Drug hypersensitivity: from pathogenesis to correct diagnosis

DIDIER EBO

UZ ANTWERPEN

JAN PALFIJN GENT

Content

- Key messages
- Adverse drug reactions (classification)
- Pathogenesis (Gell and Coombs)
- Clinical presentation
- Diagnostic work-up
- Added value of a WAO COE

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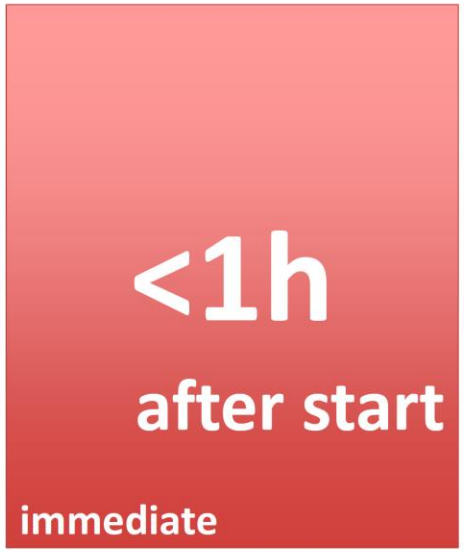

Key messages

- *Nomen est omen*
- *Post hoc, ergo propter hoc*

- Different mechanisms >
- Different clinics >
- Different diagnostics &
- Different "therapeutics"

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Key messages: correct description!

“RASH”

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Not all drug hypersensitivity reactions are drug allergies!
(and can therefore be tested)

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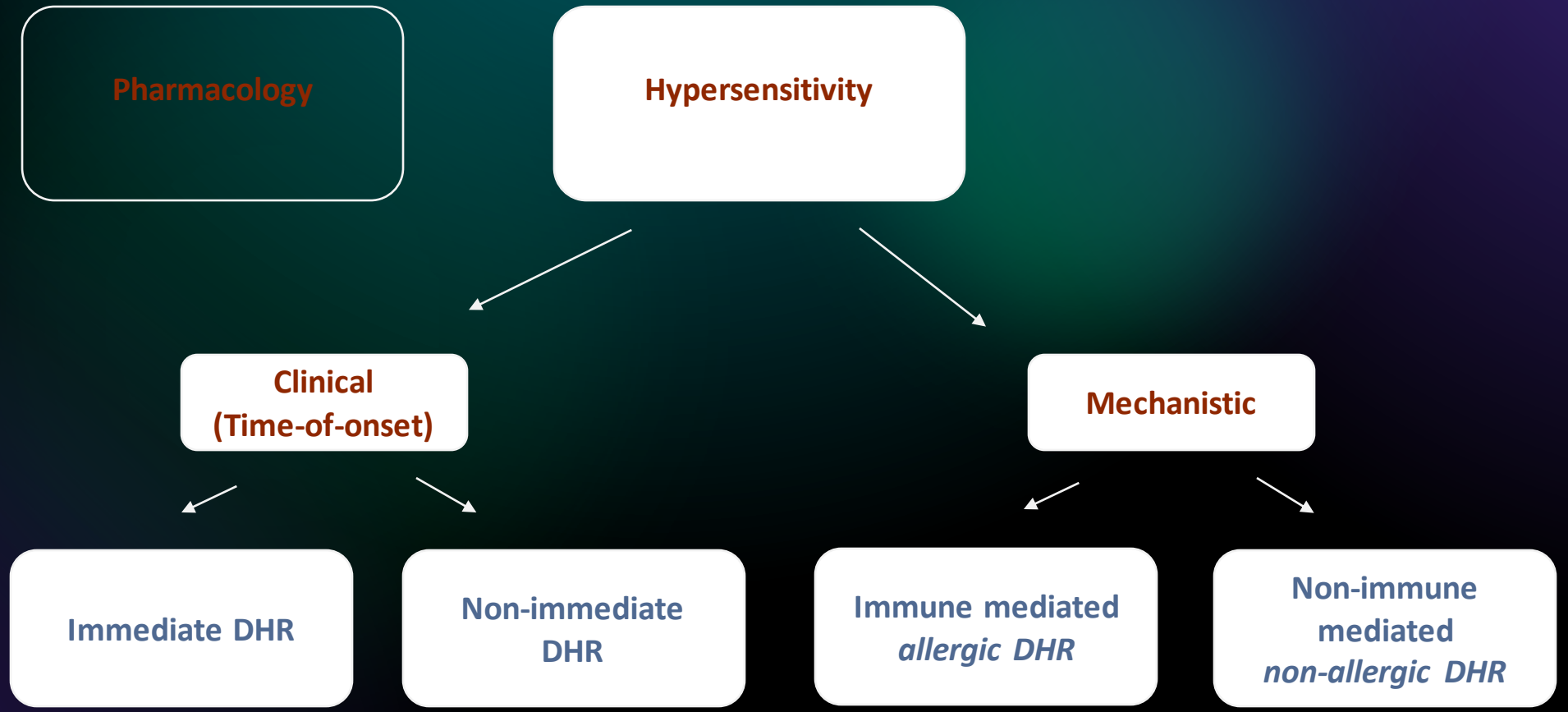
DHRs: classification



DHR: drug hypersensitivity reactions

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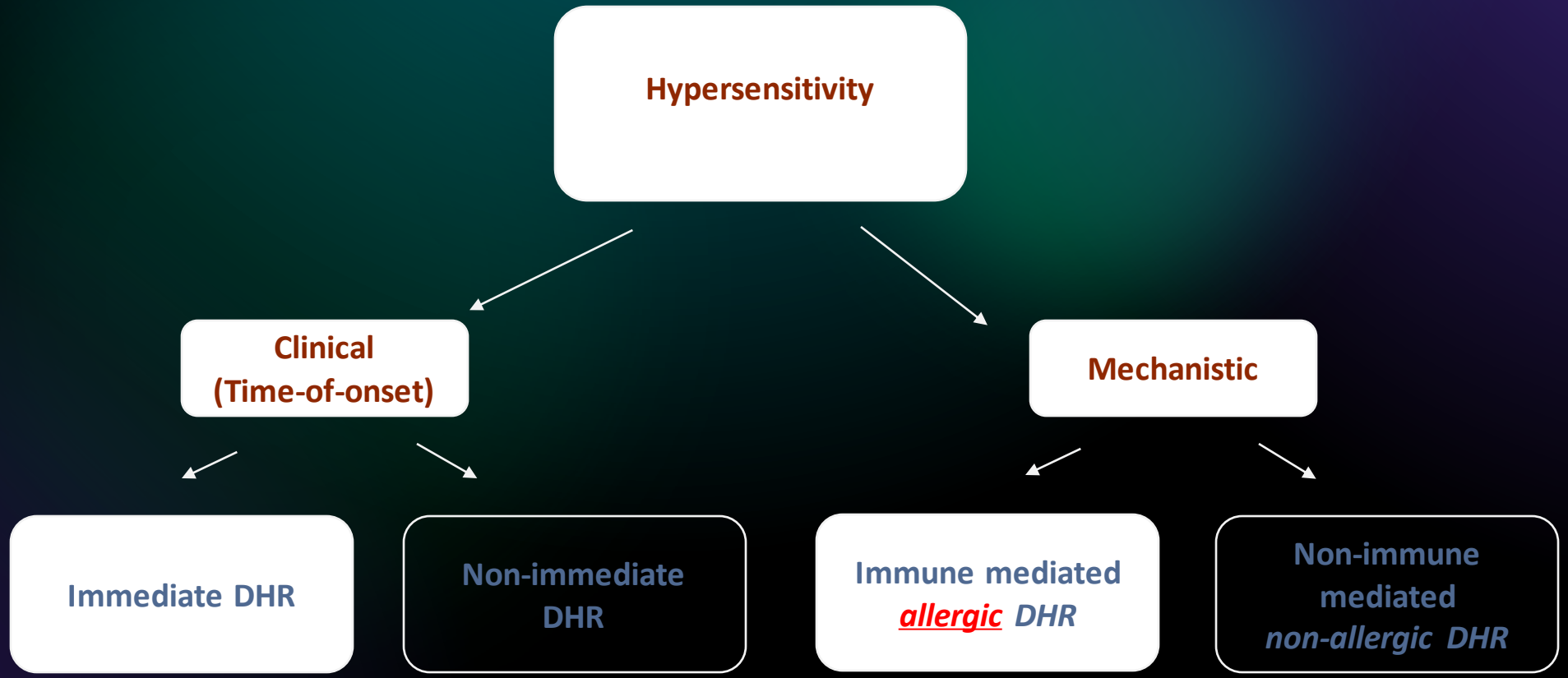
IDHRs: mechanisms – MC/(B)



IDHR: immediate drug hypersensitivity reactions

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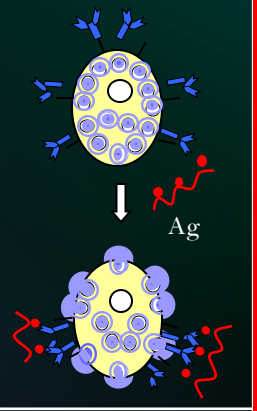
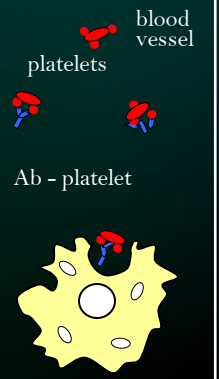
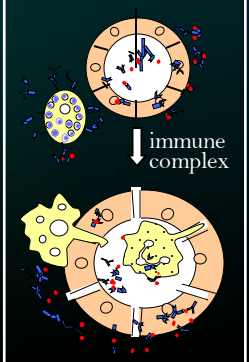
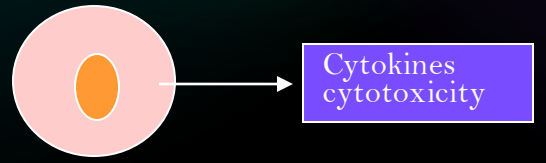
Drug allergies: classification – I (IgE)

	Type I	Type II	Type III	Type IV
Immune reactant	**IgE**	**IgG**	**IgG**	T cell
Antigen	Soluble antigen	Cell- or matrix-associated antigen	Soluble antigen	MHC-presented antigen
Effector	Mast-cell activation	FcR+ cells (phagocytes, NK cells)	FcR+ cells Complement	T-cells, via cytokines recrutement of monocytes, eosinophils, neutrophils(?)
				
Clinical picture	Urticaria, Angioedema, Bronchospasm, Cardiovascular collapse, Anaphylaxis	Hemolytic anemia, Thrombocytopenia, Petechia	Small-vessel vasculitis, Serum sickness, Arthus reaction	Maculopapular exanthema, DRESS, SJS-TEN, AGEP

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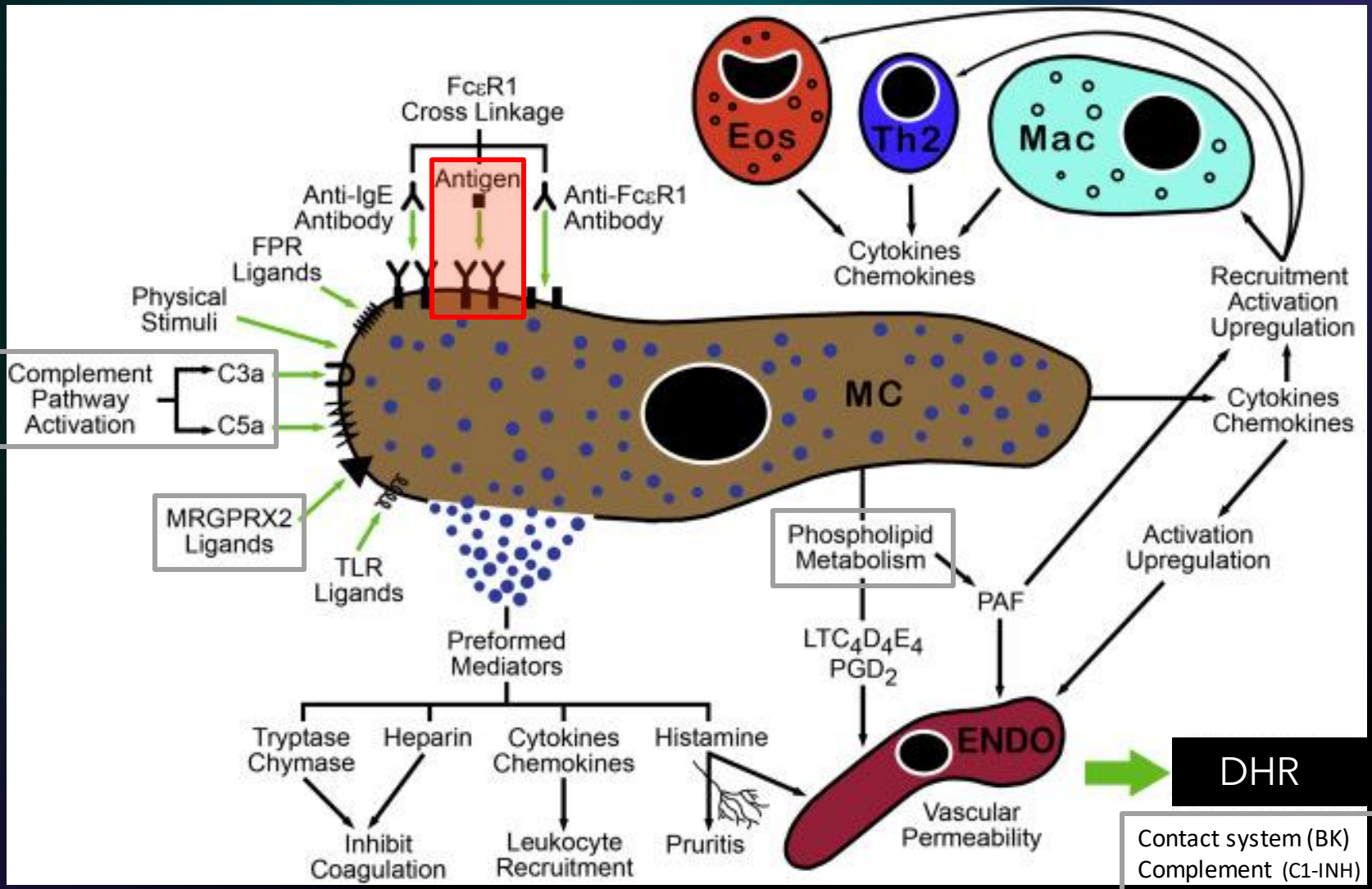
IgE



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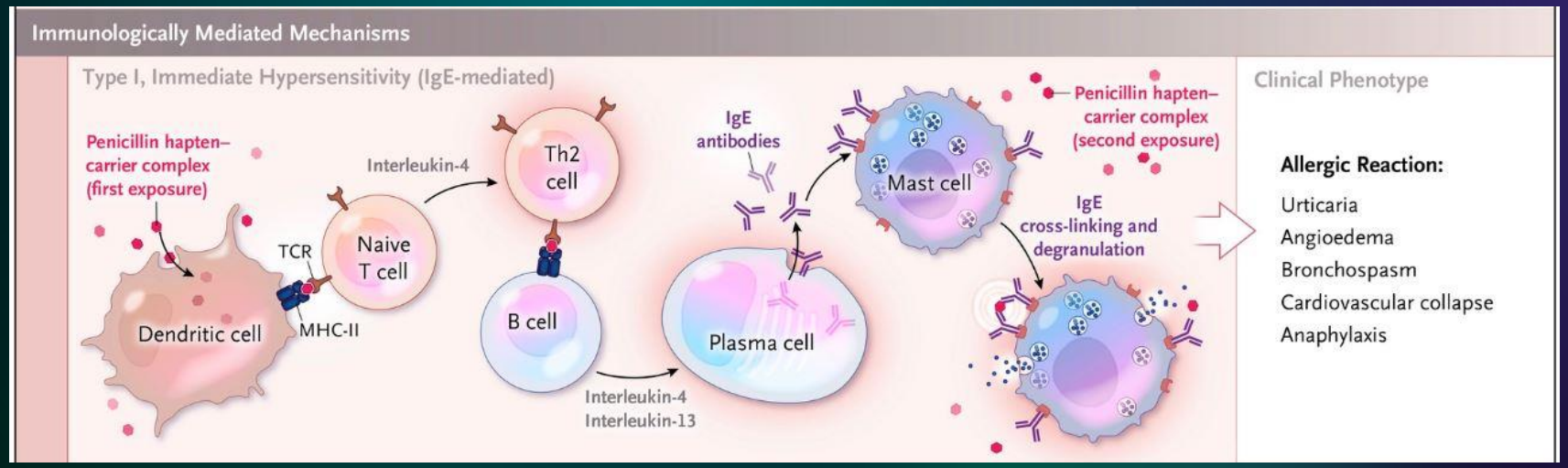

<u>Phase I</u>: Asymptomatic sensitization
Specific Th2 and B cell activation
(route, source can be obscure – cross-reactivity)

<u>Phase II</u>: Symptomatic elicitation > IDHR
MC and basophil degranulation

Diagnosis: sIgE, skin tests, BAT, pMAT, DPT

sIgE: specific IgE / ratio
BAT: basophil activation test
pMAT: passive mast cell activation test
DPT: drug provocation test

Castells M, NEJM 2019

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Anaphylaxis is highly likely when any one of the following three criteria is fulfilled:

1 Sudden onset of an illness (minutes to several hours), with involvement of the skin, mucosal tissue, or both (e.g. generalized hives, itching or flushing, swollen lips-tongue-uvula)

AND AT LEAST ONE OF THE FOLLOWING:

Sudden respiratory symptoms and signs (e.g. shortness of breath, wheeze, cough, stridor, hypoxemia)

Sudden reduced BP or symptoms of end-organ dysfunction (e.g. hypotonia [collapse], incontinence)

OR **2** Two or more of the following that occur suddenly after exposure to a *likely allergen or other trigger* for that patient* (minutes to several hours):

Sudden skin or mucosal symptoms and signs (e.g. generalized hives, itch-flush, swollen lips-tongue-uvula)

Sudden respiratory symptoms and signs (e.g. shortness of breath, wheeze, cough, stridor, hypoxemia)

Sudden reduced BP or symptoms of end-organ dysfunction (e.g. hypotonia [collapse], incontinence)

Sudden gastrointestinal symptoms (e.g. crampy abdominal pain, vomiting)

OR **3** Reduced blood pressure (BP) after exposure to a *known allergen** for that patient* (minutes to several hours):

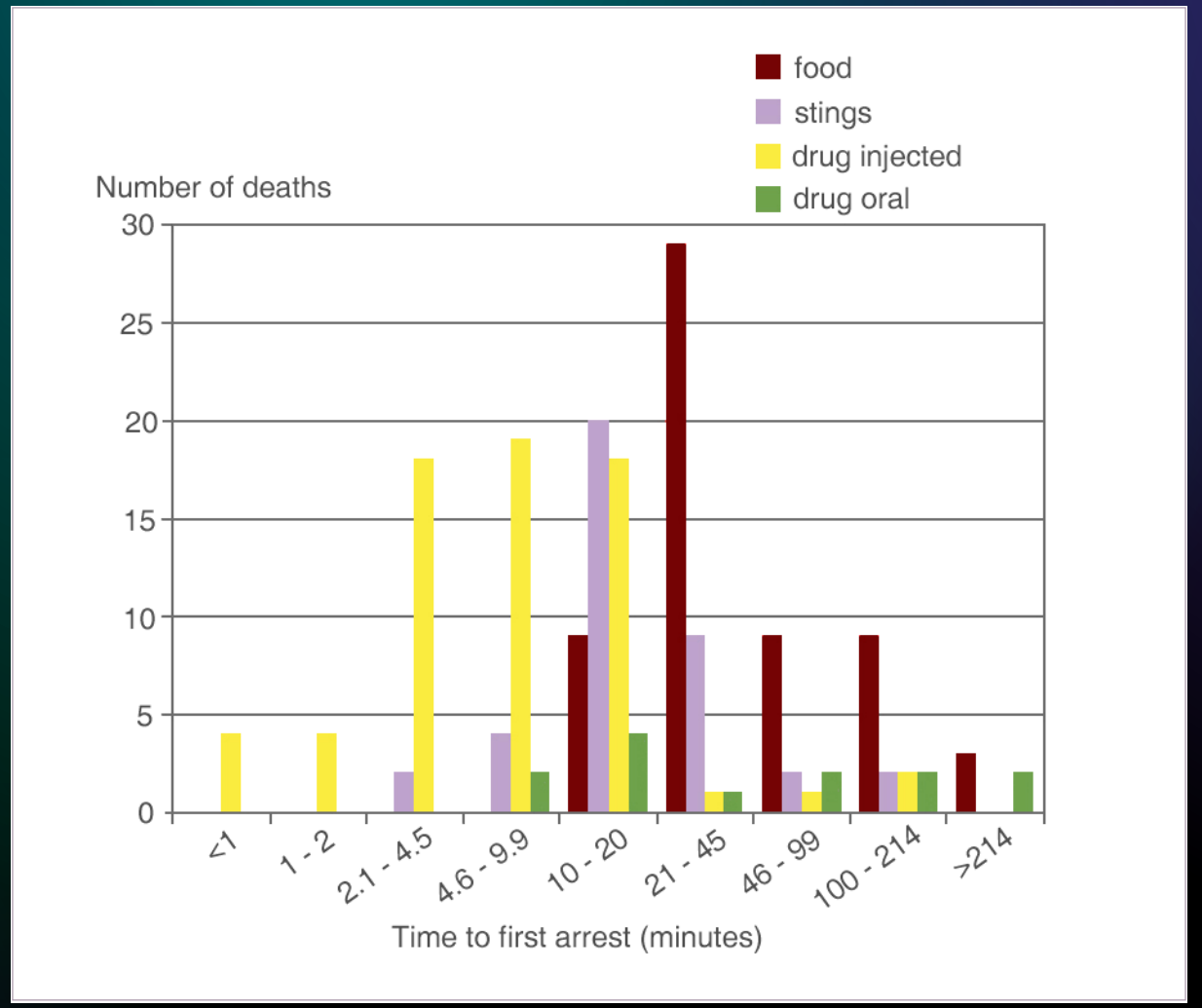
Infants and children: low systolic BP (age-specific) or greater than 30% decrease in systolic BP***

Adults: systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline

* For example, immunologic but IgE-independent, or non-immunologic (direct mast cell activation)

** For example, after an insect sting, reduced blood pressure might be the only manifestation of anaphylaxis; or, after allergen immunotherapy, generalized hives might be the only initial manifestation of anaphylaxis.

*** Low systolic blood pressure for children is defined as less than 70 mm Hg from 1 month to 1 year, less than (70 mm Hg + [2 x age]) from 1 to 10 years, and less than 90 mm Hg from 11 to 17 years. Normal heart rate ranges from 80-140 beats/minute at age 1-2 years; from 80-120 beats/minute at age 3 years; and from 70-115 beats/minute after age 3 years. In infants and children, respiratory compromise is more likely than hypotension or shock, and shock is more likely to be manifest initially by tachycardia than by hypotension.



(Emergency Treatment of Anaphylactic Reactions, Guidelines for healthcare providers, Working Group of the Resuscitation Council UK)

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Original Article

Urticaria: The 1-1-1 Criterion for Optimized Risk Stratification in β-Lactam Allergy Delabeling

Vito Sabato, MD, PhD[a,b,c,*], Francesco Gaeta, MD, PhD[d,*], Rocco Luigi Valluzzi, MD[e], Athina Van Gasse, MD, PhD[a], Didier Gaston Ebo, MD, PhD[a,b,c], and Antonino Romano, MD[f] *Ghent and Antwerpen, Belgium; and Rome and Troina, Italy*

JACIP 2021;9:3697-704

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BJA

British Journal of Anaesthesia, xxx (xxx): xxx (xxxx)

doi: 10.1016/j.bja.2019.01.031
Advance Access Publication Date: xxx
Review Article

REVIEW ARTICLE

Molecular mechanisms and pathophysiology of perioperative hypersensitivity and anaphylaxis: a narrative review

Didier G. Ebo[1,*], Russell C. Clarke[2], Paul-Michel Mertes[3], Peter R. Platt[2], Vito Sabato[1] and Paul H. M. Sadleir[2,4]

[1]Department of Immunology, Allergology and Rheumatology, University Antwerp, Antwerp University Hospital, Antwerpen, Belgium, [2]Anaesthetic Allergy Referral Centre of Western Australia, Department of Anaesthesia, Sir Charles Gairdner Hospital, Perth, Australia, [3]Department of Anesthesia and Intensive Care, Hôpitaux Universitaires de Strasbourg, Nouvel Hôpital Civil, Strasbourg, France and [4]Department of Pharmacology, University of Western Australia, Perth, Australia

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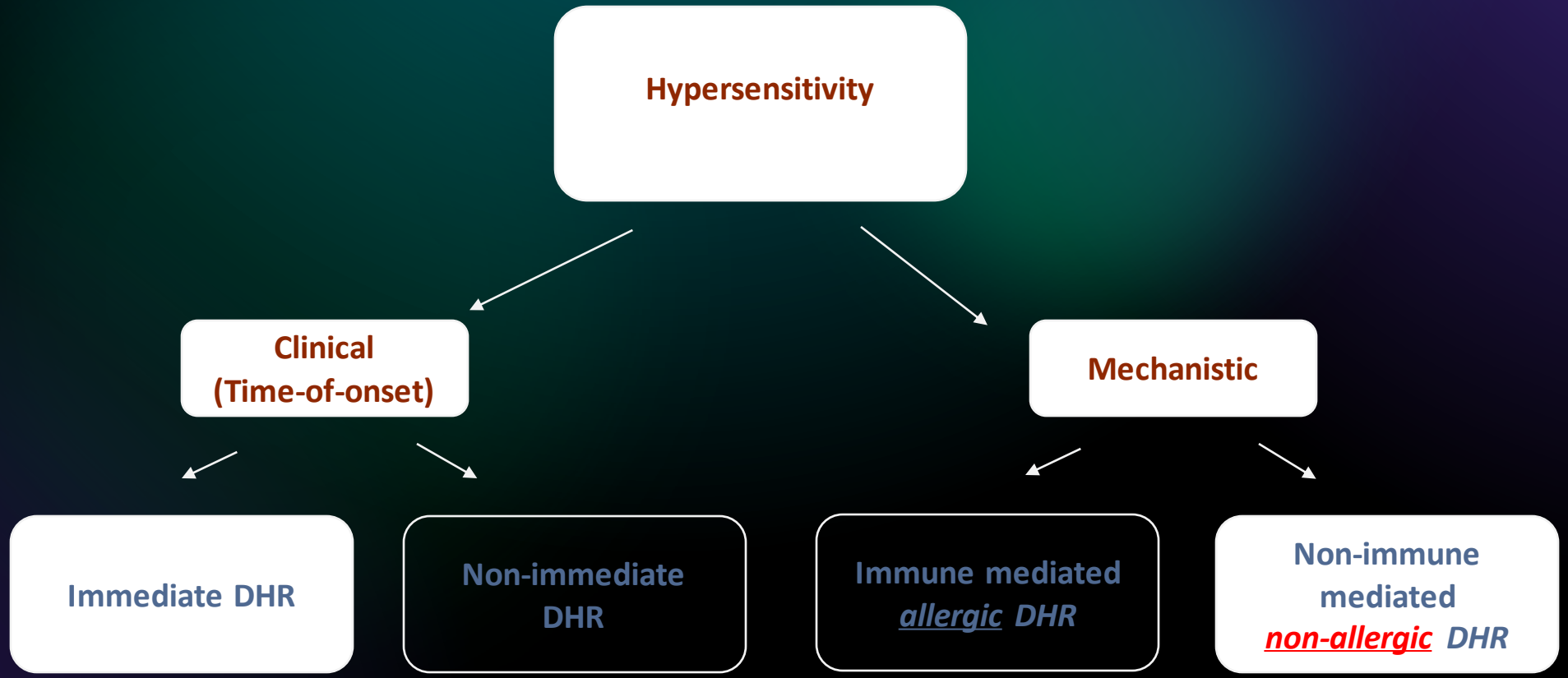
IDHRs: mechanisms-MC-non-IgE



IDHR: immediate drug hypersensitivity reactions

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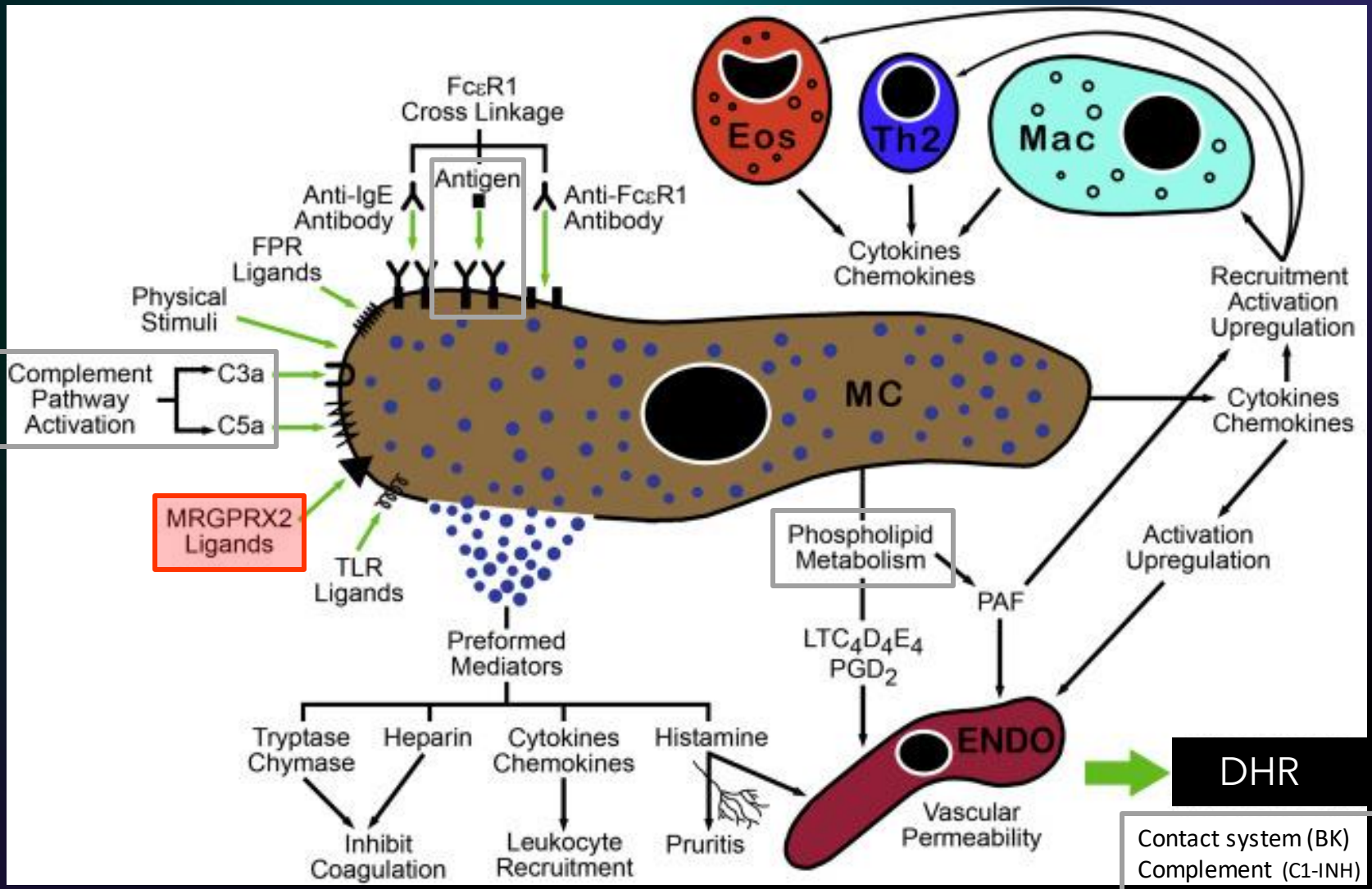
MRGPRX2



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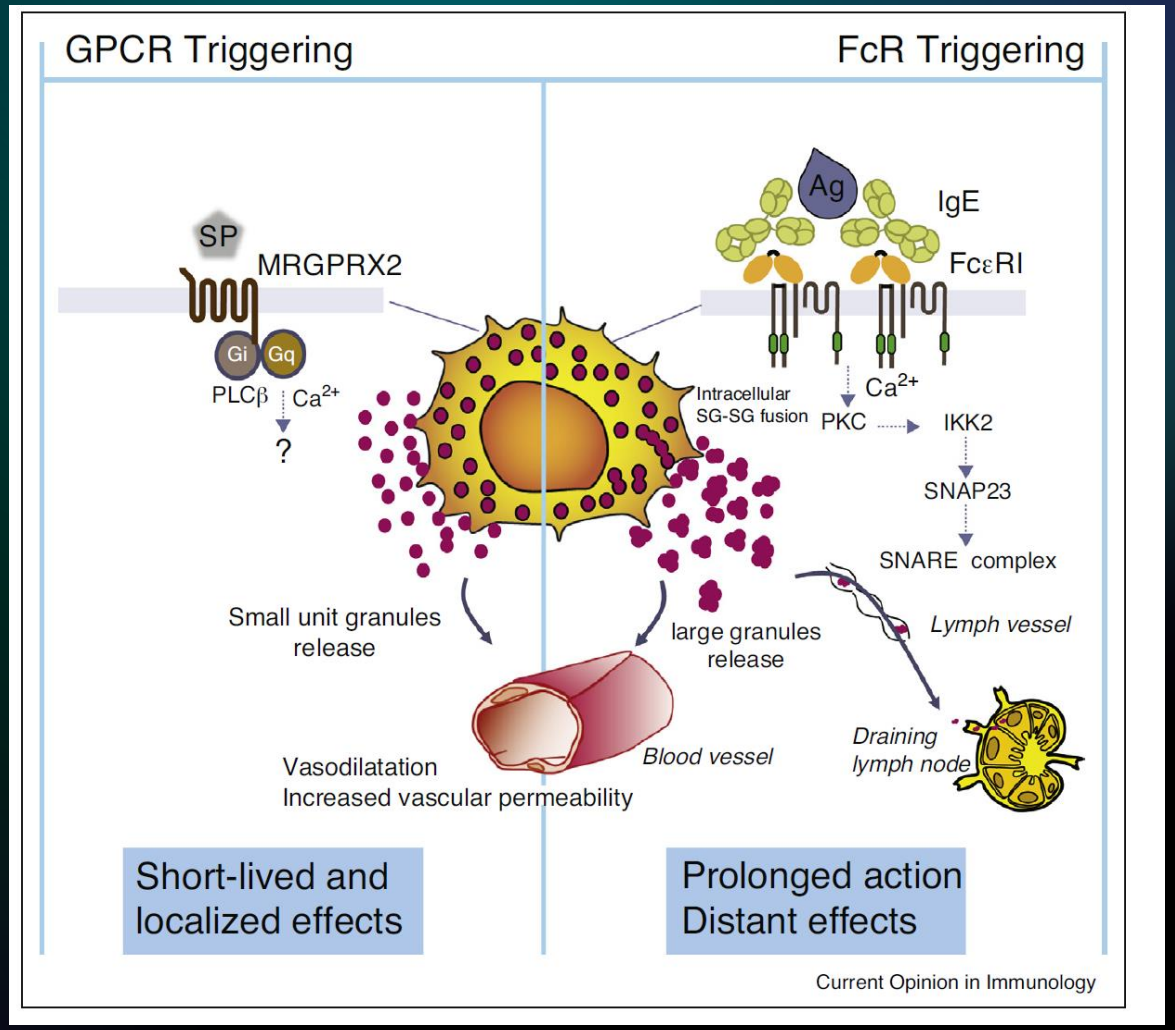
MRGPRX2



Not antigen specific (anybody, nature)
"kiss and run"
Rapid – transient (<5-30 min)
Local
<<< inflammatory mediators

Antigen specific (antibody, nurture)
Compound exocytosis
"Delayed" – sustained (5-30-60 min)
Local – regional – systemic (granule trafficing)
Inflammatory mediators

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Espinosa E and Valitutti S. Curr Opin Imm 2018

IgE *vs.* MRGPRX2

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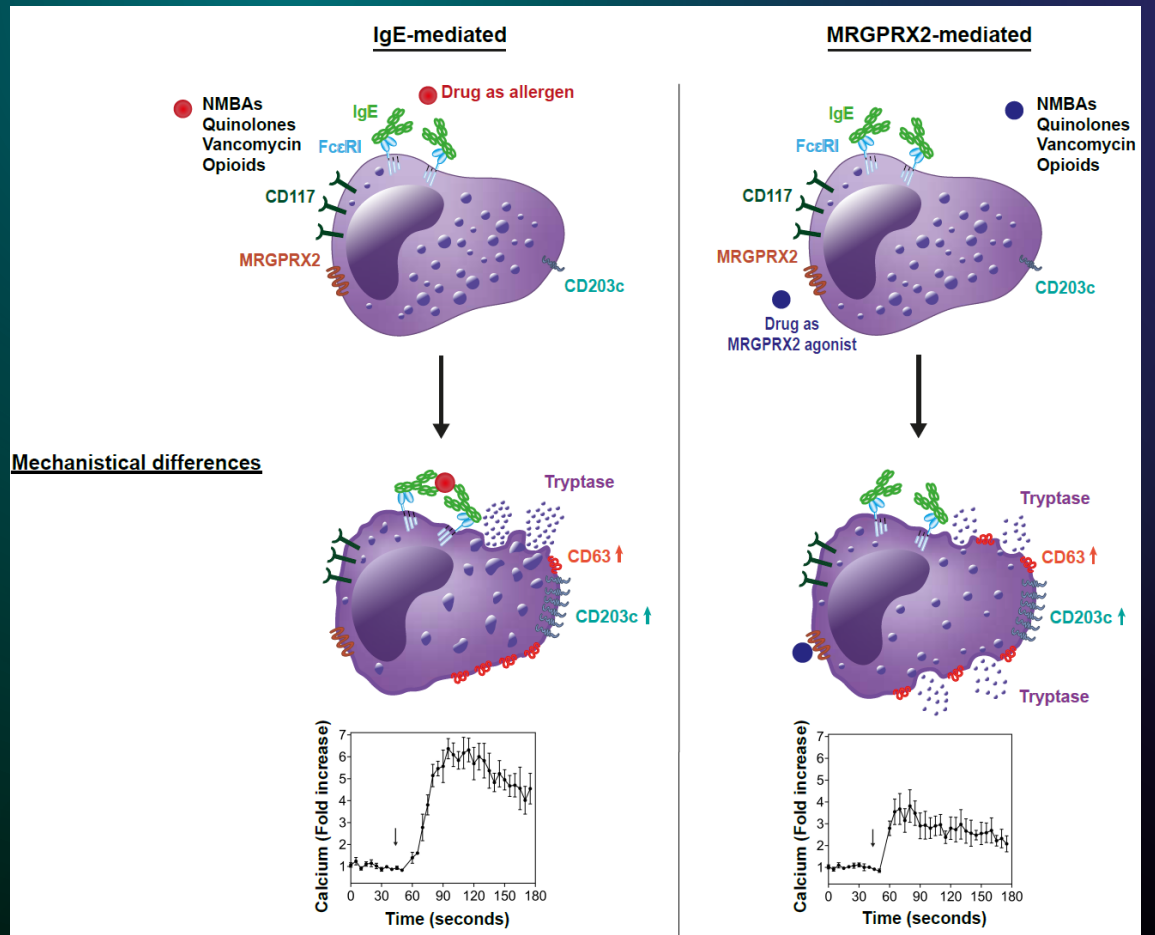

Clinical differences and similarities

	IgE-mediated	MRGPRX2-mediated
Clinics	Entrire IDHR spectrum	Entire IDHR spectrum cutaneous symptoms invariantly present
Prior exposure	Required *	Not required
Affinity (EC50)	High	Low
Dose	Low	High
Comorbidity/cofactor	Not essential	Mandatory?
Genetics	Not essential	MRGPRX2 polymorphisms
Biomarkers	Tryptase	Tryptase
Cross-reactivity	Structure related	THIQ and beyond
Diagnostics/ Mechanistic studies	Skin tests, sIgE, BAT, pMAT**, TAT	Skin tests, cBAT, MAT
Desensitization	Possible	Questionable


BJA
British Journal of Anaesthesia, xxx (xxx): xxx (xxxx)
CORRESPONDENCE

Immunoglobulin E cross-linking or MRGPRX2 activation: clinical insights from rocuronium hypersensitivity

Didier G. Ebo[1,2,3,*], Marie-Line Van der Poorten[1,4], Jessy Elst[1], Athina L. Van Gasse[1,4], Christel Mertens[1], Chris Bridts[1], Lene H. Garvey[5,6], Tatsuo Horiuchi[1,7] and Vito Sabato[1,2,3]


Received: 10 December 2021 | Revised: 1 February 2022 | Accepted: 10 February 2022
DOI: 10.1111/cea.14110
RESEARCH LETTER
WILEY

Tryptase release does not discriminate between IgE- and MRGPRX2-mediated activation in human mast cells

Elst et al. CEA

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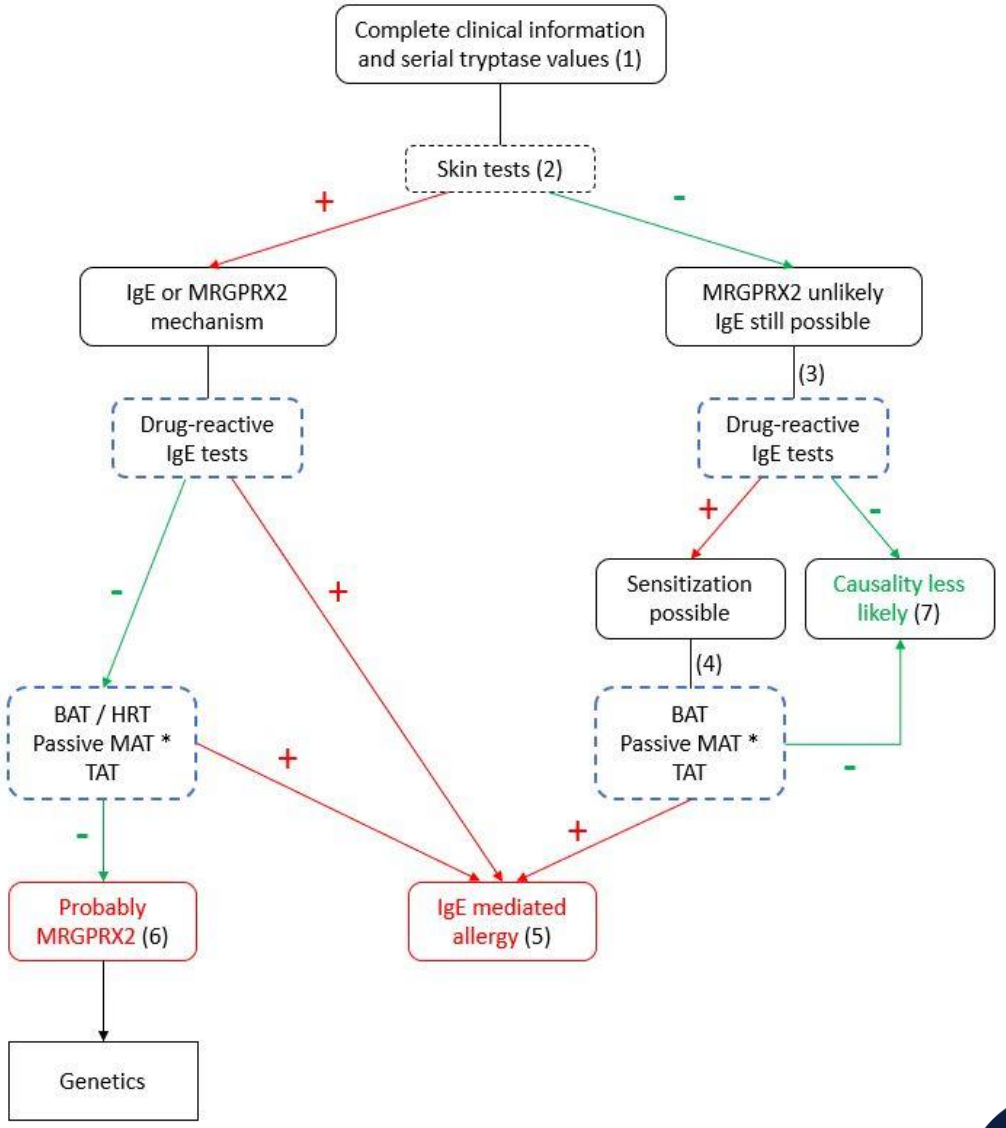
IgE *vs.* MRGPRX2 algorithm

- Same clinics, tryptase
- "Other diagnostics"
- Other management
  - "cross-reactivity"
  - re-administration
  - desensitization



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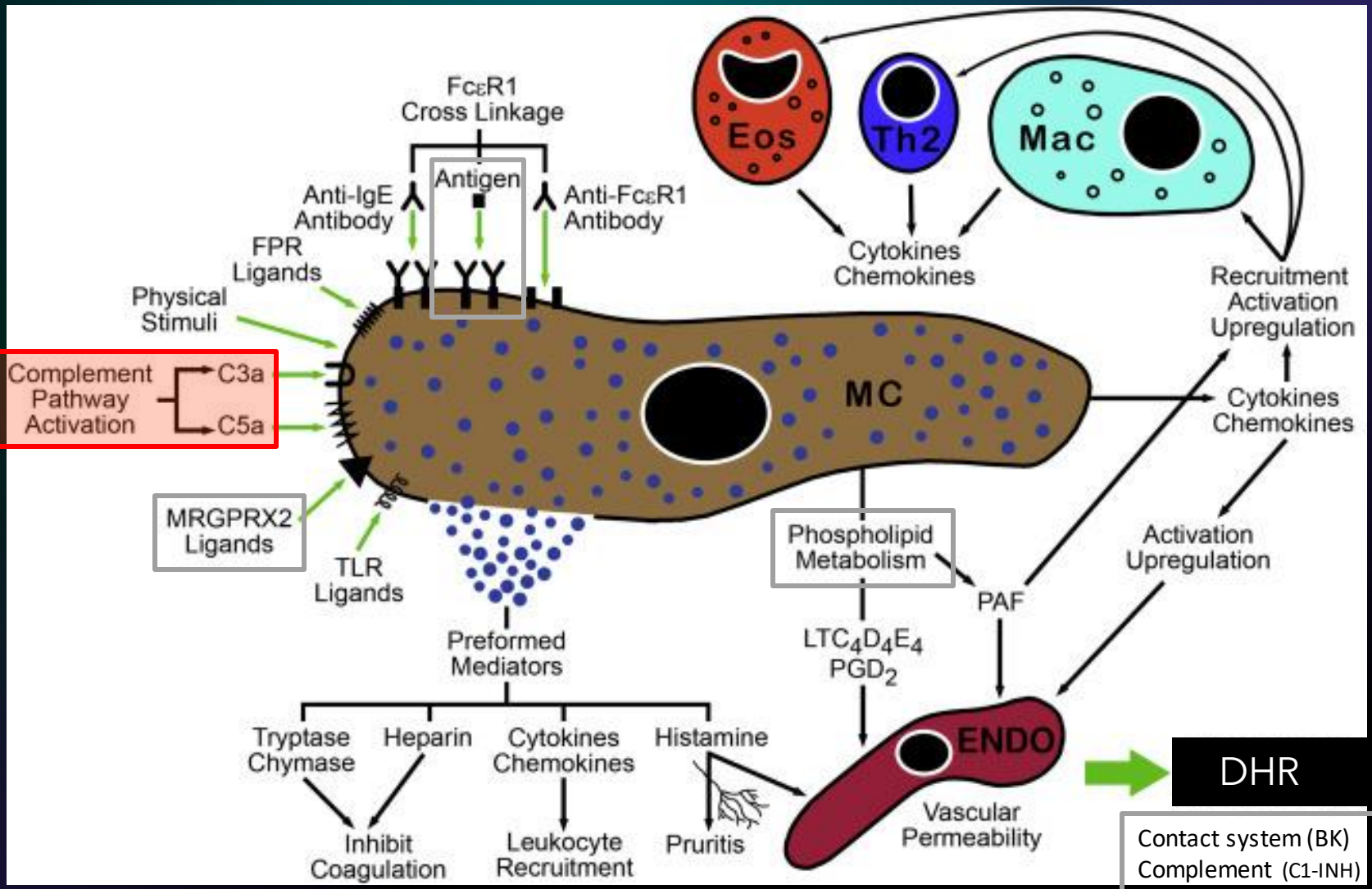

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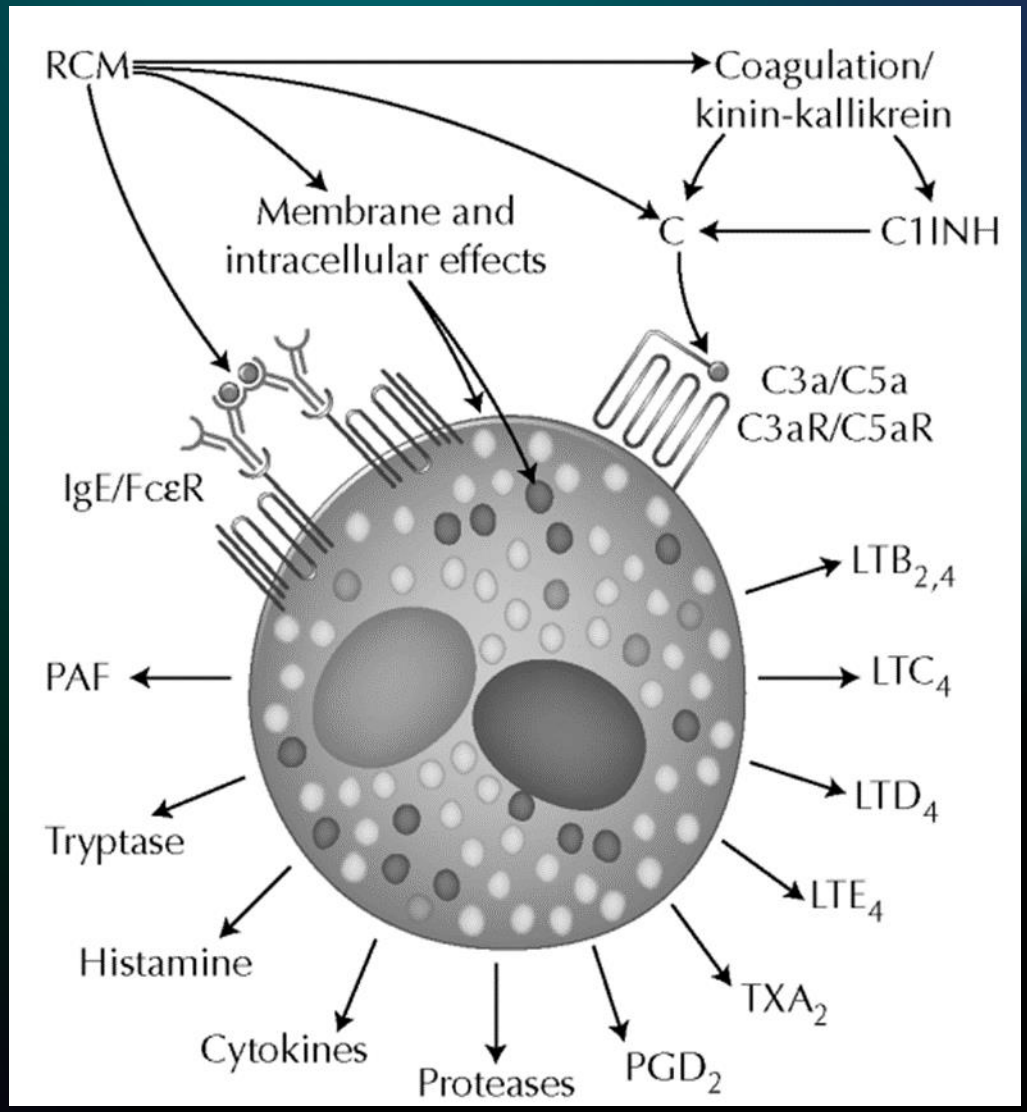

Skin tests
BAT
Provocation tests

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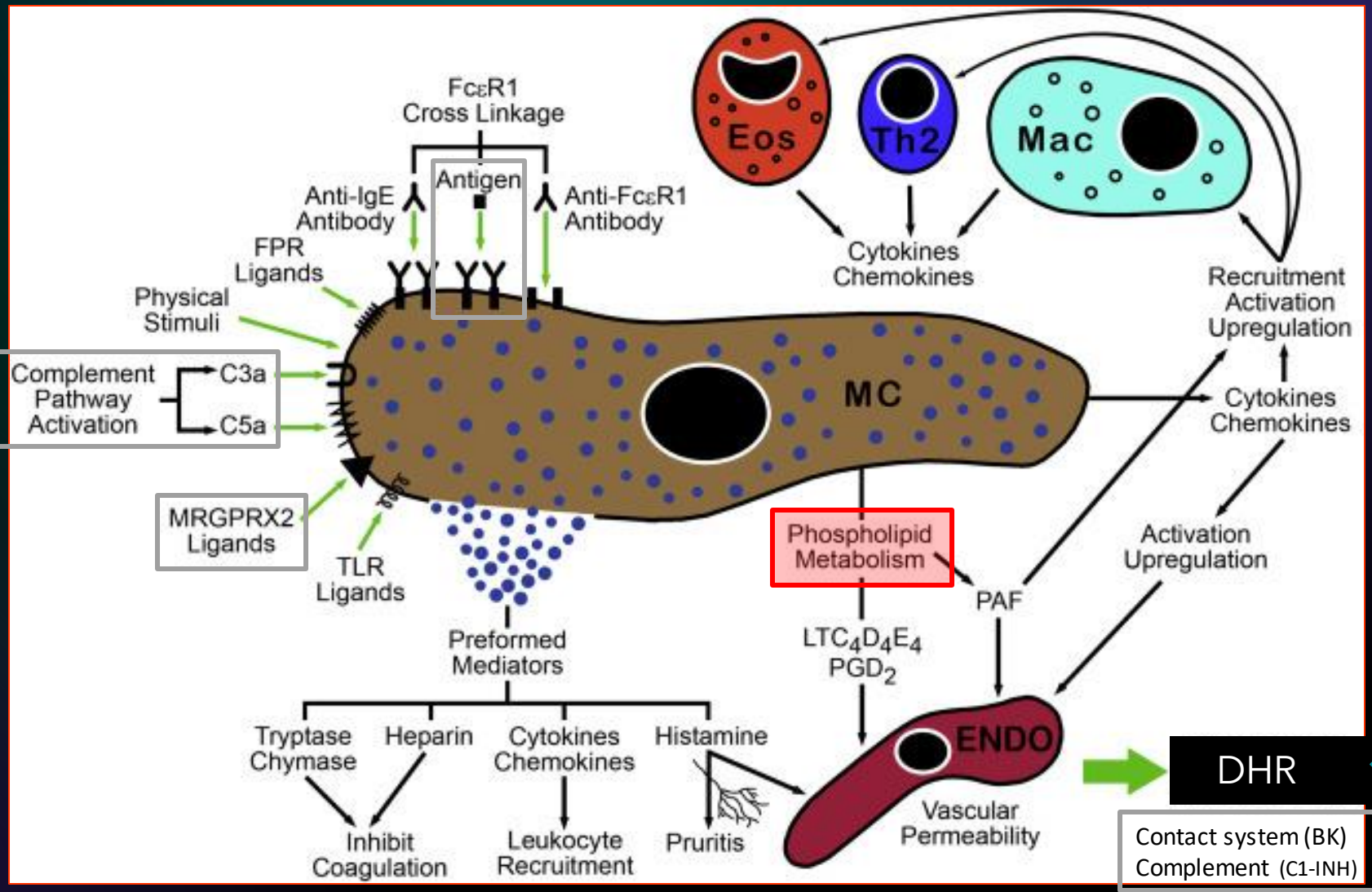
Cox-1/2



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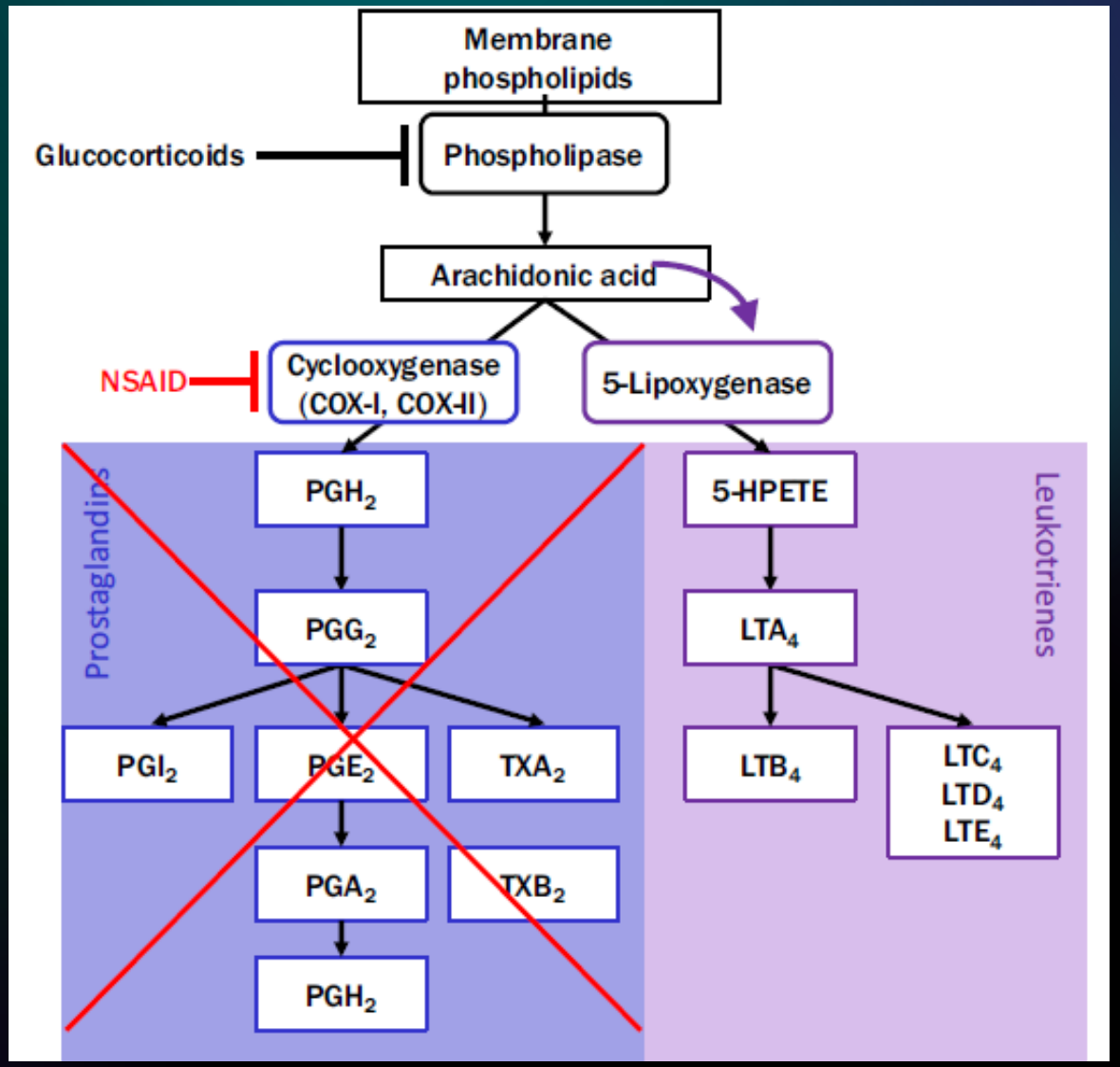

Wörhl S. Allergo J Int 2018

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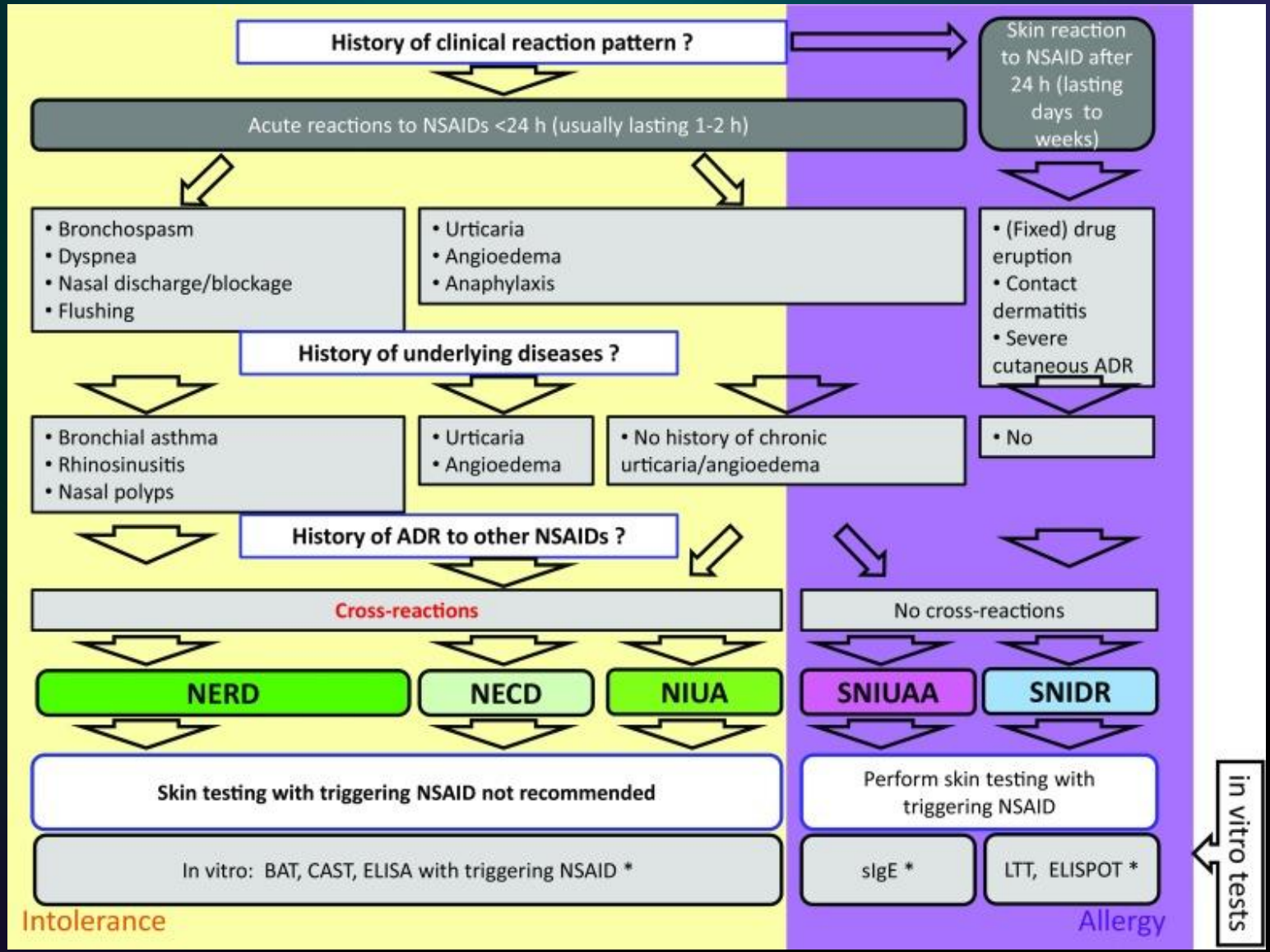
Provocation



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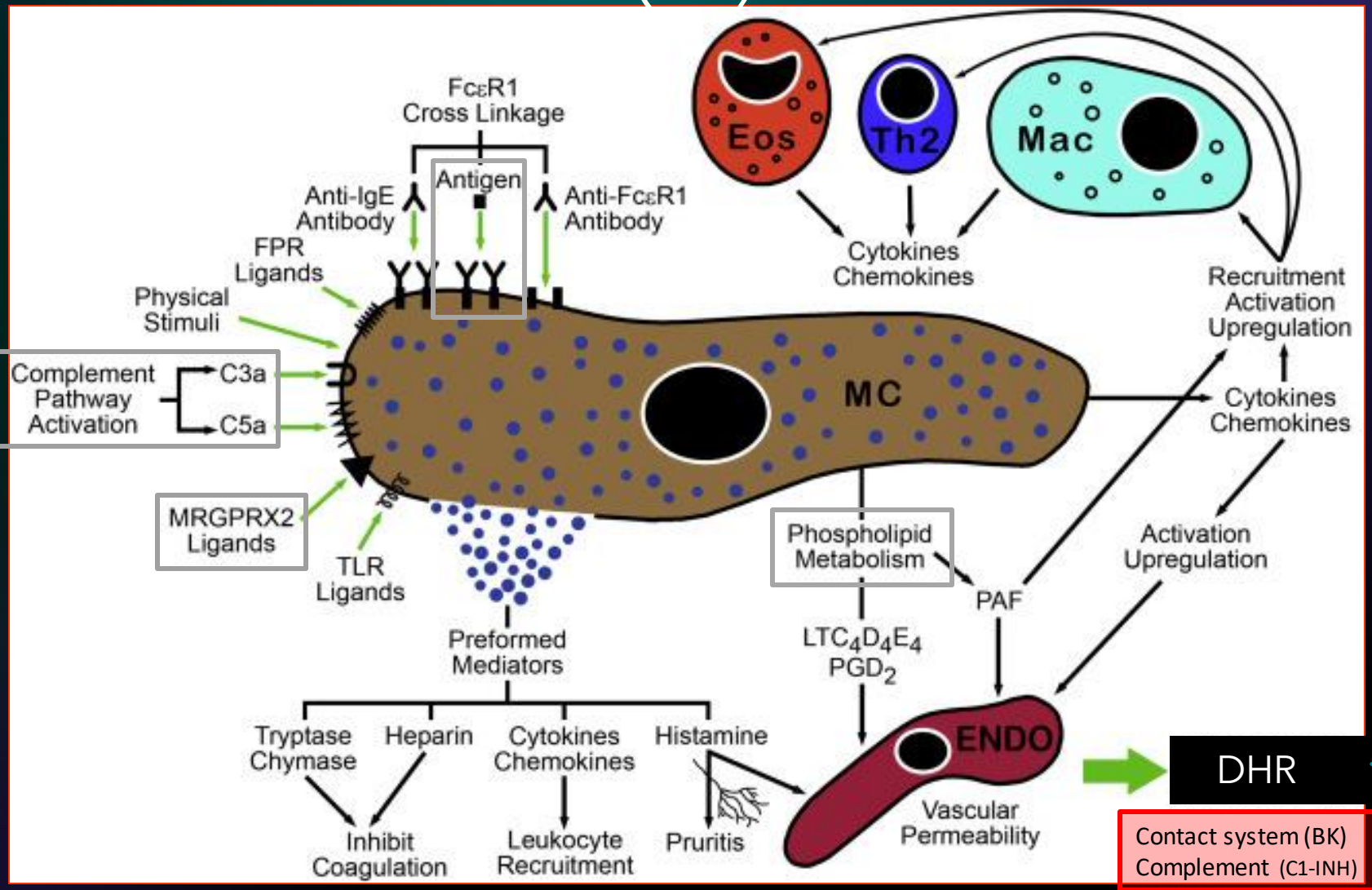
IDHR – non-MC(B)



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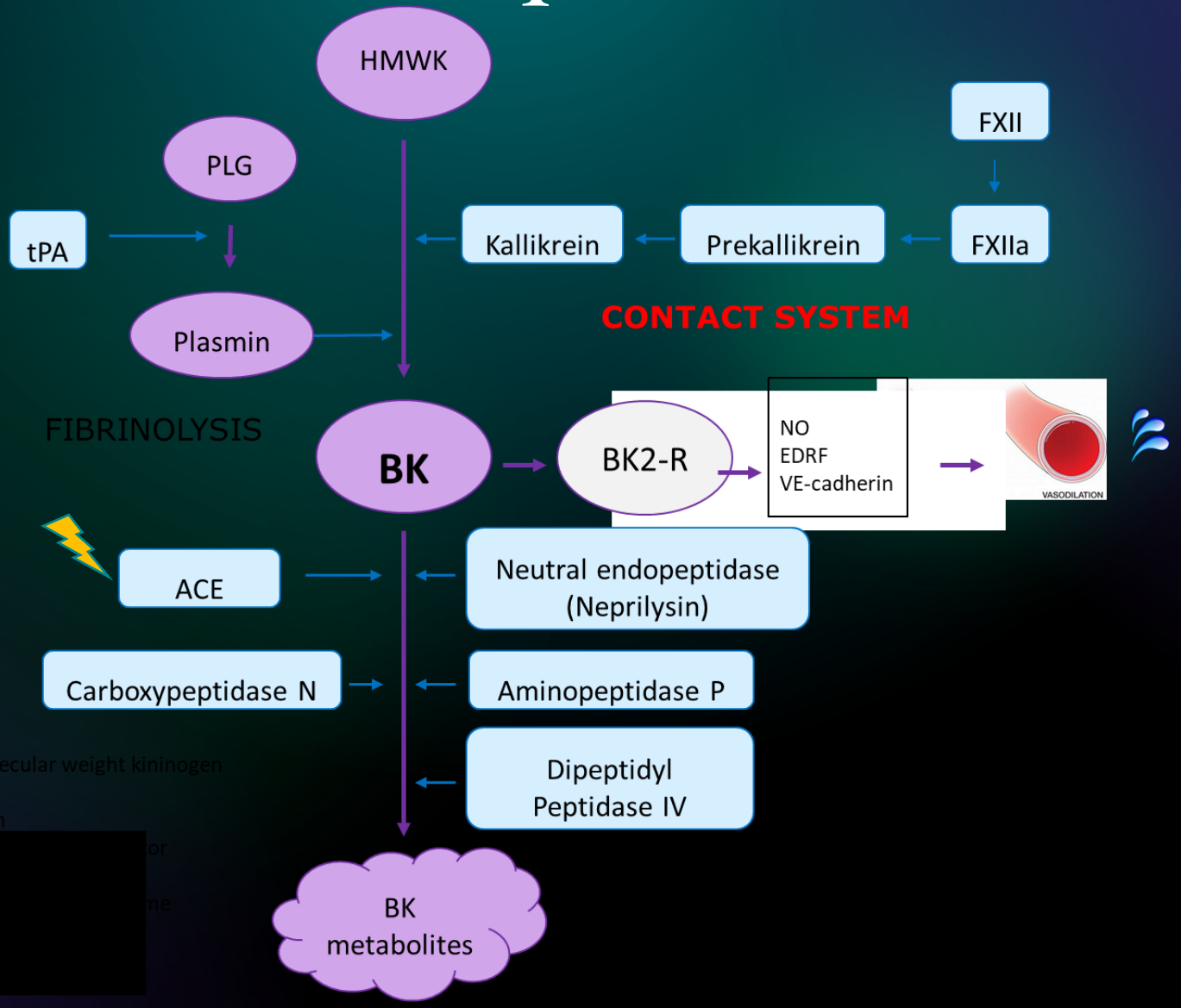
IDHRs-MC-independent



HMWK: high molecular weight kininogen
FXII: factor XII
PLG: plasminogen
tPA: tissue p[redacted]or
BK: bradykin[redacted]
ACE: angiote[redacted]me
[redacted]rady

Stop intake

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The NEW ENGLAND JOURNAL of MEDICINE

IMAGES IN CLINICAL MEDICINE

Disfiguring Angioedema

Didier G. Ebo, M.D.
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- 50-year-old woman with ACEi-angioedema of small bowel.
- CT scans show marked bowel wall enhancement with regular thickened mucosal folds (*solid straight arrows, B*),
- clear delineation of different layers of small bowel wall (*open straight arrows, A*),
- and prominent mesenteric vessels (*long thin arrows, A*).
- Fluid accumulation within dilated small-bowel loops (*open curved arrows A, B*) and ascites (*solid curved arrows, B*) are also present.

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Isolated angioedema: check for ACE-inhibitors!

… or get your C4

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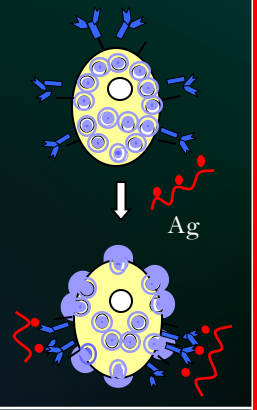
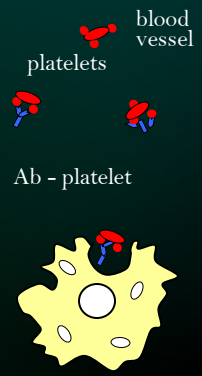
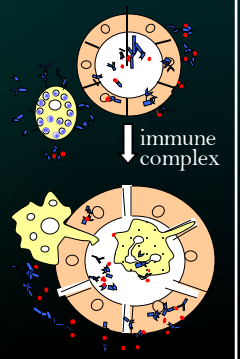
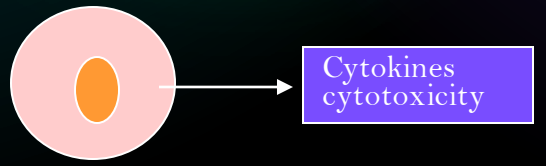
Drug allergies: classification - II

	Type I	Type II	Type III	Type IV
Immune reactant	**IgE**	**IgG**	**IgG**	T cell
Antigen	Soluble antigen	Cell- or matrix-associated antigen	Soluble antigen	MHC-presented antigen
Effector	Mast-cell activation	FcR+ cells (phagocytes, NK cells)	FcR+ cells Complement	T-cells, via cytokines recrutement of monocytes, eosinophils, neutrophils(?)
				
Clinical picture	Urticaria, Angioedema, Bronchospasm, Cardiovascular collapse, Anaphylaxis	Hemolytic anemia, Thrombocytopenia, Petechia	Small-vessel vasculitis, Serum sickness, Arthus reaction	Maculopapular exanthema, DRESS, SJS-TEN, AGEP

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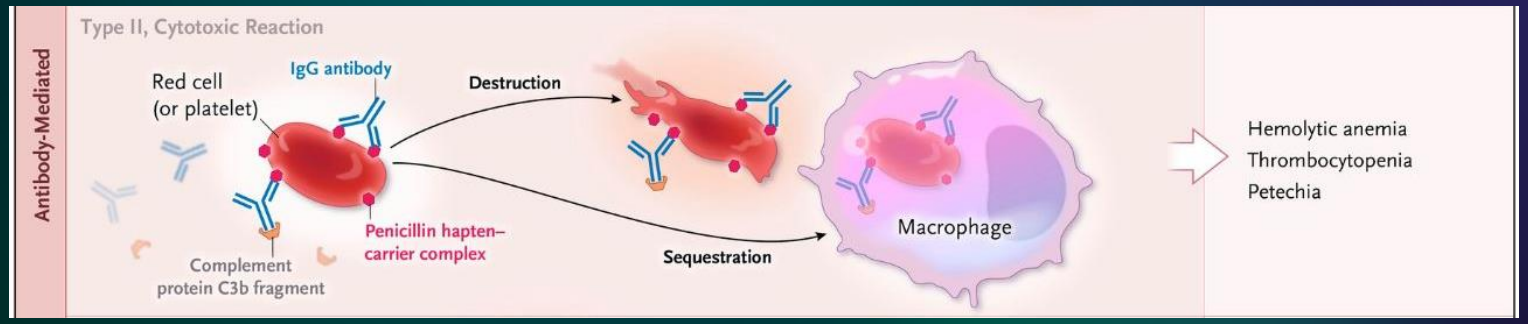

<u>Phase I</u>: Sensitization phase
Production of IgG antibodies

<u>Phase II</u>: Effector phase
Drug binds to surface of certain cell types and act as antigen
Binding of IgG antibodies to anigen
→ Activation complement → lysis
→ Phagocytosis by macrophages or neutrophils

Diagnosis: direct and/or indirect Coombs' test

Castells, NEJM 2019

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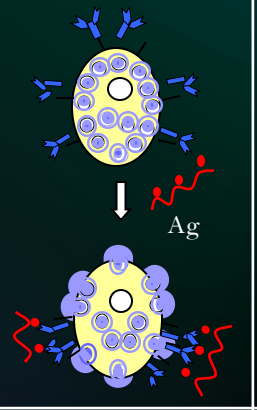
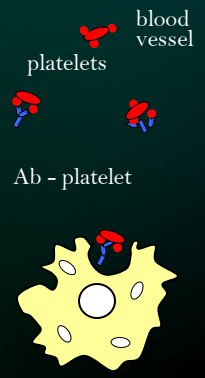
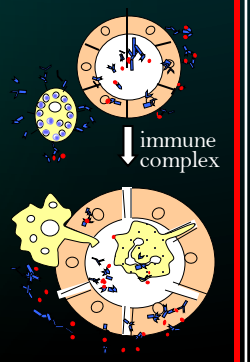
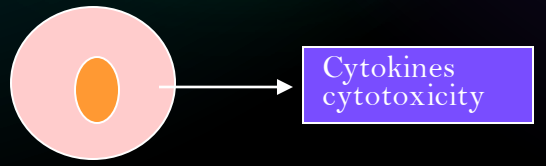
Drug allergies: classification - III

	Type I	Type II	Type III	Type IV
Immune reactant	**IgE**	**IgG**	**IgG**	T cell
Antigen	Soluble antigen	Cell- or matrix-associated antigen	Soluble antigen	MHC-presented antigen
Effector	Mast-cell activation	FcR+ cells (phagocytes, NK cells)	FcR+ cells Complement	T-cells, via cytokines recrutement of monocytes, eosinophils, neutrophils(?)
				
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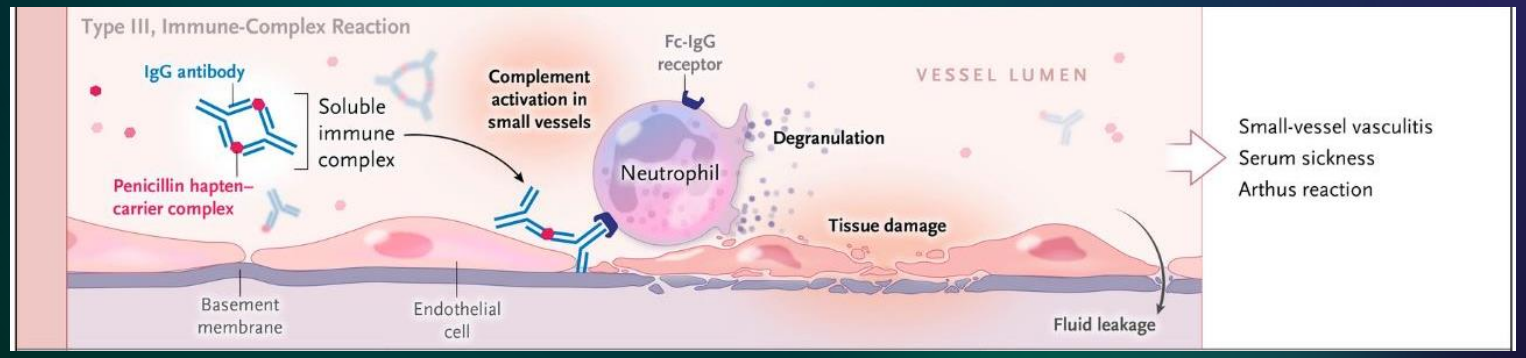

Immune complex formation
Drug triggers antibody production
Formation of circulating immune complexes

Immune complex deposition
Circulate and precipitate in various tissues

Inflammatory reaction
Activation of the classical complement pathway
Recruitment of neutrophils and macrophages


Purpura

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Diagnosis: erythrocyte sedimentation rate, C-reactive protein, complement studies

Castells, NEJM 2019

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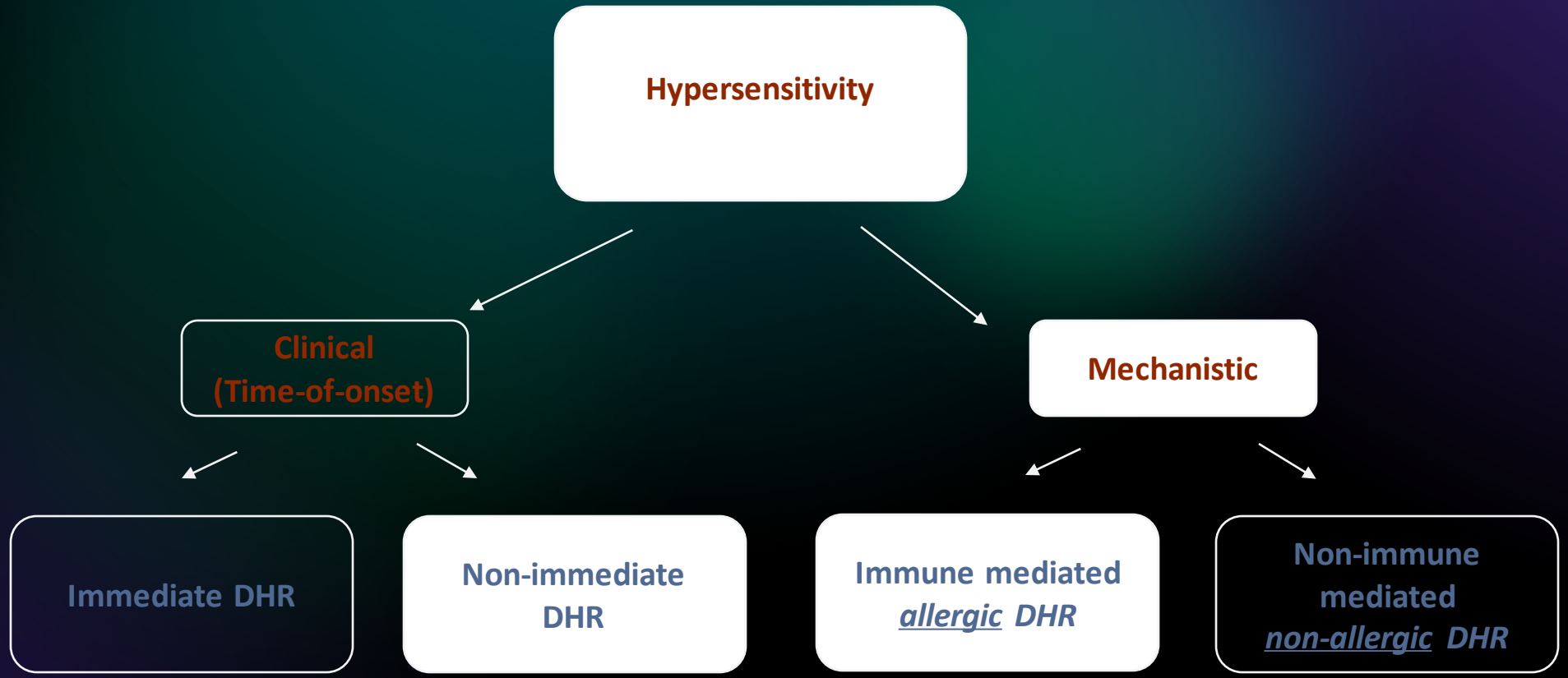
NIDHR: mechanisms



IDHR: immrediate drug hypersensitivity reactions

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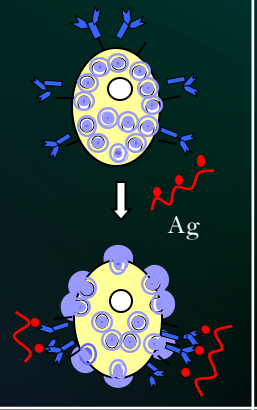
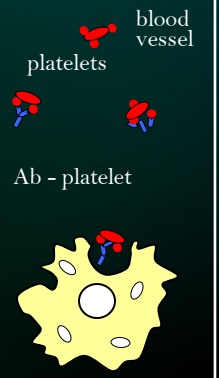
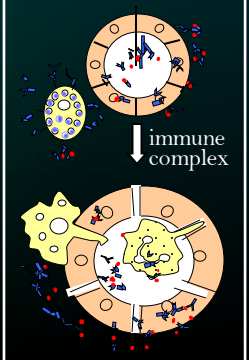
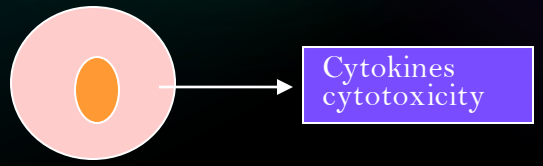
Antigen	Soluble antigen	Cell- or matrix-associated antigen	Soluble antigen	MHC-presented antigen
Effector	Mast-cell activation	FcR+ cells (phagocytes, NK cells)	FcR+ cells Complement	T-cells, via cytokines recrutement of monocytes, eosinophils, neutrophils(?)
				
Clinical picture	Urticaria, Angioedema, Bronchospasm, Cardiovascular collapse, Anaphylaxis	Hemolytic anemia, Thrombocytopenia, Petechia	Small-vessel vasculitis, Serum sickness, Arthus reaction	Maculopapular exanthema, DRESS, SJS-TEN, AGEP

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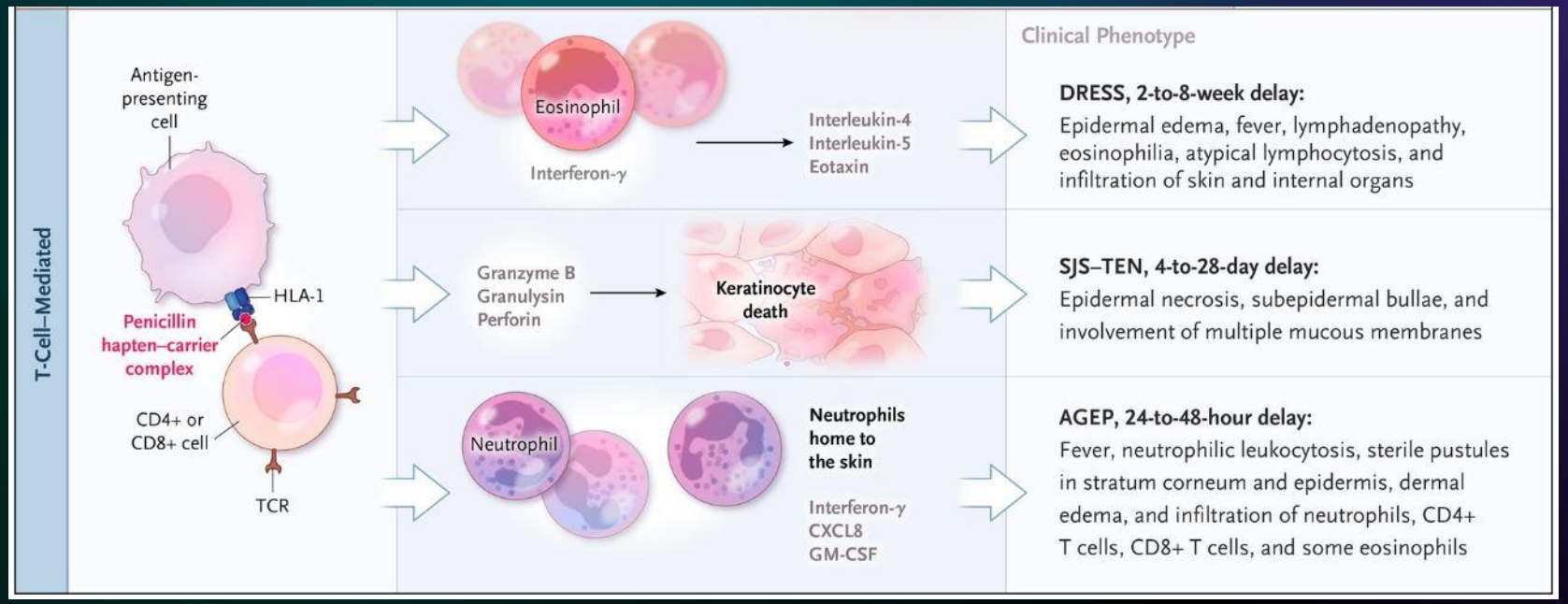

Activation of T-lymphocytes

Diagnosis: Delayed readings of patch testing and intradermal testing, “LTT”

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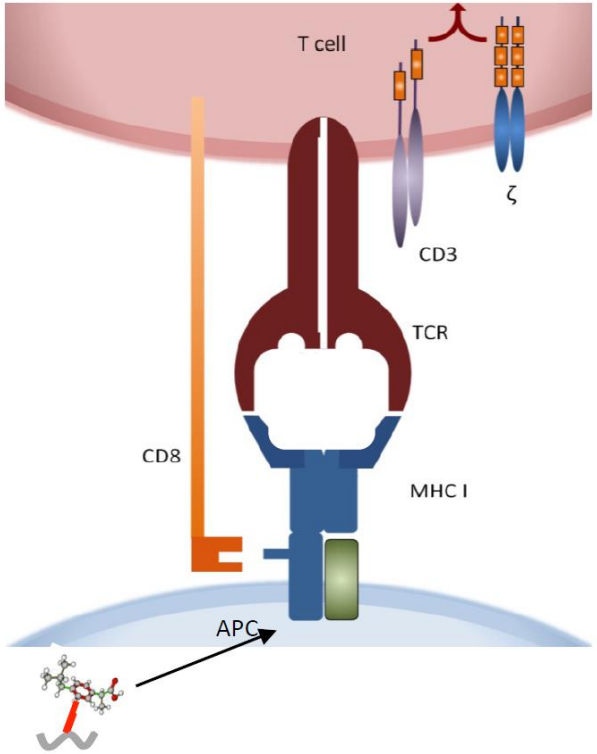
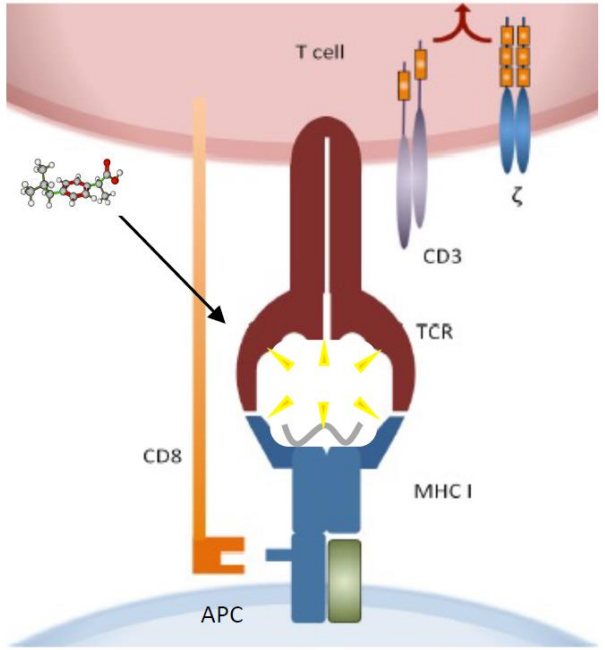
Castells, NEJM 2019

Hapten concept



p-i concept (pharmacological interaction with immune receptor)



adapted from Adam et al., Br J Clin Pharmacol., 2011

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MPE

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SJS-TEN

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DRESS

- Drug reaction
- with eosinophilia
- and systemic symptoms
- (latency 2-8 weeks)

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DRESS: facial swelling

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AGEP

Acute generalized exanthematous pustulosis

(24-48 hrs)

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Fixed drug eruption

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WARNING SIGNS

Mucosal involvement

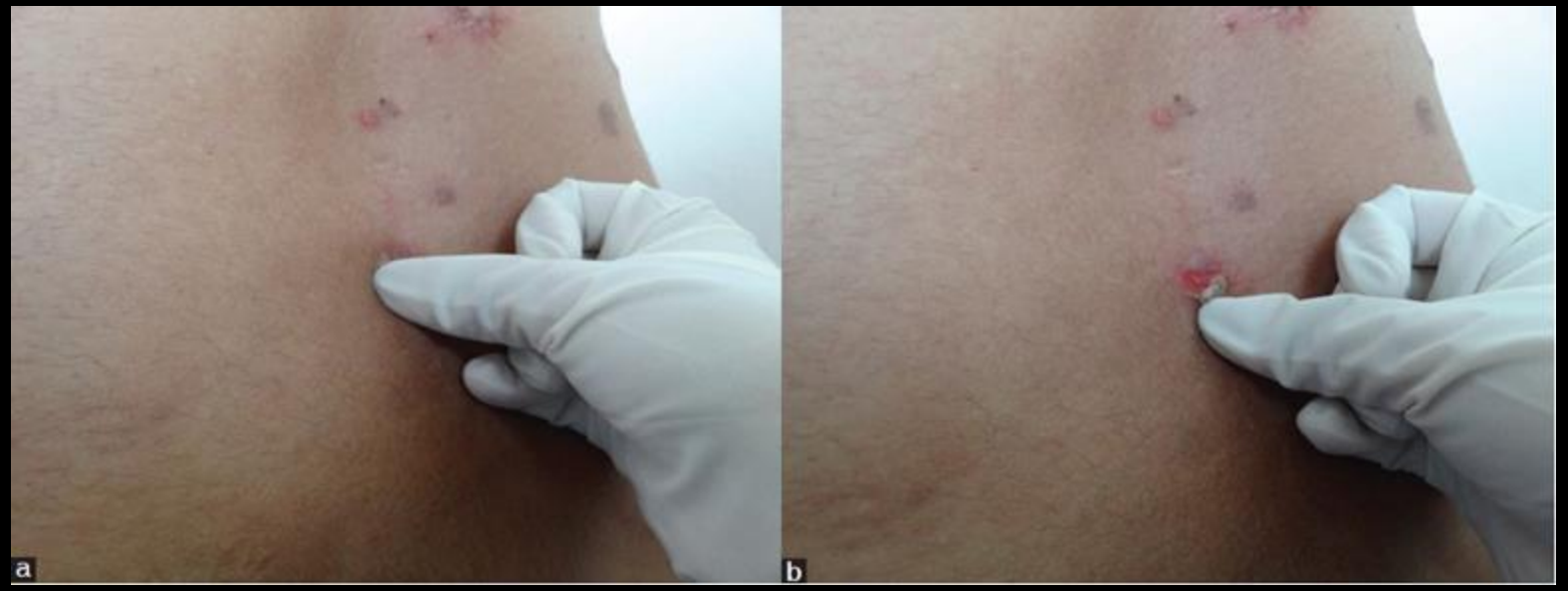
Bullae (blisters)

Fever

Systemic signs

Hepatic, renal signs

Eosinophilia



Nikolsky's sign

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Diagnostics

History

- Which agent(s)
  - Generic + trade name (excipients)
- What were the symptoms (pictures)
- When did symptoms start (time-of-onset)
- Was the drug stopped / did symptoms (dis)(re)appear
- First or prior intake (similars)
- Subsequent exposure(s) (similars)
- How was patient treated

Signs & symptoms

Immediate

- Tryptase
- sIgE
- Skin tests (SPT, IDT)
- BAT
- (p)MAT
- T cells
- DPT

Nonimmediate

- Patch tests
- Skin tests (IDT)
- T cells
- DPT

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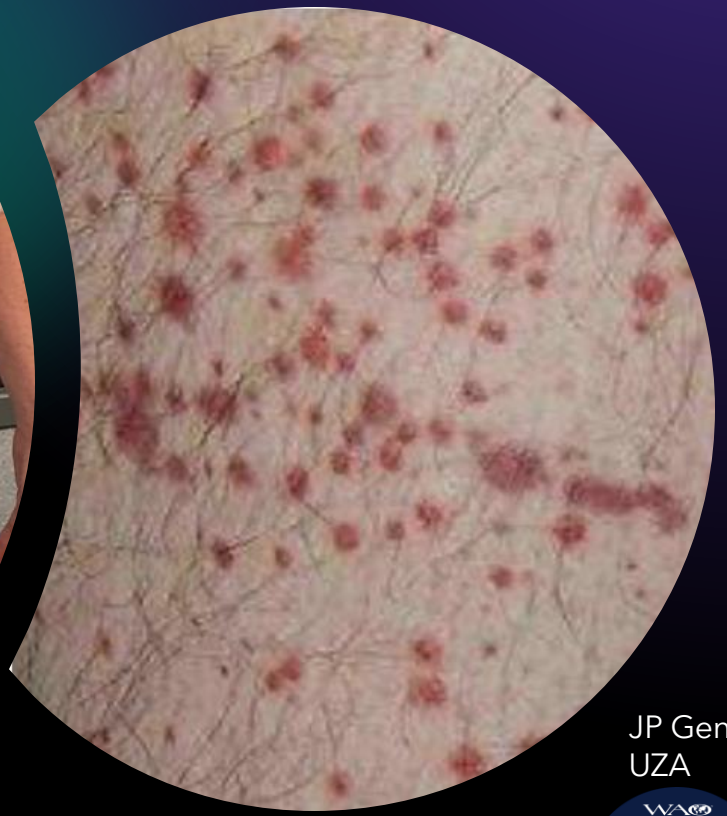
This is NOT a “rash”



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- **DIFFERENT CLINICS**
- **DIFFERENT MECHANISMS**
- **DIFFERENT DIAGNOSTICS**
- **DIFFERENT "THERAPEUTICS"**

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Diagnostics

History

- Which agent(s)
  - Generic + trade name (excipients)
- What were the symptoms (pictures)
- When did symptoms start (time-of-onset)
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Nonimmediate

- Patch tests
- Skin tests (IDT)
- T cells
- DPT

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Tryptase

- MCA: 1.2 (baseline) + 2
- < 11.4 µg/mL !

ELSEVIER SAUNDERS

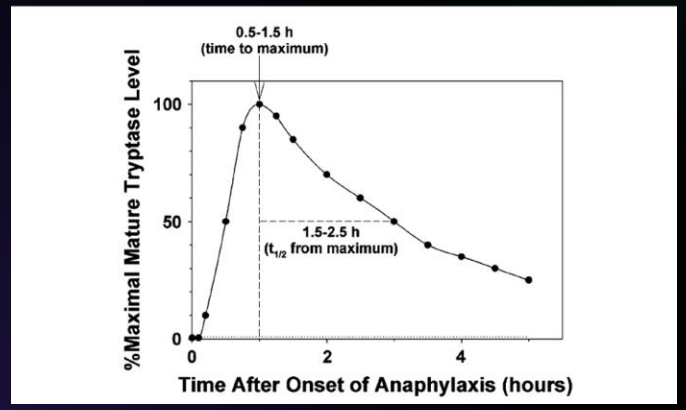
Immunol Allergy Clin N Am
26 (2006) 451–463

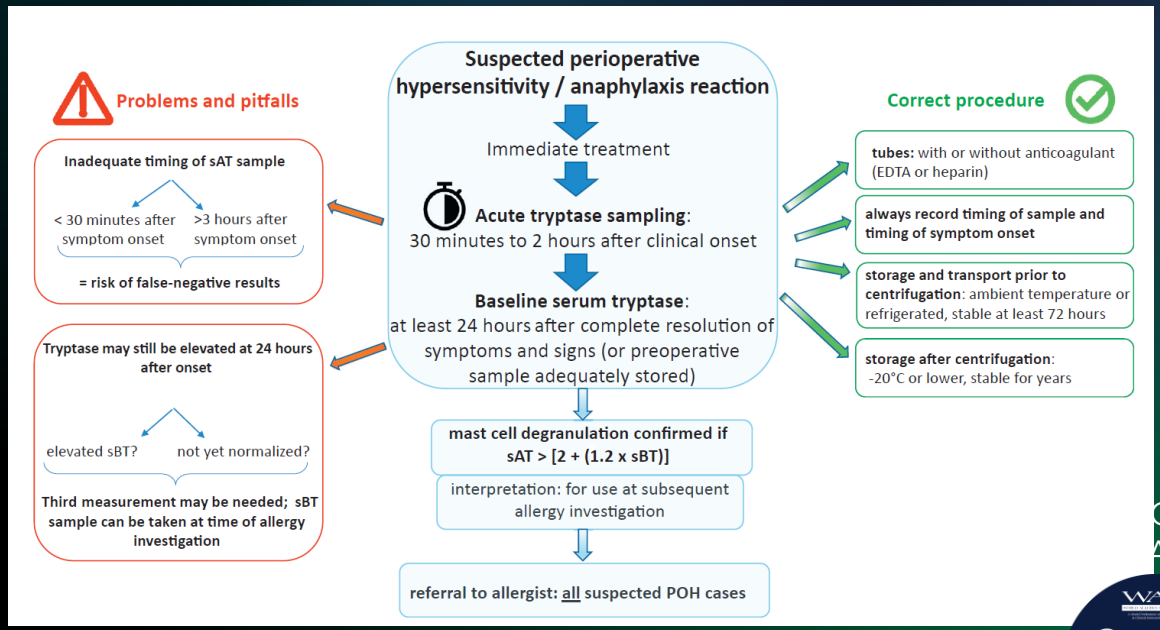
IMMUNOLOGY AND ALLERGY CLINICS OF NORTH AMERICA

Diagnostic Value of Tryptase in Anaphylaxis and Mastocytosis

Lawrence B. Schwartz, MD, PhD

Division of Rheumatology, Allergy, and Immunology, Department of Internal Medicine, Virginia Commonwealth University, PO Box 980263, McGuire Hall 4-110, Richmond, VA 23298, USA





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IgE

Clinica Chimica Acta 504 (2020) 119–124

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/cca

Review

Serum specific IgE antibodies in immediate drug hypersensitivity

Marie-Line M. van der Poorten[a,b], Athina L. Van Gasse[a,b], Margo M. Hagendorens[a,b], Margaretha A. Faber[a], Leander De Puysseleyr[a], Jessy Elst[a], Christel M. Mertens[a], Vito Sabato[a], Didier G. Ebo[a,*]

[a] Faculty of Medicine and Health Sciences, Department of Immunology, Allergology, Rheumatology and Infla-Med Centre of Excellence, University of Antwerp and Antwerp University Hospital, Antwerp, Belgium
[b] Faculty of Medicine and Health Sciences, Department of Paediatrics, University of Antwerp, and Antwerp University Hospital, Antwerp, Belgium

Clinica Chimica Acta 460 (2016) 184–189

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Review

Quantification of specific IgE antibodies in immediate drug hypersensitivity: More shortcomings than potentials?

I.I. Decuyper [a,b], D.G. Ebo [a,*], A.P. Uyttebroek [a], M.M. Hagendorens [b], M.A. Faber [a], C.H. Bridts [a], L.S. De Clerck [a], V. Sabato [a]

[a] Faculty of Medicine and Health Science, Department of Immunology, Allergology, Rheumatology, University of Antwerp, Antwerp University Hospital, Belgium
[b] Faculty of Medicine and Health Science, Department of Pediatrics, University of Antwerp, Antwerp University Hospital, Belgium

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When 99% is not good enough

Table 1
Specific IgE to β-lactam antibiotics (β-LABs) (actualised from [77]).

Compound(s)	Reference test	Assay	Sensitivity	Specificity	N°	Reference
Various β-LABs	H + ST	CAP-FEIA	BPO + AXO + peni G + AMP: 31.8%	BPO + AXO + peni G + AMP: 88.6%	58	[78]
Various β-LABs	H ± ST ± DCT	CAP-FEIA	BPO: 32% AXO: 43% BPO + AXO: 50%	BPO: 98% AXO: 98% BPO + AXO: 96%	129	[79]
Various β-LABs	H ± ST ± DCT	CAP-FEIA	BPO: 10–68% AXO: 41–53%	BPO: 98% AXO: 95%	410	[6]
Various β-LABs	H	CAP-FEIA	37.9%	86.7%	58	[80]
Various β-LABs[1]	H ± ST ± DCT	CAP-FEIA RAST[2]	0–25%[2] 42.9–75%[2]	83.3–100%[2] 66.7–83.3%[2]	45	[2]
Various β-LABs	H ± ST	CAP-FEIA CAP-FEIA	85%[3] 44%[4]	54%[3] 80%[4]	176	[11]
Various β-LABs	H ± ST	CAP-FEIA	66%	52%	293	[12]
Amoxicillin	H + ST + DCT	CAP-FEIA	19%	NA	57	[81]
Cefazolin	H + ST ± DCT	CAP-FEIA	49%[5]	94%[5]	80	[8]

H: history, ST: skin test, DCT: drug challenge test, N°: number.
CAP-FEIA: fluorescence enzyme immunoassay available from Phadia Thermofisher. RAST: radio allergo sorbent test.
Peni G: penicillin G, AMP: ampicillin, BPO: benzyl penicilloyl, AXO: amoxicillin.
Note that there is no IgE for clavulanic acid available

[1] Home-made assay.
[2] Sensitivity and specificity vary according to clinical manifestations.
[3] For a threshold of 0.10 kUA/L.
[4] For a threshold of 0.35 kUA/L.
[5] According to a sIgE/tIgE ratio of 1.42 × 10^{-3} (see text).

Received: 13 February 2020 | Revised: 6 March 2020 | Accepted: 21 March 2020
DOI: 10.1111/all.14292

LETTER TO THE EDITOR

Allergy EAACI WILEY

Prevalence of self-reported and confirmed penicillin allergy in a Belgian outpatient population

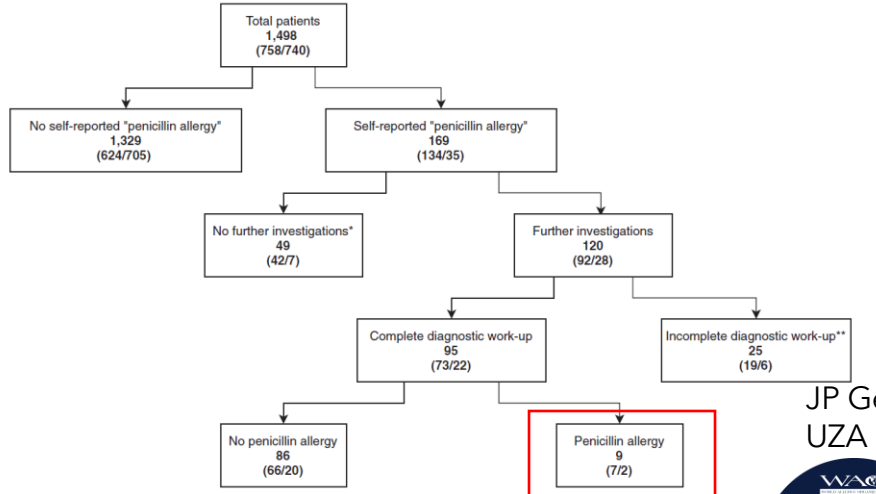

FIGURE 1 This flowchart gives an overview of the study population. The information in brackets displays the number of ad
*No further investigations were planned because either the patient considered the "penicillin allergy" to lack sufficient priorit
the allergist decided, based on a thorough history, that the index reaction was not compatible with a DHR (n = 4). **Investigat
be postponed for various reasons (eg, pregnancy and intake of antihistamines). In 2 out of these 25 participants, the DC resul
subjective symptoms (itch, epigastric pain, shortness of breath). As both were unwilling to repeat the DC, they were included
the patients with incomplete diagnostic work-up.

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Pretest probability is 5%
TP: 2-3
FP: > 20-30 (perpetuation)

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Skin tests

+ Immediate reading IDT

+ Delayed reading IDT

+ Patch test

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Immediate readings

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Intradermal test results positive for AX and AM

Patch test results positive for AX and AM

FDE: patch/IDT *in situ*

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- DRUG PROVOCATION
  - NEG TESTS/ALTERNATIVES
  - NO OTHER MEANS
    - (e.g. NSAIDs)

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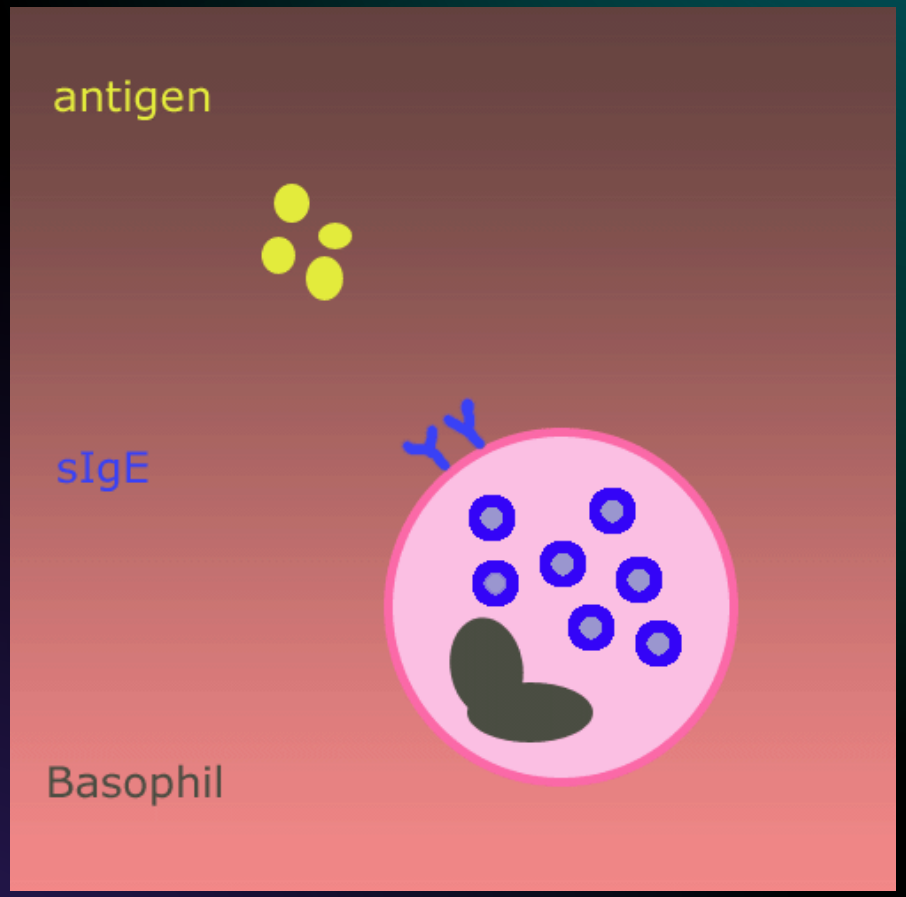
IDHRs



Current perspectives JACI 2020

Principles, potential, and limitations of *ex vivo* basophil activation by flow cytometry in allergology: A narrative review

Didier G. Ebo, MD, PhD,[a,b,c,d] Chris H. Bridts, MLT,[a,b,c] Christel H. Mertens, MLT,[a,b,c] and Vito Sabato, MD, PhD[a,b,c,d]
Antwerp and Ghent, Belgium

Journal of Immunological Methods 495 (2021) 113050

Contents lists available at ScienceDirect

Journal of Immunological Methods

journal homepage: www.elsevier.com/locate/jim

Basophil and mast cell activation tests by flow cytometry in immediate drug hypersensitivity: Diagnosis and beyond

Jessy Elst [a], Vito Sabato [a,b], Marie-Line M. van der Poorten [a,c], Athina L. Van Gasse [a,c], Michel Van Houdt [a], Chris H. Bridts [a], Mark Walschot [a], Jean-Pierre Timmermans [d], Isabel Pintelon [d], Christel Mertens [a], Didier G. Ebo [a,b,*]

[a] *Department of Immunology, Allergology, Rheumatology and the Infla-Med Centre of Excellence, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp (Belgium) and Immunology, Allergology, Rheumatology, Antwerp University Hospital, Antwerp, Belgium*
[b] *Department of Immunology, AZ Jan Palfijn Hospital Gent, Ghent, Belgium*
[c] *Department of Pediatrics, Faculty of Medicine and Health Sciences, University of Antwerp and Antwerp University Hospital, Antwerp, Belgium*
[d] *Laboratory of Cell Biology and Histology, Department of Veterinary Sciences, University of Antwerp, Antwerp, Belgium*

Mast cell activation tests by flow cytometry: A new diagnostic asset?

Jessy Elst[1] | Marie-Line M. van der Poorten[1,2] | Athina L. Van Gasse[1,2] | Leander De Puysseleyr[1] | Margo M. Hagendorens[1,2] | Margaretha A. Faber[1] | Michel Van Houdt[1] | Egle Passante[3] | Rajia Bahri[4] | Mark Walschot[1] | Christel Mertens[1] | Chris H. Bridts[1] | Vito Sabato[1,5] | Didier G. Ebo[1,5]

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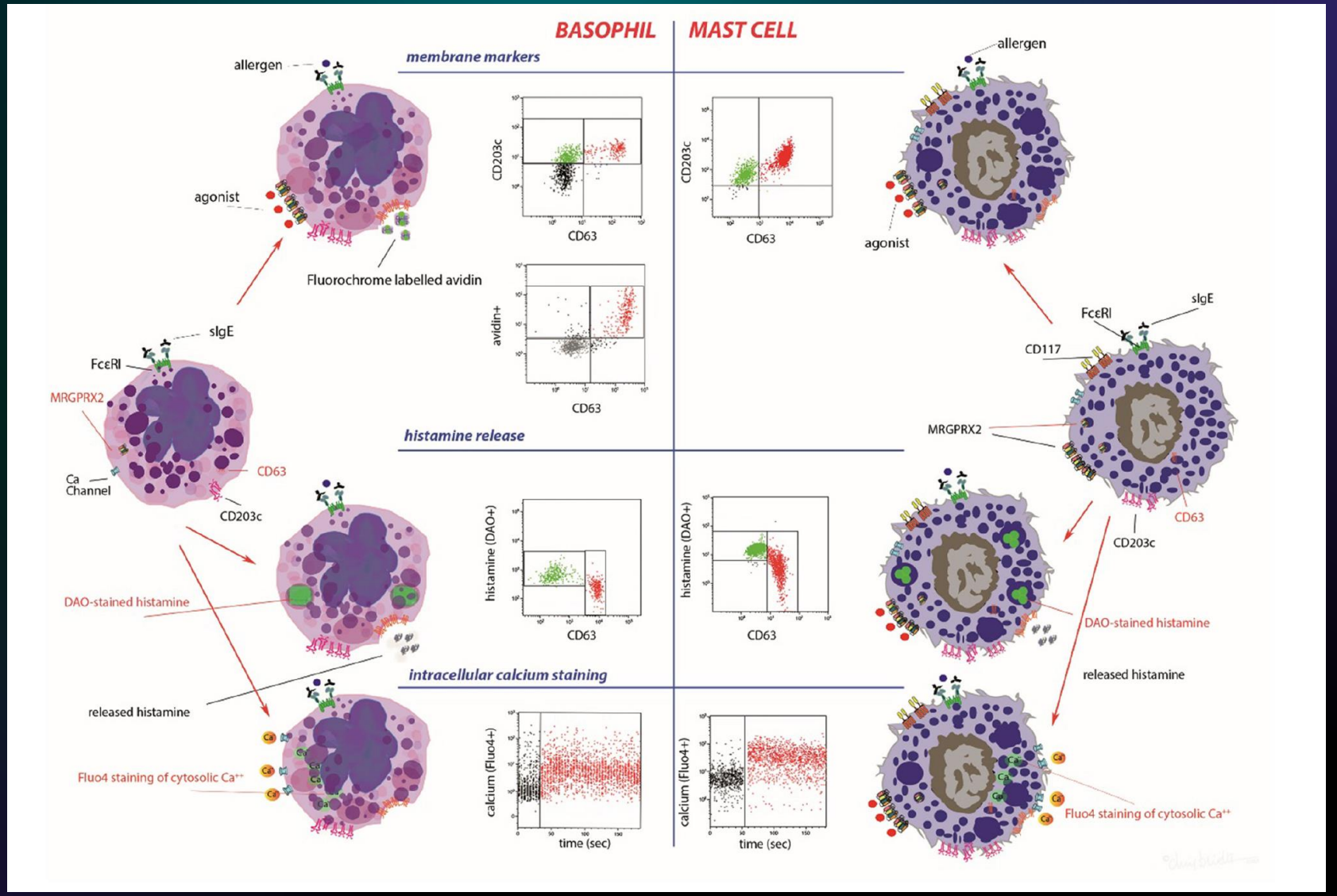

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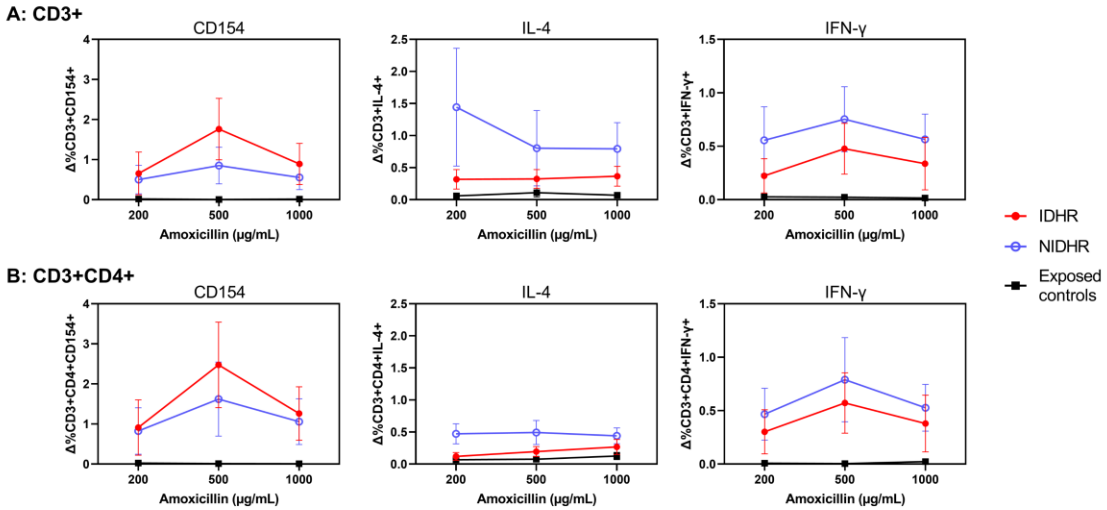
Elst J et al. JIM 2021



Received: 7 January 2020 | Accepted: 8 February 2020
DOI: 10.1111/cea.13581

Check for updates

RESEARCH LETTER

WILEY

CD154 (CD40L): A novel aid to document nonimmediate hypersensitivity to amoxicillin or amoxicillin clavulanic acid

Van Gasse AL et al. CEA 2020

(N)IDHRs

T cell phenotyping

Intracellular cytokines

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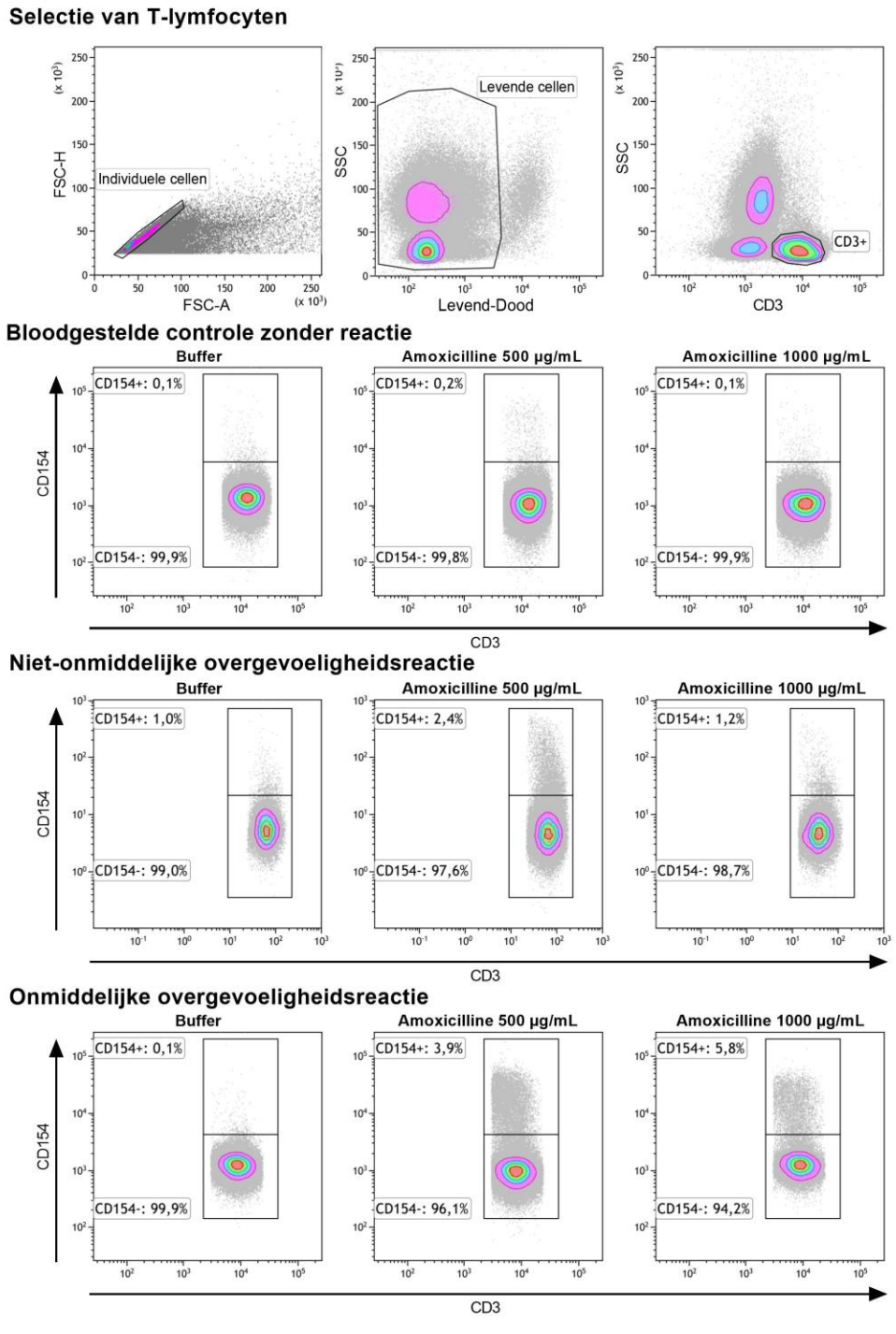
The T …. is the key



Alvarez-Cuesta et al. World Allergy Organization Journal (2022) 15:100640
http://doi.org/10.1016/j.waojou.2022.100640

WORLD ALLERGY ORGANIZATION JOURNAL

Open Access

Standards for practical intravenous rapid drug desensitization & delabeling: A WAO committee statement

Original Article

"Treating Through" Decision and Follow-up in Antibiotic Therapy-Associated Exanthemas

Axel Trautmann, MD, Sandrine Benoit, MD, Matthias Goebeler, MD, and Johanna Stoevesandt, MD *Würzburg, Germany*

Treatment

- Avoidance (alternatives)
- Desensitization
- Treating through

Dept. Immunologie - Allergologie

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- Prof. Dr V. Sabato
- Prof. Dr M.M. Hagendorens
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