



**VENOLYMPHATIC MALFORMATION** in a 4 year old  
male treated with **PICIBANIL (OK-432)**  
with **SYSTEMIC INFLAMMATORY RESPONSE SYNDROME**  
as a complication

A CASE REPORT

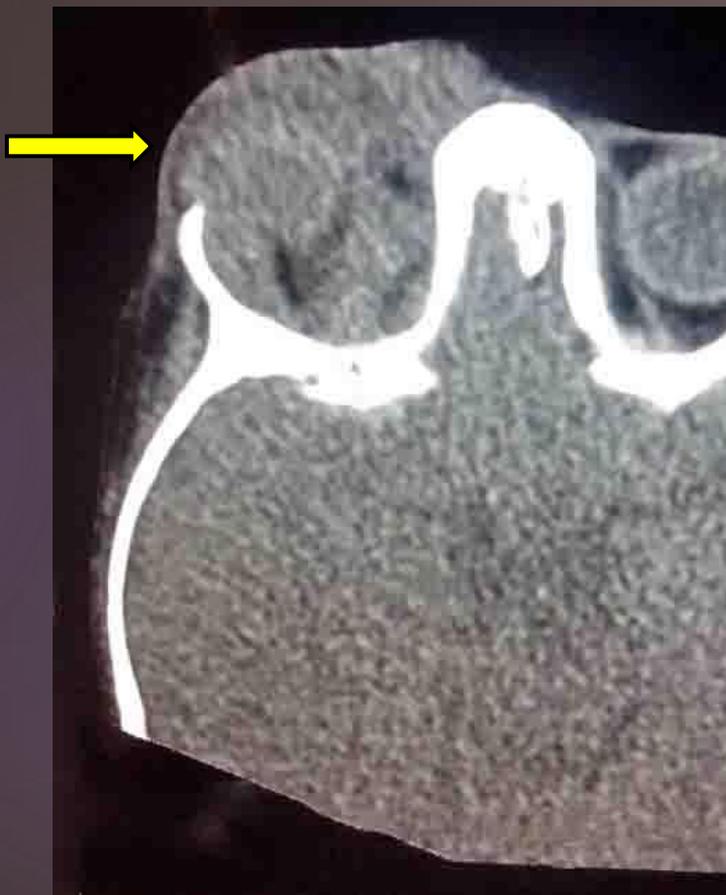
PADUA, PAULA FRANCESCA C.

# OBJECTIVES

- ▶ To present a **case of venolymphatic malformation** & OK-432 as its management
- ▶ To discuss the **mechanism of action** of OK-432
- ▶ To discuss the known **complications** of OK-432



# CT SCAN



# Injection of OK-432



**Before  
Therapy**



**1 Day  
Post-Therapy**



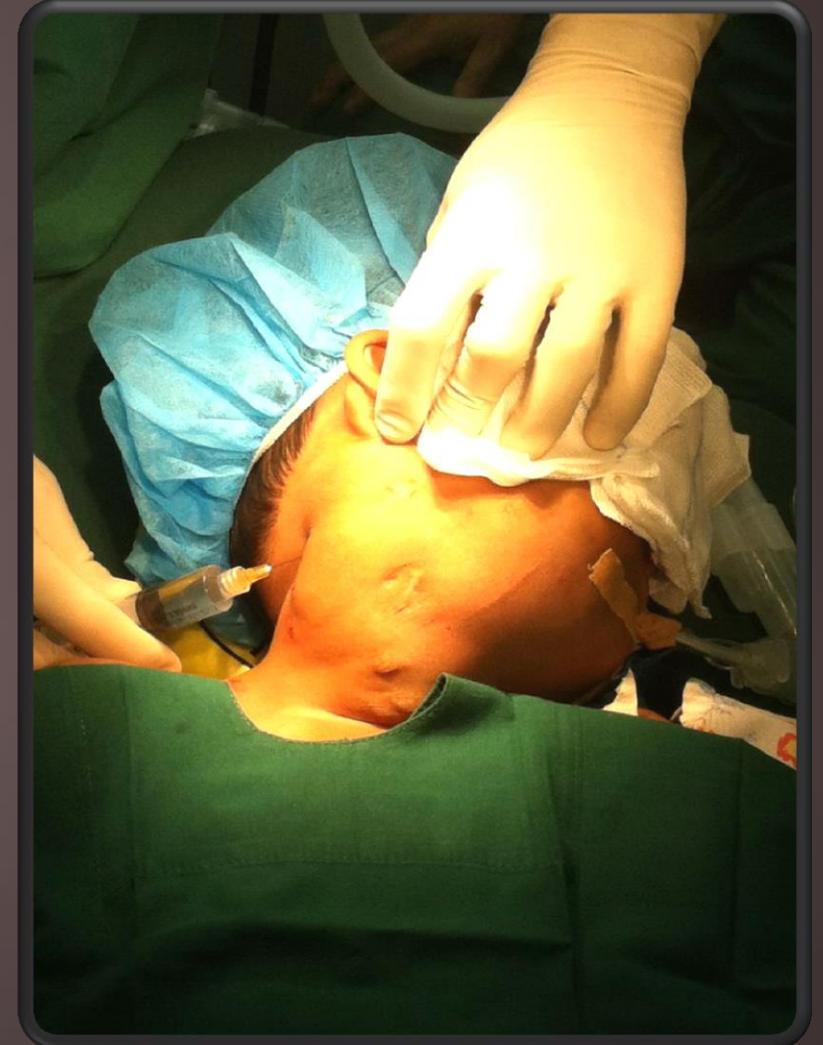
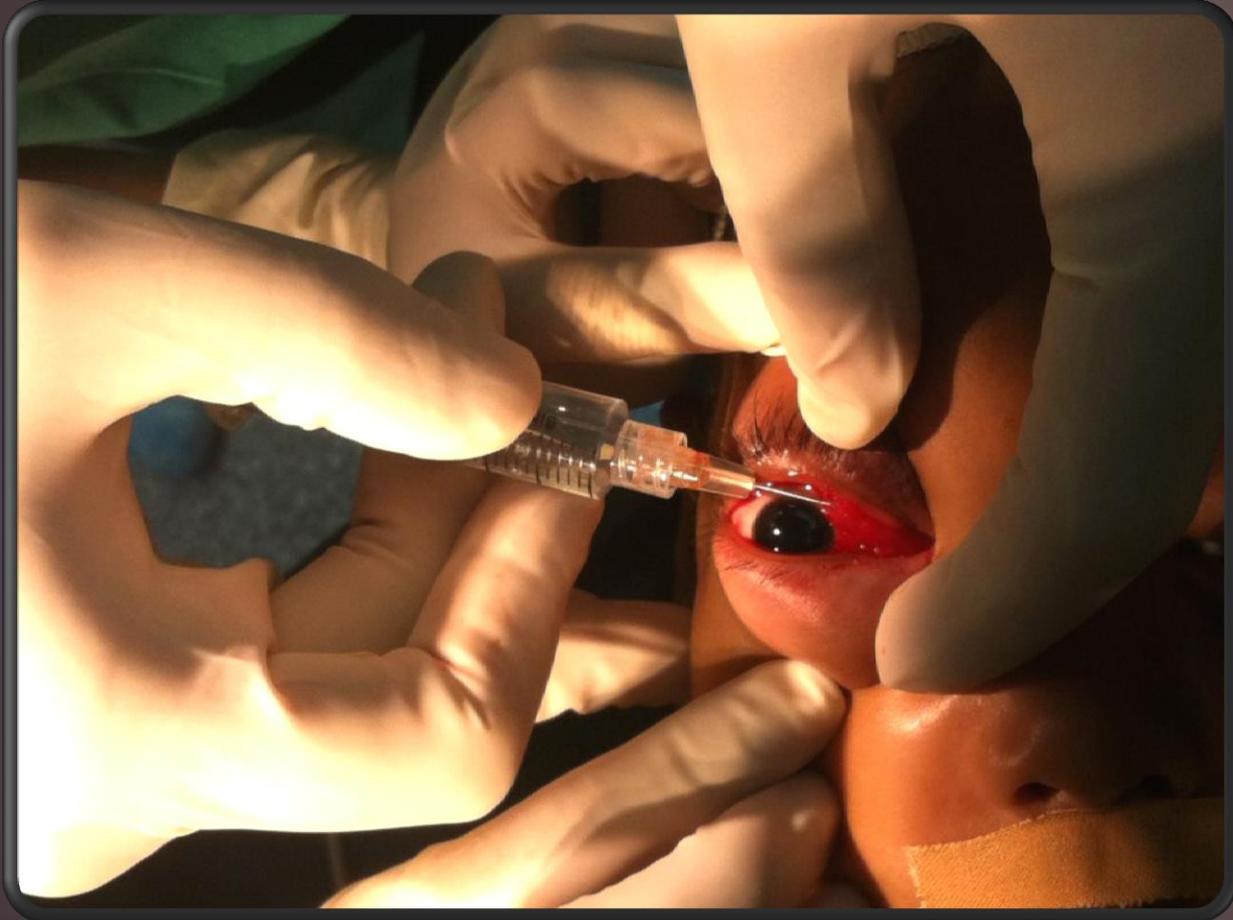
**2 Mos  
Post-Therapy**



**3 Mos  
Post-Therapy**



# 2<sup>nd</sup> Injection of OK-432





**Respiratory  
distress**

**Hypotensive  
episodes**

**Decreased  
sensorium**

# Sepsis?

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Equivocal  
Serum Pro-Calcitonin

Negative Cultures:

ETA

Urine

Blood

CSF

= Not Sepsis

# Anaphylaxis?

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Elevated

IgE

Hours after event:

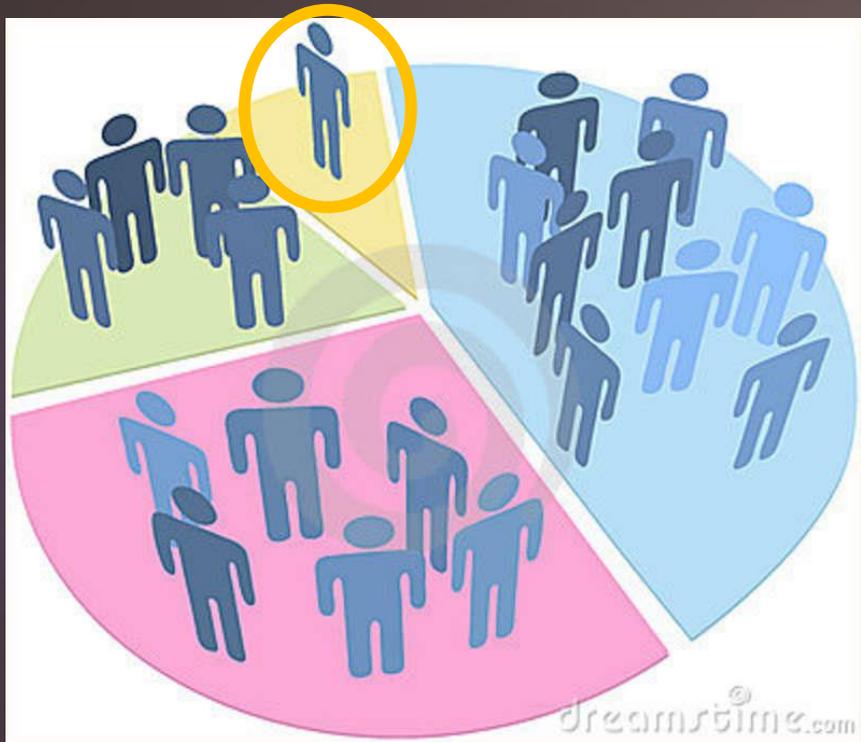
>24 Hours

= Not Anaphylaxis

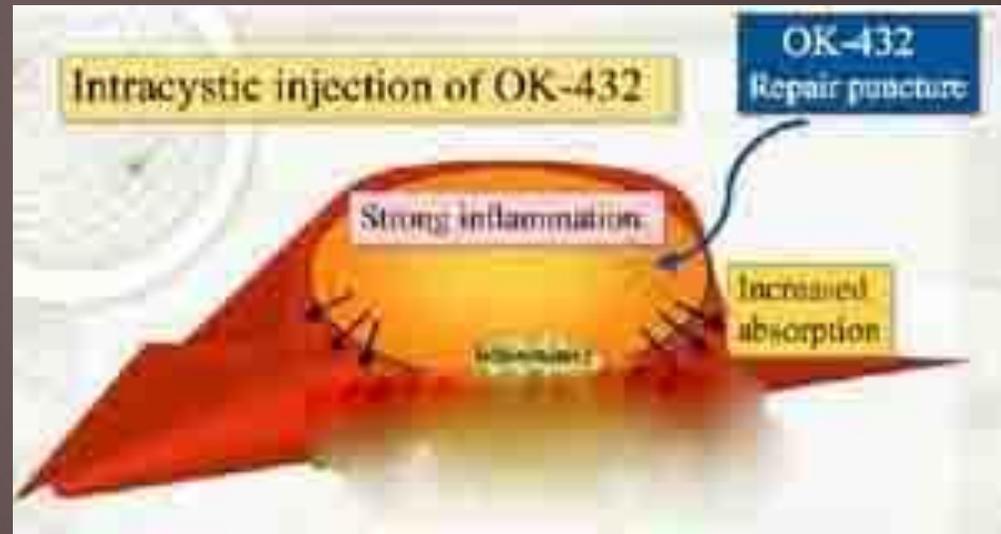


*So what is it then?*

# Venolymphatic Malformation



# OK-432 (PICIBANIL)



# COMPLICATIONS

- ▶ Local inflammatory reaction
- ▶ Fever

# SERIOUS SIDE EFFECTS

## ~~► Hypopharyngeal edema~~

The first serious side effect encountered with OK-432, which is soft tissue swelling after **Dexamethasone** hypopharyngeal edema with swallowing problems.

Laranne, et al

## **Intubation**

...15% of all children reviewed required a tracheostomy tube.

Boardman, et al

# SERIOUS SIDE EFFECTS

- ~~▶ Hypopharyngeal edema~~
- ~~▶ Systemic Immunomodulatory Response~~

*Injections induce systemic immunomodulatory responses with sepsis-like, life threatening*

**Ultrasound Guidance**

**Check for backflow**

*this would*

*Bittmann, et al*



# SERIOUS SIDE EFFECTS

- ▶ ~~Hypopharyngeal edema~~
- ▶ ~~Systemic Immunomodulatory Response~~
- ▶ ~~Anaphylaxis~~

Other potential risks include hypersensitivity to either the bacteria-derived protein or **Skin Test** within the preparation (used for bacterial breakdown). That is why hypersensitivity to penicillin must be ruled out before treatment... These kinds of complications would all develop within a few hours after Picibanil injections.

Bittmann, et al

# ~~Lymphocytopenia...~~

## ▶ Another possible cause?

*Patients with large abscesses often have low numbers of bacteria, making them at risk for bacterial dissemination secondary to reduced immunomodulatory response.*

**Procalcitonin = Equivocal**, et al

# Systemic Inflammatory Response Syndrome?

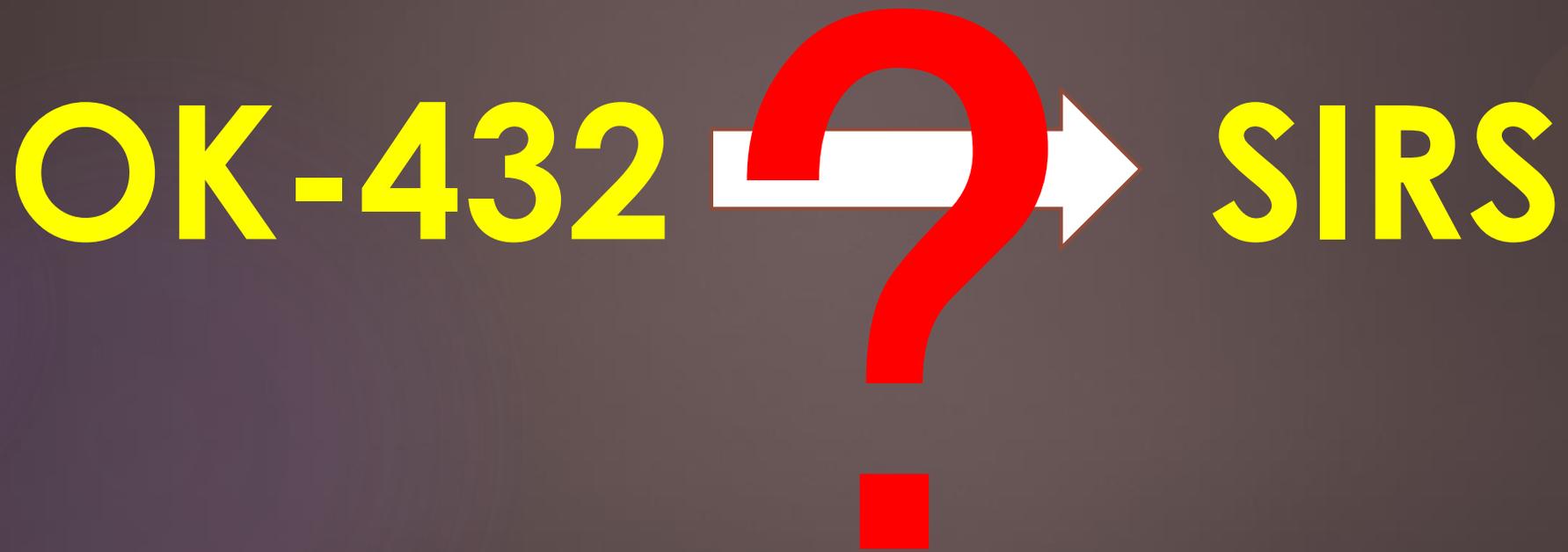
**Table 1** Definitions associated with the SIRS (adapted from Bone *et al.*, 1992)

## *SIRS*

The systemic inflammatory response to a variety of severe clinical insults. Manifested by two or more of the following:

- (1) body temperature  $>38^{\circ}\text{C}$  or  $<36^{\circ}\text{C}$ ,
- (2) heart rate  $>90$  beats per minute,
- (3) tachypnoea: respiratory rate  $>20$  breaths per minute or  $\text{PaCO}_2 <4.3$  kPa (or 32 mmHg),
- (4) white blood cell count  $>12\,000/\text{mm}^3$  or  $<4000/\text{mm}^3$  or  $>10\%$  immature bands.

These changes should represent an acute change from baseline and be unexplained by other causes.



# Conclusion

- ▶ OK-432 showed promising results of regression of malformations in published literature.
- ▶ We are presented with a case of SIRS after OK-432 use.
- ▶ Further studies are recommended to establish if there is an association between SIRS and OK-432 use.

**Thank You!**