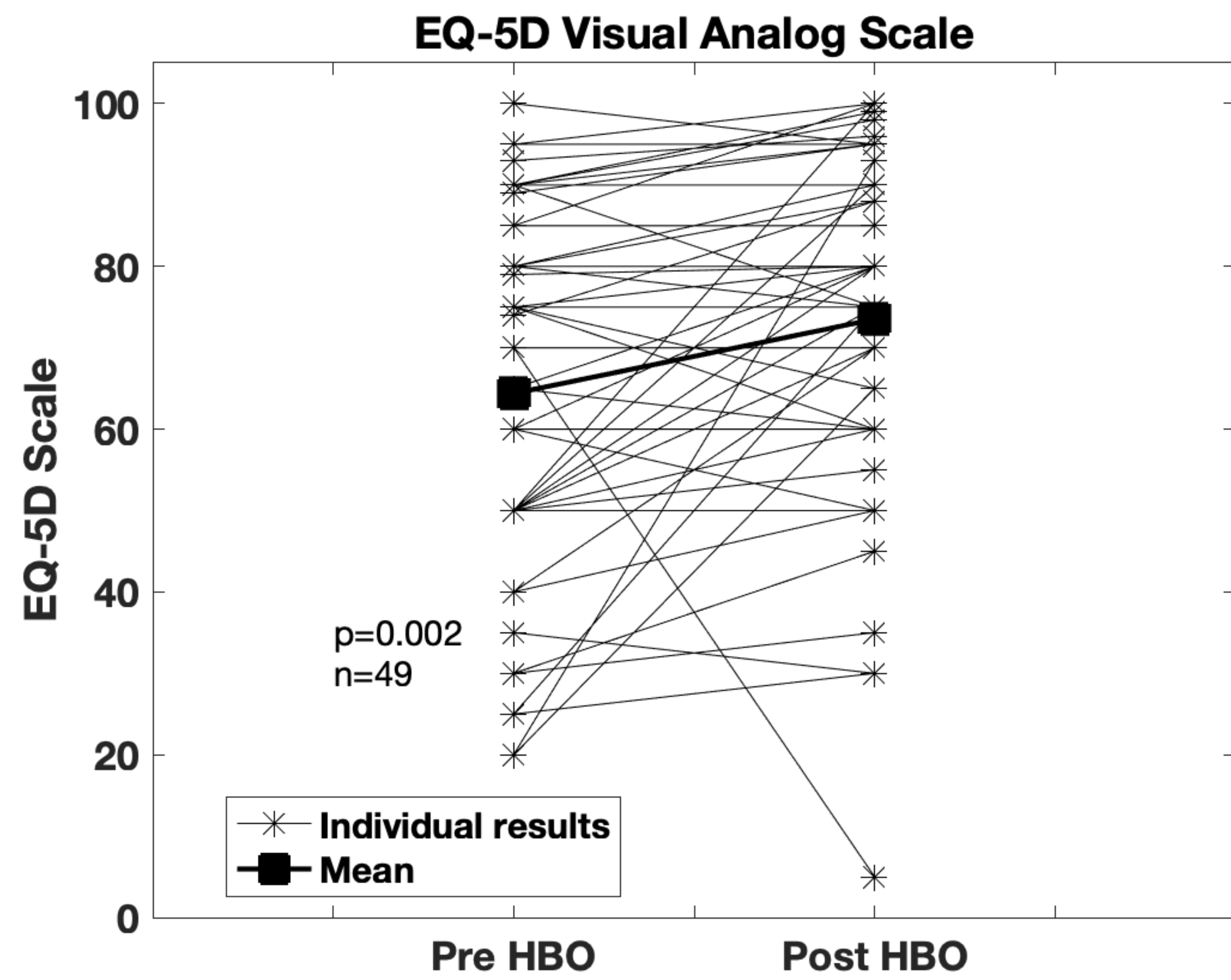


- Case mix for the program

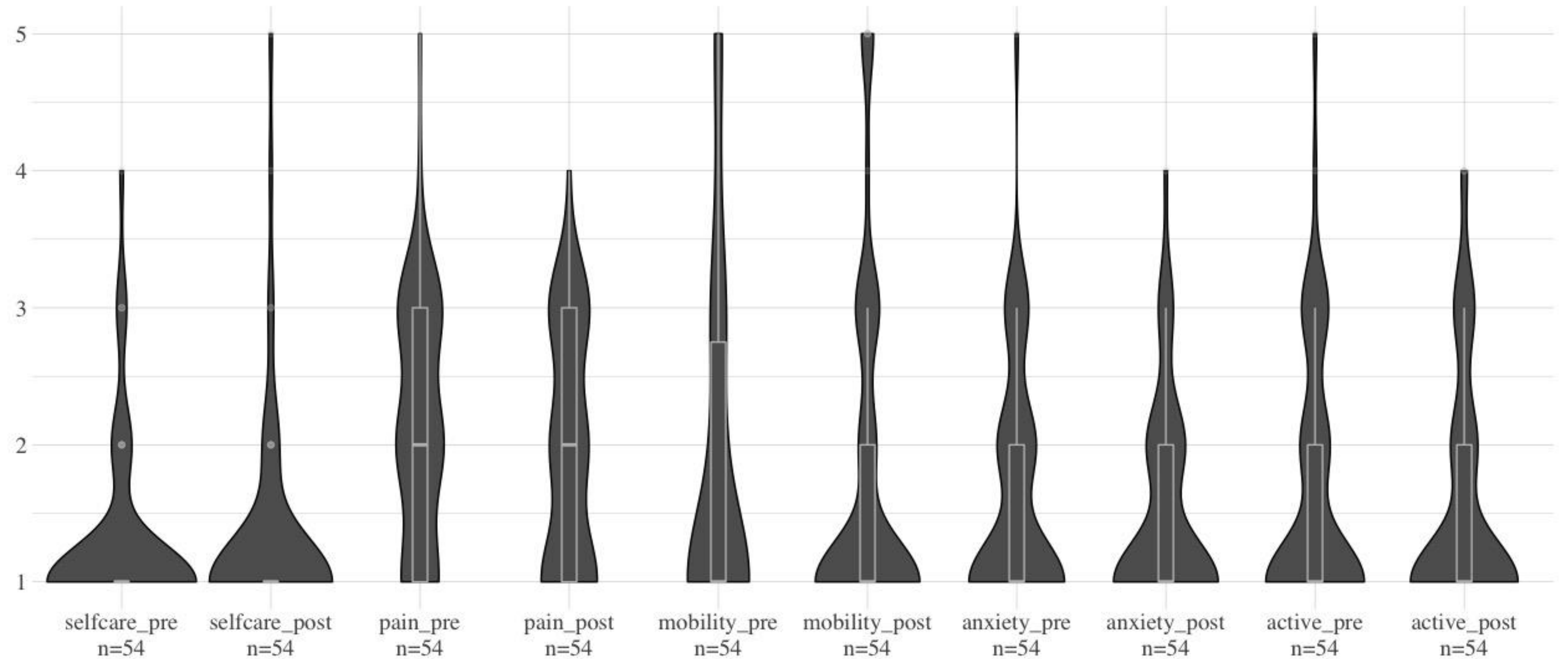
- Cases of non-UHMS approved indications



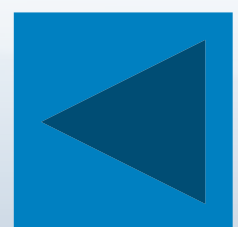
Results (Quality of Life)



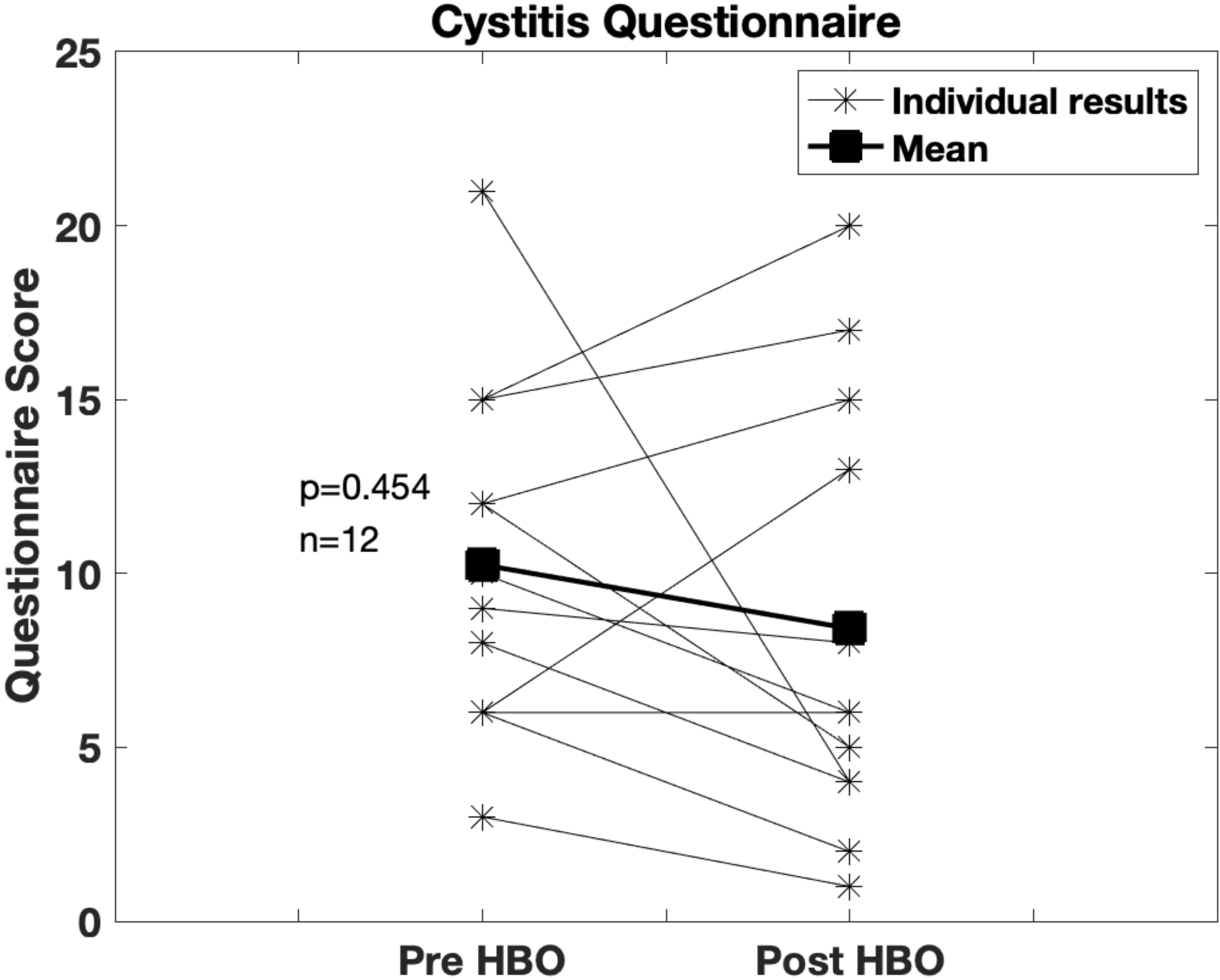
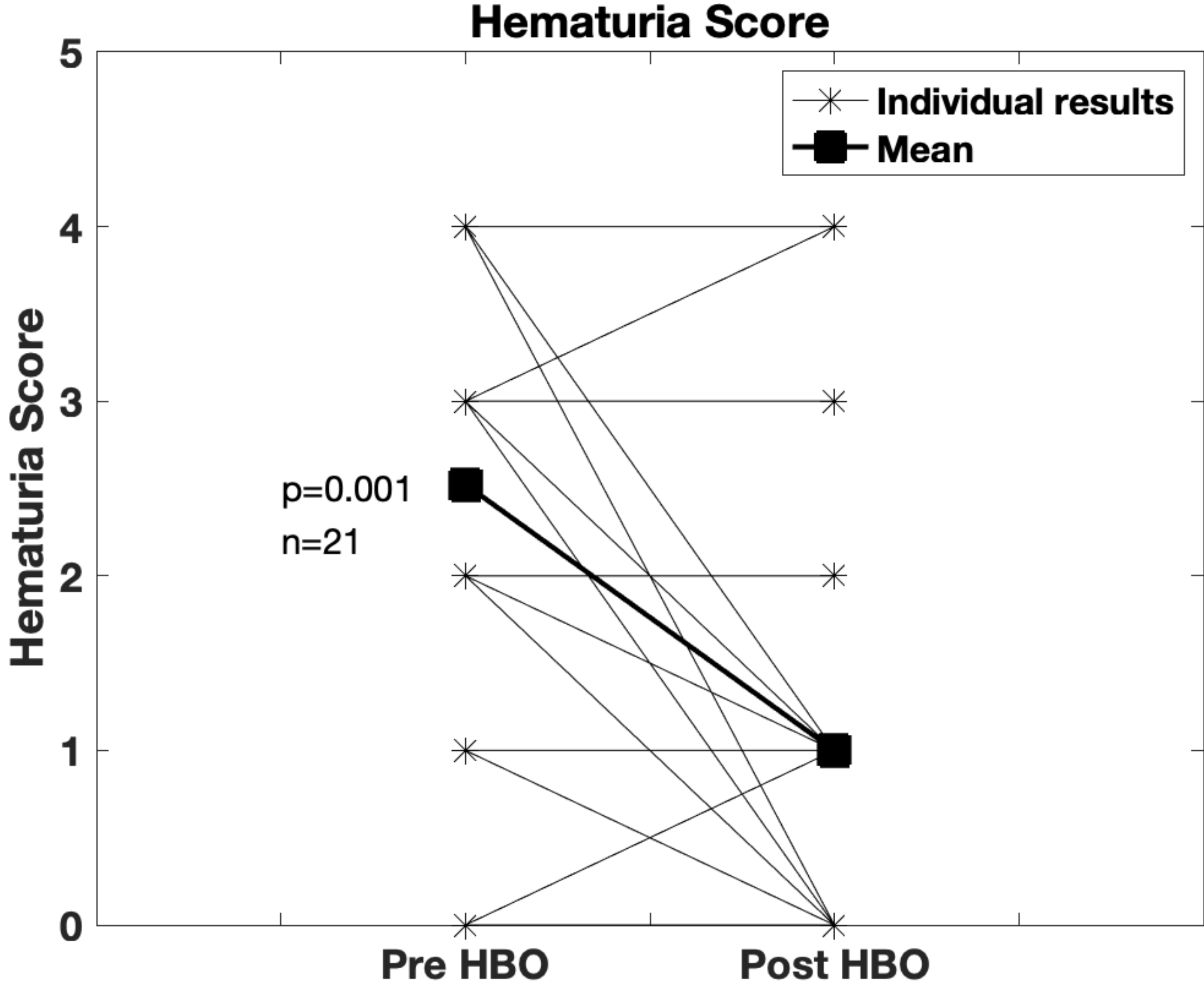
EQ5D Measures Pre/Post



- Results from the EQ-5D-5L quality of life instrument. The visual analog scale results (0=worst health, 100=best health) are on the left. The right shows the results from the individual subscales (1=best, 5=worst).



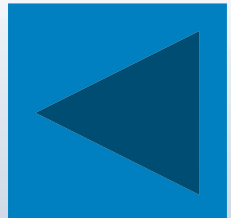
Results (Radiation Cystitis)



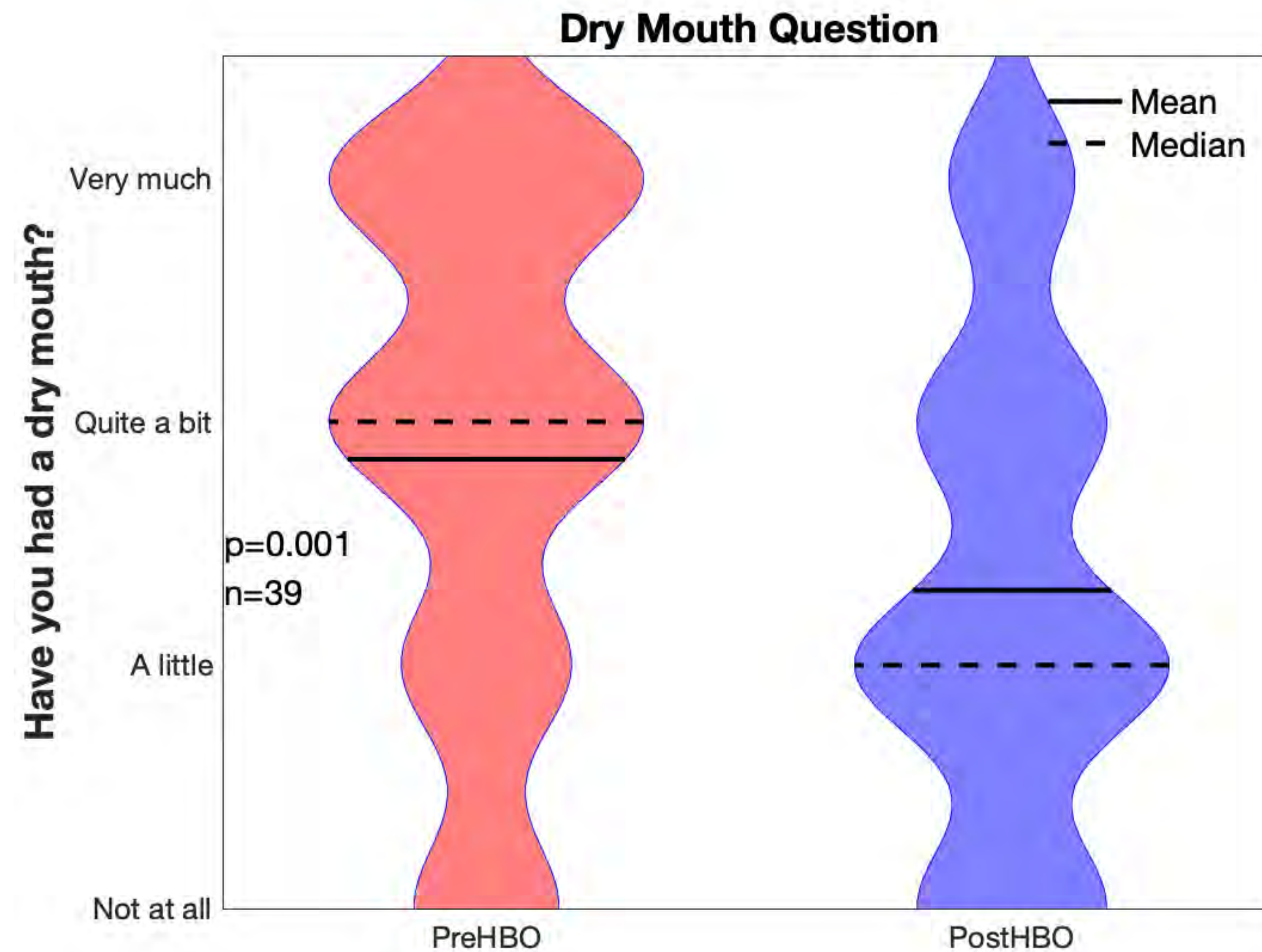
- 0 - No symptoms
- 1 - Microscopic hematuria
- 2 - Macroscopic hematuria
- 3 - Frequent macroscopic hematuria
- 4 - Severe hemorrhagic

- Continuous, integer scale based on 8 questions.
- From 0 (no symptoms) through 26 (maximum symptoms)

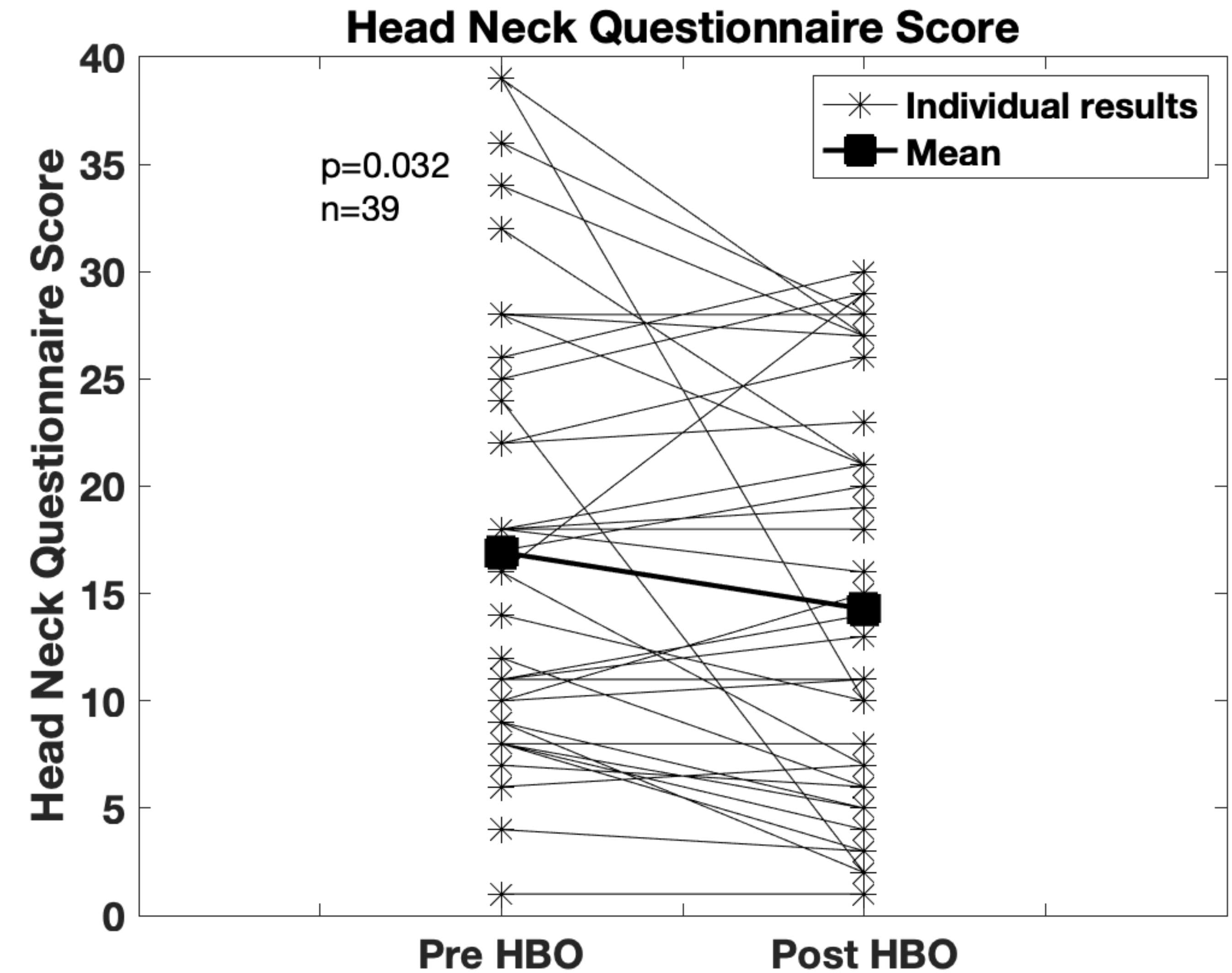
● With only 21 people the reductions in the hematuria score are highly significant. Responses to the cystitis questionnaire are variable.



Results (Head and Neck)



- 0 – Not at all
- 1 – A little
- 2 – Quite a bit
- 3 – Very much

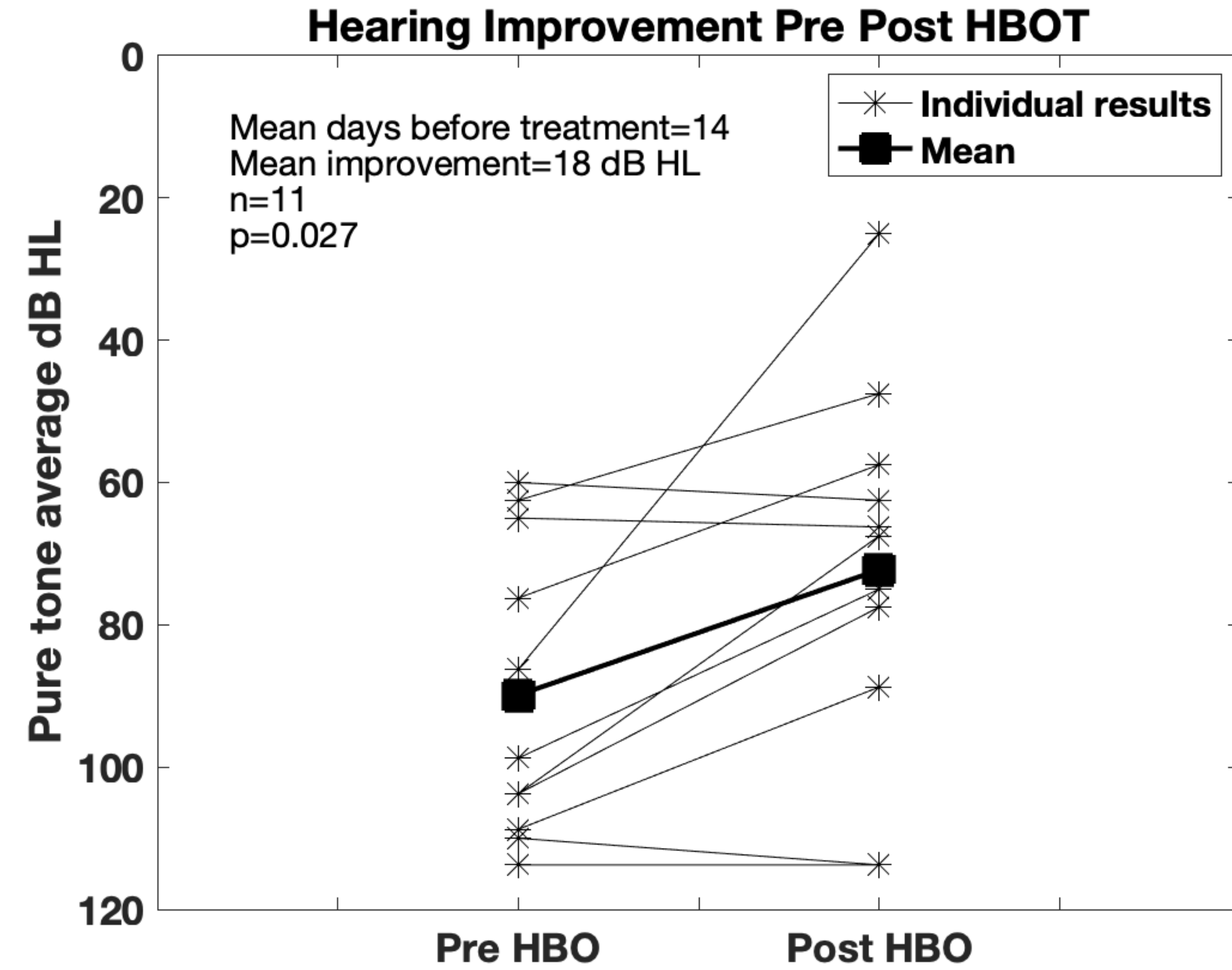
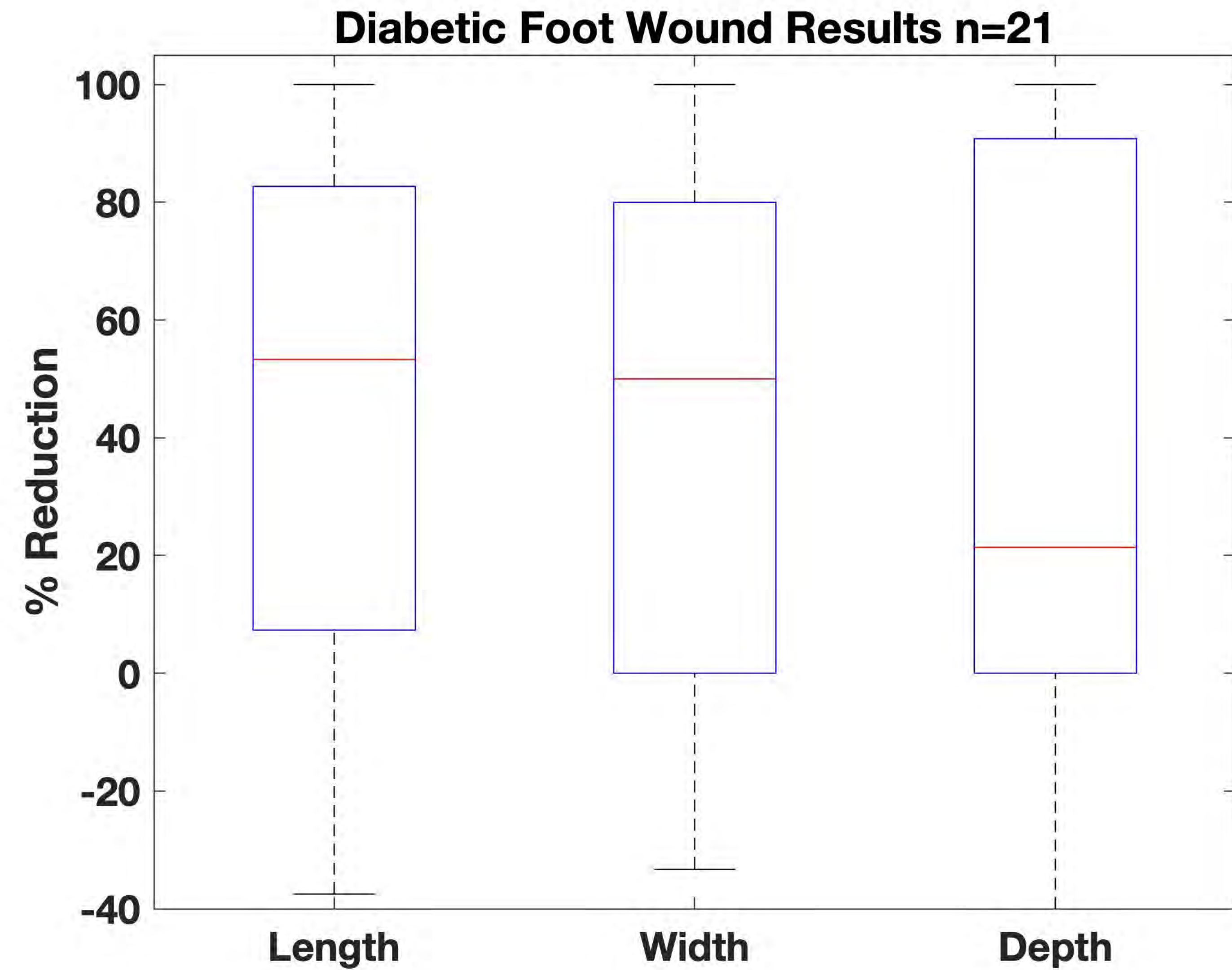


- Continuous, integer scale based on 26 questions.
- From 0 (no symptoms) through 68 (maximum symptoms). Asks about pain, swallowing, dry mouth, taste, cough, hoarseness.

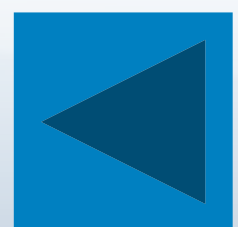
- Response to the “dry mouth” question showing a significant improvement (left). Responses to the head and neck questionnaire are significantly lower after treatments (right).



Results (Diabetic Foot Wounds and ISSNHL)



- In patients with diabetic foot wounds the median percentage reduction in wound length was 53% and the median percentage reduction in width was 50% (left).
- Patients with idiopathic sudden sensorineural hearing loss show improvements in audiometry (right).



Challenges and Solutions for Registry

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



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Conclusions

- By using defined outcomes in an outcomes registry, patient results can be combined easily.
- Significant results on some measures are already apparent due to the consistent data collection procedures.
- 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.
- 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 particular indication.

