

2015 ACR/EULAR Gout Classification Criteria



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SPECIAL ARTICLE

2015 Gout Classification Criteria

An American College of Rheumatology/European League Against Rheumatism
Collaborative Initiative

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Criteria

2015 Gout classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative

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BMJ

Neogi T, et al. *Ann Rheum Dis* 2015;0:1–10. doi:10.1136/annrheumdis-2015-208237

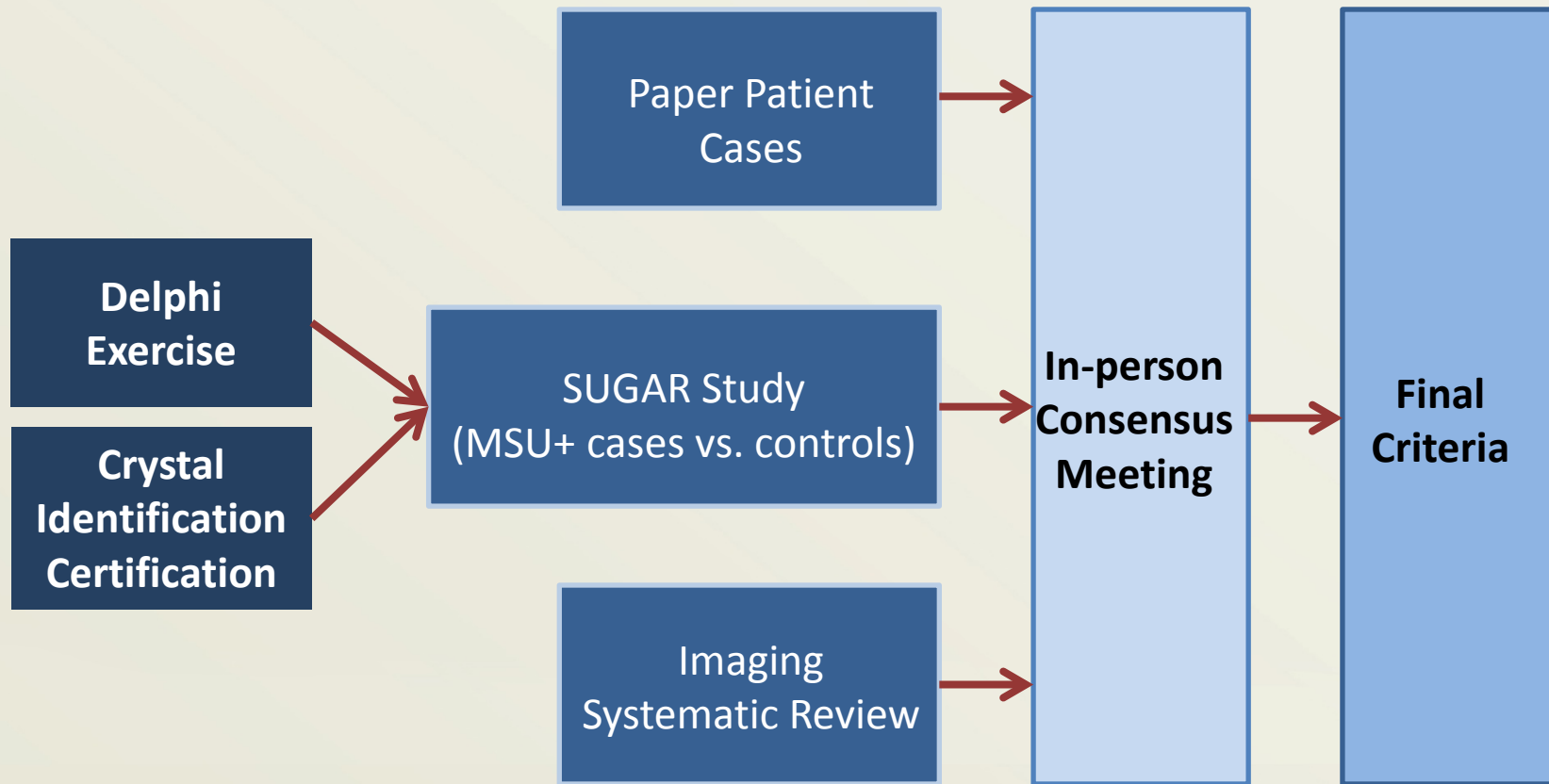
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Intent of Gout Classification Criteria

- To identify, in a standardized manner, a relatively homogeneous group of individuals with gout for enrollment into clinical studies
- Gout classification criteria focus on key features of the disease intended to capture the majority of patients with gout
 - Classification criteria cannot capture all possible presentations of a disease nor avoid capturing presentations of other diseases

Overall Project Structure



Delphi Exercise

Prowse, et al. *J Rheumatol*. 2013;40:498-505

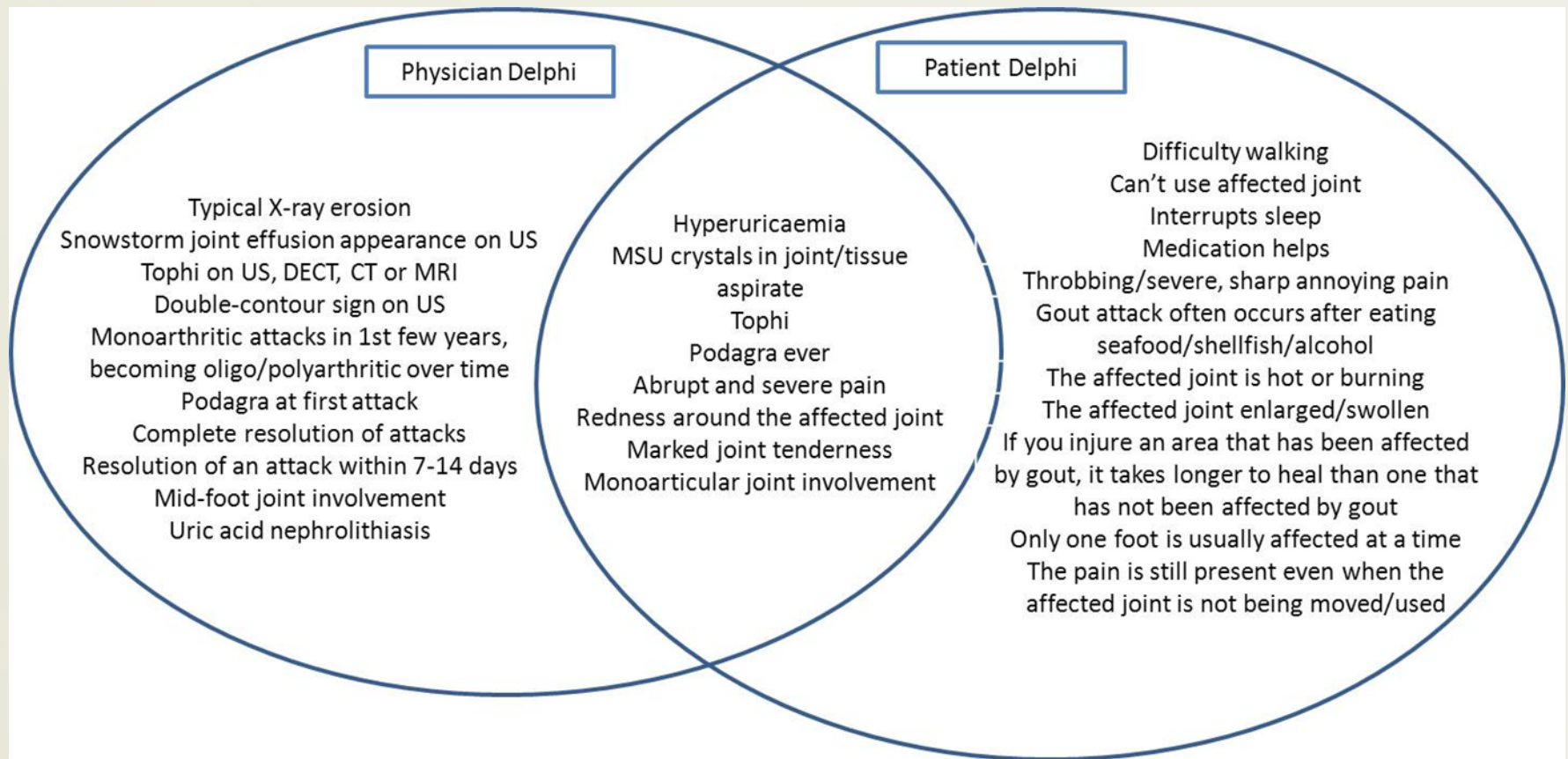


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Delphi Results: Item Generation

Items rated as definitely discriminatory by physicians and/or patients with gout:



Imaging Systematic Literature Review

Ogdie, et al. *ARD*. 2014. Online first 10-JUN-14.
doi:10.1136/annrheumdis-2014-205431



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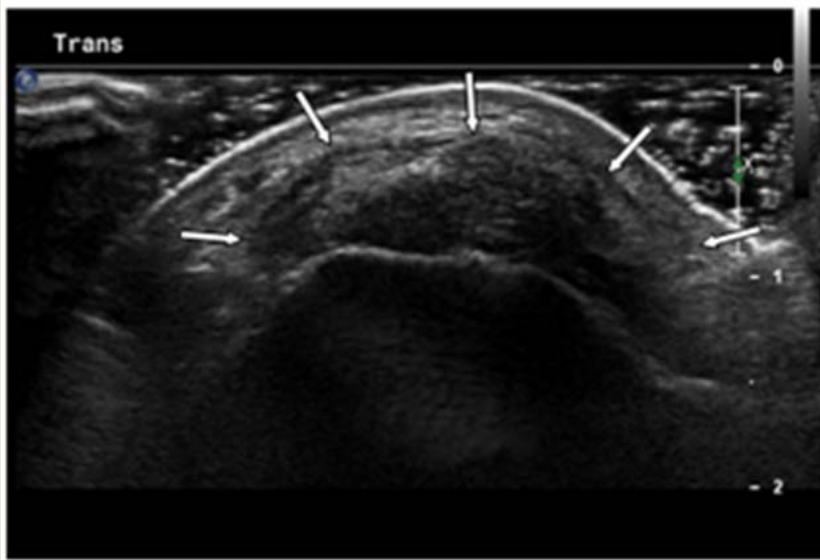
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Imaging Review Results

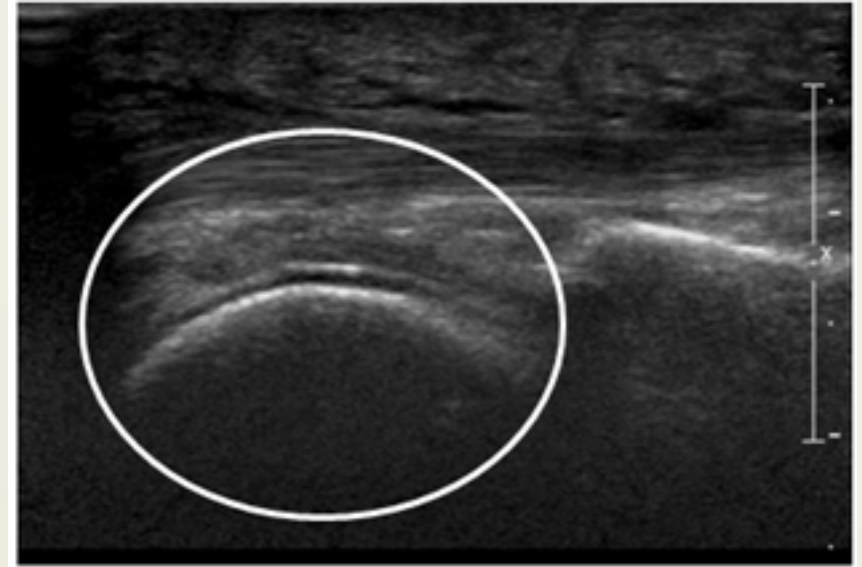
- 10 studies met inclusion/exclusion criteria
 - Studies in which diagnosis was confirmed by MSU identification
 - Literature reviewed to March 2013, plus abstracts from ACR + EULAR 2007-2013



Two Key Ultrasound Features



Ultrasound – tophus
Sensitivity: 0.65
Specificity: 0.80



Ultrasound – double contour sign
Sensitivity: 0.80
Specificity: 0.76



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Dual Energy CT (DECT)



DECT-evidence of urate deposition

Sensitivity: 0.87

Specificity: 0.76



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SUGAR: Study for Uppdated Gout Classification Criteria

Taylor, et al. *AC&R*. 2015. Online first 16-MAR-15.
doi:10.1002/acr.22585



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SUGAR

- International, multicenter cross-sectional study of patients with possibility of gout
 - 25 centers from 16 countries and 4 continents
 - 983 subjects; 653 used as development sample
- Aim: to identify key features that differentiate MSU-crystal proven gout from MSU-negative conditions in patients presenting with joint pain and/or swelling



SUGAR

- All patients underwent synovial fluid or tophus aspirate with polarizing microscopy by a certified* observer to ascertain MSU status, irrespective of clinical diagnosis

*All participating investigators passed a web-based crystal certification examination and examination of a reference set of synovial fluid samples

Final model with optimal performance (c-statistic 0.93):

Item	Odds Ratio (95% CI), p-value
Joint erythema	2.1 (1.1-4.3), p=0.03
≥1 episode difficulty walking	7.3 (1.2-46.1), p=0.03
Time to maximal pain <24 hours	1.3 (0.7-2.5), p=0.4
Resolution by 2 weeks	3.6 (1.9-7.0), p=0.0002
Tophus	7.3 (2.4-22.0), p=0.0004
1 st MTP ever involved	2.3 (1.2-4.5), p=0.01
Location of currently tender joints	(referent: proximal to ankle)
Other foot/ankle joint	2.3 (1.0-5.2)
1 st MTP	2.8 (1.4-5.8) } p=0.01
Serum urate >6mg/dL (0.36mmol/L)	3.4 (1.6-7.2), p=0.002
Ultrasound double contour sign	7.2 (3.5-15.0), p<0.0001
Radiographic erosion or cyst	2.5 (1.3-4.9), p=0.009

Distribution of Joint Involvement

Gout subjects		Non-gout subjects	
Joint pattern	Prevalence (%)	Joint pattern	Prevalence (%)
MTP1	39.4	Knee only	56.8
Knee/ankle	37.1	Any lower extremity joint	30.1
Elbow/wrist/hand	14.9	Wrist/hand + knee	8.0
Polyarticular	8.6	Polyarticular	5.1

Latent class analysis-derived clusters of joint involvement determined from currently tender or swollen joints within each patient group.

Consensus Meeting using Multicriterion Decision Analysis Methodology



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Rationale for Final Phase

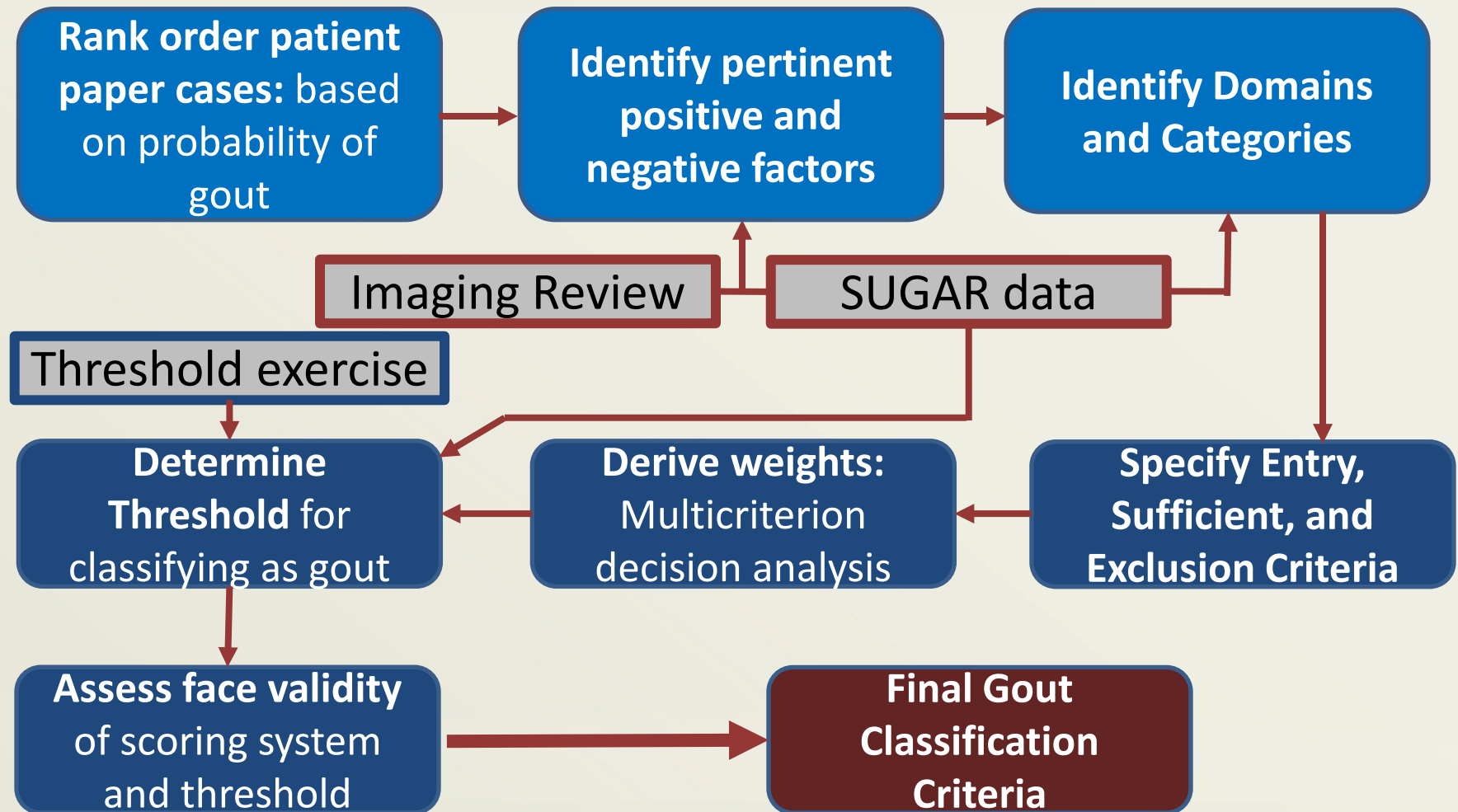
- SUGAR
 - Requirement for MSU determination could lead to potential for selection bias (larger joints, more severe disease, tophaceous disease)
- Imaging systematic literature review
 - Sufficient data may not be present in existing literature
- How to “value” and “weight” each item of information?

Complementary Phase

- To consider a broader spectrum of clinical gout through patient paper cases
- Use multicriterion decision analysis methodology (conjoint analysis) to derive weights for final criteria
 - Similar process to RA and SSc classification criteria



Overview of Approach Used



Entry and Sufficient Criteria

- **Entry:** at least one episode of swelling, pain, or tenderness in a peripheral joint or bursa
 - If not fulfilled, do not apply criteria
- **Sufficient:** Presence of MSU crystals in symptomatic joint or bursa (i.e., in synovial fluid) or tophus
 - If present, can classify as gout without further assessment of criteria
 - Microscopy should be performed by competent examiner



Exclusion Criteria

- ***There are no exclusion criteria***
 - Gout can coexist with other conditions



Domains

- ***Clinical (4):***
 - Pattern of joint/bursa involvement, characteristics of episodes, time-course of episodes, clinical evidence of tophus
- ***Laboratory (2):***
 - MSU crystals, serum urate
- ***Imaging (2):***
 - Evidence of urate deposition (ultrasound double contour sign or DECT), evidence of gout-related joint damage (radiographic gouty erosion)

Clinical Domains



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1. Pattern of Joint/Bursa Involvement

- During symptomatic episode(s) ever:
 - Involvement of 1st MTP joint as part of monoarticular or oligoarticular episode
 - Involvement of ankle *OR* midfoot as part of monoarticular or oligoarticular episode without involvement of the 1st MTP
 - Any other pattern, including 1st MTP/ankle/midfoot as part of ***polyarticular*** presentation

2. Characteristics of Episodes

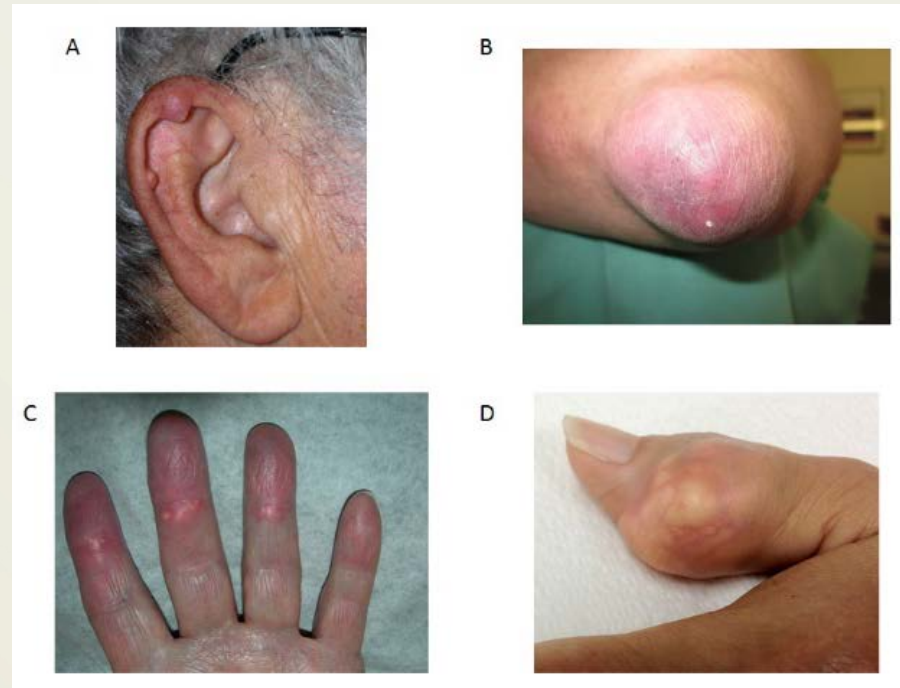
- Characteristics of symptomatic episode(s) ever:
 - Erythema overlying affected joint
 - Can't bear touch or pressure to affected joint
 - Great difficulty with walking or inability to use joint
- Scored as none, one, two, or three characteristics present

3. Time-course of Episodes

- “Typical episode”: Presence (ever) of ≥ 2 of the following during symptomatic episode(s), irrespective of anti-inflammatory treatment
 - Time to maximal pain < 24 hours
 - Resolution of symptoms ≤ 14 days
 - Complete resolution (to baseline level) between symptomatic episodes
- Scored as none, one, or recurrent typical episodes

4. Clinical Evidence of Tophus

- Draining or chalk-like subcutaneous nodule under transparent skin with overlying vascularity
- Typical locations:
 - Ears, olecranon bursa, finger pads, tendon (e.g., Achilles)
- Scored as absent or present



Laboratory Domains



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5. Serum Urate

- Measured by uricase method
- **Ideally**, should be scored at a time when patient was not taking ULT, and patient was beyond 4 weeks of start of an episode (i.e., during intercritical period)
- **If** practicable, retest under those conditions
- **Highest value**, irrespective of timing, should be scored



5. Serum Urate (continued)

- Scored based on SUA value:
 - <4 mg/dL (<0.24 mmol/L)
 - 4 - <6 mg/dL (0.24 - <0.36 mmol/L)
 - 6 - <8 mg/dL (0.36 - <0.48 mmol/L)
 - 8 - <10 mg/dL (0.48 - <0.60 mmol/L)
 - ≥ 10 mg/dL (≥ 0.60 mmol/L)



6. Synovial Fluid Analysis

- Synovial fluid analysis of a symptomatic (ever) joint or bursa assessed by a trained observer*
- Scored as negative or not done
- *If it was positive, then the subject would have met the sufficient criterion and would not need to be further assessed with the criteria scoring



Imaging Domains

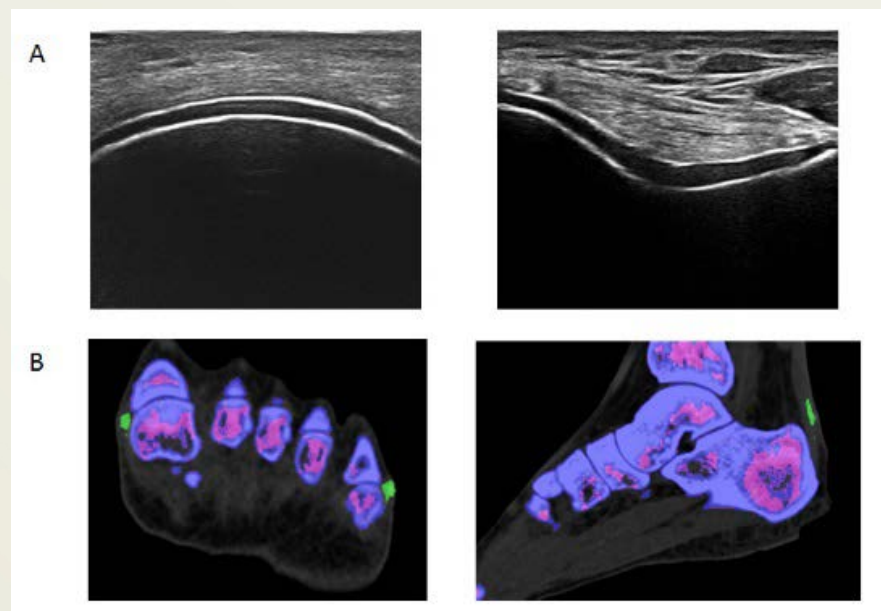


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7. Imaging Evidence of Urate Deposition

- Imaging evidence of urate deposition in symptomatic (ever) joint or bursa:
 - Ultrasound evidence of double contour sign (A)
 - DECT demonstrating urate deposition (B)

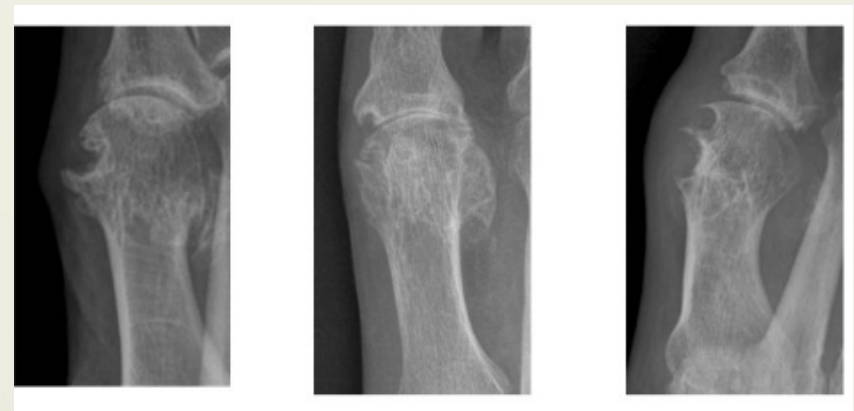


- Score as present (either modality) or absent/not done



8. Imaging Evidence of Gout-related Joint Damage

- Conventional radiography of hands and/or feet demonstrate at least one erosion
 - Erosion: cortical break with sclerotic margin and overhanging edge
 - Excludes: DIP joints, gull wing appearance (to exclude OA-related findings)
- Score as present or absent/not done



Threshold for Classifying Gout

- The ***total*** possible score is 23
- The ***threshold*** for classifying as gout is ≥ 8
 - Balance of Sensitivity and Specificity
 - Performance tested in independent dataset (N=330):
 - Sensitivity: 0.92
 - Specificity: 0.89
 - AUC: 0.95



Comparison with Existing Criteria

Criteria	AUC	Sensitivity	Specificity
2015 ACR/EULAR Criteria	0.95	0.92	0.89
Clinical only (no synovial fluid or imaging information)	0.89	0.85	0.78
ARA 1977 (full)	0.83	1.00*	0.51
ARA 1977 (survey)	0.83	0.84	0.62
Rome	0.95	0.97	0.78
Rome (clinical)	NA	0.77	0.78
New York	0.83	1.00*	0.79
New York (clinical)	NA	0.79	0.78
Mexico	0.84	1.00*	0.44
Mexico (clinical)	NA	0.95	0.44
Netherlands	0.87	0.95	0.59

*100% sensitive by definition with MSU positivity; such individuals would meet sufficient criterion for 2015 ACR/EULAR criteria

ACR-EULAR 2015 Gout Classification Criteria



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ENTRY CRITERION: Has the patient/subject had at least one episode of swelling, pain, or tenderness in a peripheral joint or bursa?

YES

NO



Do not score

SUFFICIENT CRITERION:
MSU+?

YES

NO (UNKNOWN)

**SUBJECT CAN BE
CLASSIFIED AS
GOUT**



**PROCEED TO
CLASSIFICATION
CRITERIA SCORING**



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2015 ACR-EULAR Gout Classification Criteria (1)

Criteria (to be used if Sufficient Criterion not met): Score ≥ 8 required for classification as gout		Categories	Score
CLINICAL	Pattern of joint/bursa involvement during symptomatic* episode(s) ever	Joint(s) or bursa(e) other than ankle, midfoot or 1 st MTP (or their involvement only as part of a polyarticular presentation)	0
		Ankle OR midfoot (as part of monoarticular or oligoarticular episode without MTP1 involvement)	1
		MTP1 (as part of monoarticular or oligoarticular episode)	2
	Characteristics of symptomatic episode(s) ever: i) Erythema overlying affected joint (patient-reported or physician-observed) ii) can't bear touch or pressure to affected joint iii) great difficulty with walking or inability to use affected joint	No characteristics	0
		One characteristic	1
		Two characteristics	2
		Three characteristics	3
	Time-course of episode(s) ever: Presence (ever) of ≥ 2 , irrespective of anti-inflammatory treatment: i) Time to maximal pain < 24 hours ii) Resolution of symptoms in ≤ 14 days iii) Complete resolution (to baseline level) between symptomatic episodes	No typical episodes	0
		One typical episode	1
		Recurrent typical episodes	2
	Clinical evidence of tophus: Draining or chalk-like subcutaneous nodule under transparent skin, often with overlying vascularity, located in typical locations: joints, ears, olecranon bursae, finger pads, tendons (e.g., Achilles).	Absent	0
		Present	4

2015 ACR-EULAR Gout Classification Criteria (2)

LAB	Serum urate: Measured by uricase method. Ideally should be scored at a time when the patient was not taking urate-lowering treatment and patient was beyond 4 weeks of the start of an episode (i.e., during intercritical period); <i>if</i> practicable, retest under those conditions. The highest value irrespective of timing should be scored.	<4mg/dL [$<0.24\text{mM}$] [†]	-4
		4-<6mg/dL [0.24-<0.36mM]	0
		6-<8mg/dL [0.36-<0.48mM]	2
		8-<10mg/dL [0.48-<0.60mM]	3
		≥10mg/dL [≥0.60mM]	4
	Synovial fluid analysis of a symptomatic (ever) joint or bursa:** Should be assessed by a trained observer.	Not done	0
	MSU negative	-2	
IMAGING [‡]	Imaging evidence of urate deposition in symptomatic (ever) joint or bursa: Ultrasound evidence of double-contour sign [¶] <u>or</u> DECT demonstrating urate deposition [§] .	Absent OR Not done	0
		Present (either modality)	4
	Imaging evidence of gout-related joint damage: Conventional radiography of the hands and/or feet demonstrate at least one erosion.**	Absent OR Not done	0
		Present	4
TOTAL SCORE			

Maximum score is 23. Threshold to classify as gout is ≥8.

Criteria		Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle OR midfoot (mono-/oligo-)	1
		MTP1 (mono-/oligo-)	2
	Characteristics of episode(s) ever	One characteristic	1
		Two characteristics	2
		Three characteristics	3
	Time-course of episode(s) ever	One typical episode	1
		Recurrent typical episodes	2
	Clinical evidence of tophus	Present	4
L A B	Serum Urate	<4mg/dL [$<0.24\text{mM}$]	-4
		6-<8mg/dL [$0.36-<0.48\text{mM}$]	2
		8-<10mg/dL [$0.48-<0.60\text{mM}$]	3
		$\geq 10\text{mg/dL}$ [$\geq 0.60\text{mM}$]	4
	Synovial Fluid examination for MSU crystals	negative	-2
I M A G E	Imaging evidence of urate deposition	Present	4
	Imaging evidence of gout-related joint damage	Present	4
Maximum Possible Total Score			23



A web-based calculator can be
accessed at:

<http://goutclassificationcalculator.auckland.ac.nz>



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Illustrative Examples

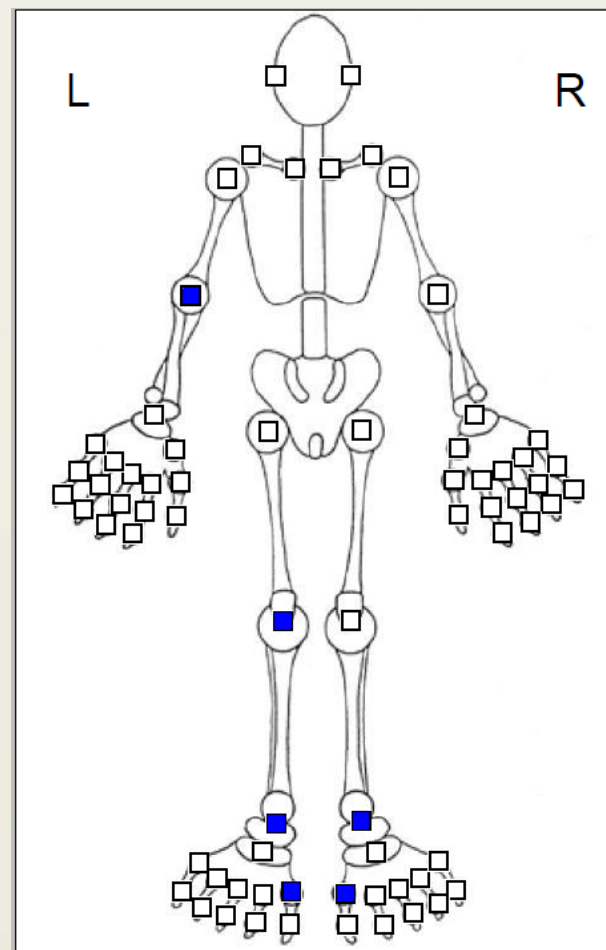


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Case Examples – #1

- 68 y.o. F
- MTP1 – ≥ 1 monoarticular episode (plus other patterns)
- Erythema, can't bear pressure, great difficulty
- Recurrent 'typical' episodes
 - Maximal pain within 12 hrs
 - Resolution within 7 days
 - Complete resolution between episodes
- Clinical tophus (pinnae of ears)
- SUA 0.71mM (~11.8mg/dL)
- No SF/tophus aspiration
- U/S: +double contour sign
- No x-ray performed



Case Examples – #1, cont'd

- MTP1 – monoarticular
- Erythema, can't bear pressure, great difficulty
- Recurrent 'typical' episodes
 - Max pain within 12 hours
 - Resolution within 7 days
 - Complete resolution between episodes
- Clinical tophus (ears)
- SUA 0.71mM (~11.8mg/dL)
- No SF/tophus aspiration
- U/S: +double contour sign
- X-ray not done

Criteria		Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle/midfoot	1
		MTP1	2
	Characteristics of episode(s) ever	One	1
		Two	2
		Three	3
	Time-course of episode(s) ever	One typical	1
		Recurrent	2
	Clinical tophus	Present	4
L A B	Serum Urate	<4mg/dL	-4
		6-<8mg/dL	2
		8-<10mg/dL	3
		≥10mg/dL	4
	Synovial fluid MSU	negative	-2
I M A G E	U/S or DECT +	Present	4
	X-ray gout erosion	Present	4

Case Examples – #2

- 25 y.o. M, multiple episodes
- MTP1 – monoarticular
- Characteristics: can't bear touch, great difficulty walking
- Time-course: maximal pain within 12 hrs; resolves by 14 days; never complete resolution to baseline
- No tophus
- SUA: 0.49 mM (~8.2 mg/dL)
- MSU: negative
- U/S: + DCS
- X-ray: negative

Criteria	Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle/midfoot 1
		MTP1 2
	Characteristics of episode(s) ever	One 1
		Two 2
		Three 3
	Time-course of episode(s) ever	One typical 1
		Recurrent 2
	Clinical tophus	Present 4
L A B	Serum Urate	<4mg/dL -4
		6-<8mg/dL 2
		8-<10mg/dL 3
		≥10mg/dL 4
	Synovial fluid MSU	negative -2
I M A G E	U/S or DECT +	Present 4
	X-ray gout erosion	Present 4

Case Examples – #3

- 46 y.o. M, multiple episodes
- Ankle/midfoot – mono (no MTP1 monoarticular episodes)
- Characteristics: erythema, can't bear touch, great difficulty walking
- Time-course: maximal pain within 12 hrs; no resolution by 14 days; complete resolution to baseline between episodes
- No tophus
- SUA: 0.43mM (~7.2 mg/dL)
- MSU: not done
- U/S, DECT: not done
- X-ray: negative

Criteria	Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle/midfoot 1
		MTP1 2
	Characteristics of episode(s) ever	One 1
		Two 2
L A B		Three 3
	Time-course of episode(s) ever	One typical 1
		Recurrent 2
	Clinical tophus	Present 4
L A B	Serum Urate	<4mg/dL -4
		6-<8mg/dL 2
		8-<10mg/dL 3
		≥10mg/dL 4
I M A G E	Synovial fluid MSU	negative -2
	U/S or DECT +	Present 4
	X-ray gout erosion	Present 4

Case Examples – #4

- 47 y.o. M, multiple episodes
- Oligoarticular MTPs (other)
- Characteristics: can't bear touch, great difficulty walking, erythema
- Time-course: maximal pain within 12 hrs; no resolution by 14 days; never complete resolution to baseline
- No tophus
- SUA: 0.43 mM (~7.2 mg/dL)
- MSU: negative
- U/S: - DCS, DECT not done
- X-ray: +erosion

Criteria	Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle/midfoot 1
		MTP1 2
	Characteristics of episode(s) ever	One 1
		Two 2
		Three 3
	Time-course of episode(s) ever	One typical 1
		Recurrent 2
	Clinical tophus	Present 4
L A B	Serum Urate	<4mg/dL -4
		6-<8mg/dL 2
		8-<10mg/dL 3
		≥10mg/dL 4
	Synovial fluid MSU	negative -2
I M A G E	U/S or DECT +	Present 4
	X-ray gout erosion	Present 4

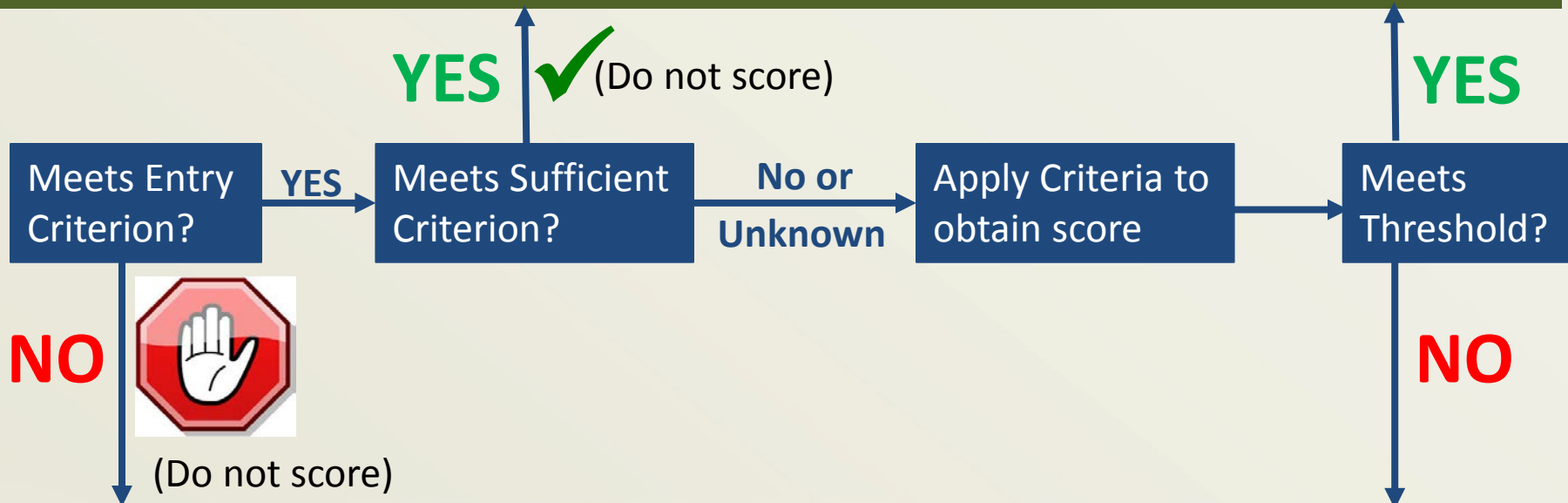
Case Examples – #5

- 62 y.o. F, multiple episodes
- Oligo- upper extremity; polyarticular with lower
- Characteristics: erythema, can't bear pressure
- Time-course: max pain >24hrs, resolution >14 days, never complete resolution
- No tophus
- SUA 5.2mg/dL, during joint pain
- MSU negative
- U/S or DECT not done
- X-ray negative

Criteria	Categories	Score
C L I N I C A L	Pattern of joint/bursa involvement	Ankle/midfoot 1
		MTP1 2
	Characteristics of episode(s) ever	One 1
		Two 2
L A B		Three 3
	Time-course of episode(s) ever	One typical 1
		Recurrent 2
	Clinical tophus	Present 4
I M A G E	Serum Urate	<4mg/dL -4
		6-<8mg/dL 2
		8-<10mg/dL 3
		≥10mg/dL 4
	Synovial fluid MSU	negative -2
	U/S or DECT +	Present 4
	X-ray gout erosion	Present 4

Summary of Steps for Classification of Gout:

Classify as Gout



Do NOT Classify as Gout



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Summary

- New classification criteria for gout have been developed and validated through an international collaborative effort



Acknowledgements (1)

Steering committee: Nicola Dalbeth, Jaap Fransen, Tim L. Jansen (EULAR PI), Tuhina Neogi (ACR PI), H. Ralph Schumacher, William Taylor

Fellows: Dianne Berendsen (EULAR), Alexis Ogdie (ACR)

SUGAR investigators: Melanie Brown, Worawit Louthrenoo, Janitzia Vazquez-Mellado, Maxim Eliseev, Geraldine McCarthy, Lisa K. Stamp, Fernando Perez-Ruiz, Francisca Sivera, Hang-Korng Ea, Martijn Gerritsen, Carlo Scire, Lorenzo Cavagna, Chingtsai Lin, Yin-Yi Chou, Anne-Kathrin Tausche, Ana Beatriz Vargas dos Santos, Matthijs Janssen, Jiunn-Horng Chen, Ole Slot, Marco Cimmino, Till Uhlig

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