Decision algorithms for the re-treatment with viscosupplementation in patients suffering from knee osteoarthritis.
Recommendations from the EUROpean VIScosupplementation COnsensus group

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Background

❖ **Viscosupplementation (VS) is a symptomatic treatment of knee osteoarthritis (KOA).**

❖ **Although systematic reviews of its repeat use showed favorable benefit/risk ratio, no study was focused on the indication of re-treatment.**

❖**A task force, the "EUROVISCO group", has met to look at issues regarding the decision making of re-treatment with VS in KOA.**

Methods

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❖ **10 experts in OA:**

  ❖ from **6** EU countries

  ❖ rheumatologists, orthopedic surgeons, specialists in rehabilitation

  ❖ University / public hospital / private practice

Methods

❖ **3** members of the group were tasked to collate an exhaustive literature analysis on the topic.

❖ **18** statements were discussed during the meeting. After extensive debate, the expert panel had to give opinion on **88** issues within the 18 statements.

Step **1**   Step **2**   Step **3**

❖ **1**: to define "success" and "failure" of VS.

❖ **2**: to determine when and how to re-treat patients in whom VS previously failed.

❖ **3**: to determine when to re-treat patients, successfully treated by a previous VS.

Methods

❖ **Scoring and voting methods:**

    ❖ **For each statement, the experts had to score according to their degree of agreement, using an 4-point Likert scale (0-3), 0 meaning « I don't agree », 1 "I tend to disagree", 2 "I tend to agree" and 3 «I fully agree ». Each item was finally classified into 2 categories: "Agree"or "Disagree".**

    ❖ **After debate and review of literature a statement was adopted and was included into the decision algorithm only if 8 experts or more voted "I Agree" .**

    ❖ **At the end of the session, 2 "Decision Trees" regarding re-treatment with VS were built according to the results of the votes after taking into account all suggestions and comments.**

Definition of treatment "failure"

Issues on Definition of Treatment Failure in Knee OA	Level of Consensus	Agreement	
		Agree	Disagree
Do you agree or disagree with the following definition of "treatment failure six months after VS"?			
Pain decrease on VAS <20 mm	Moderately in favor	7	3
Pain decrease on VAS or WOMAC score <50%	Strongly against	2	8
Pain decrease on VAS or WOMAC score <MCII	Strongly in favor	8	2
Remaining pain >PASS	Strongly in favor	9	1
Pain decrease <MCII and pain >PASS	Moderately in favor	7	3
Pain decrease >MCII and pain <PASS but patient dissatisfied	Strongly in favor	8	2
Pain decrease <MCII and pain >PASS but patient satisfied	Strongly against	2	8

The « Patient Acceptable Symptom State » PASS, and the patient self-assessment of satisfaction were considered as the most relevant tools, to define treatment failure.

Definition of treatment "failure"

To demonstrate the "treatment failure," what are the most useful tools, in daily practice			
WOMAC pain score variation	No consensus	5	5
KOOS variation	Strongly against	2	8
MCII	Weakly in favor	6	4
PASS	Strongly in favor	8	2
OMERACT-OARSI response criteria	Moderately against	3	7
Patient's overall opinion	Unanimously in favor	10	0

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Predictive factors of"failure"

Among the following items which are those you consider as predictive factors of viscosupplementation failure?

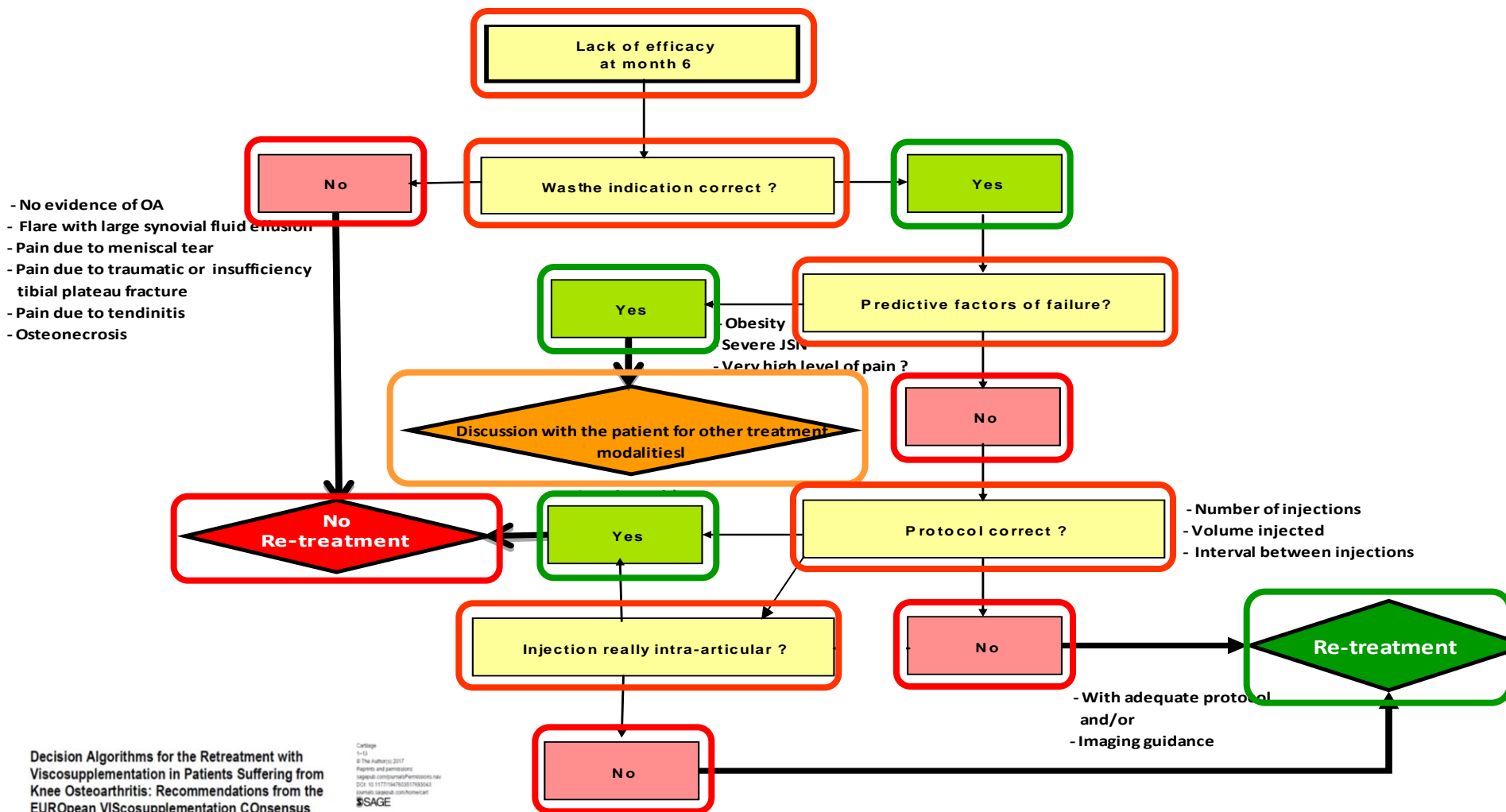|			
Kellgren-Lawrence grade III and IV	Moderate against	3	7
Kellgren-Lawrence grade IV only	Unanimous in favour	10	0
Overweight (BMI between 25 and 30)	No consensus	5	5
Obesity (BMI>30).	Unanimous in favour	10	0
Clinical severity: pain on VAS >6 and ≤8	Strong against	2	8
Clinical severity: pain on VAS ≥8	Weak in favour	6	4
Severe patello-femoral involvement	Strong in favour	9	1
Isolated patello-femoral OA	Strong in favour	8	2
Synovial fluid effusion<10 ml	Strong against	2	8
Synovial fluid effusion >10 ml	Moderate in favour	7	3
Pain due to meniscus tear.	Strong in favour	9	1
OA flare	Strong in favour	8	2

❖ Protocol of injections:

Do you think the dosing regimen must be supported by evidence-based-medicine?	Unanimous in favour	10	0
Do you agree with these assertions?			
Only cross-linking allows a "single injection" regimen?	Unanimous in favour	10	0
Repeated injections (minimum 3) are always necessary for viscosupplements made of linear HA ?	Strong in favour	8	2

❖ Accuracy of injections:

How to ensure the intra-articular administration of the viscosupplement ?			
Imaging guidance	Moderate in favour	7	3
Synovial fluid aspiration	Strong in favour	9	1
Absence of pain at injection	Weak against	4	6
Lateral mid-patellar route of injection	Strong in favour	9	1
Physician experience	Strong in favour	9	1

Algorithm in case of failure

Lack of efficacy at month 6

Was the indication correct ?

No

Yes

- No evidence of OA
- Flare with large synovial fluid effusion
- Pain due to meniscal tear
- Pain due to traumatic or insufficiency tibial plateau fracture
- Pain due to tendinitis
- Osteonecrosis

Predictive factors of failure?

- Obesity
- Severe JSN
- Very high level of pain ?

Yes

No

Discussion with the patient for other treatment modalitiesl

No Re-treatment

Yes

Protocol correct ?

- Number of injections
- Volume injected
- Interval between injections

Injection really intra-articular ?

No

Re-treatment

- With adequate protocol and/or
- Imaging guidance

No

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Re-treatment after success of viscosupplementation

| Issues on re-treatment after success of viscosupplementation	Level of consensus	Agreement	
		Agree	Disagree
Re-treatment with VS must be considered			
Systematically every 6 to 12 months, even if patients remain asymptomatic	Strong against	2	8
Only if pain returns to pre-treatment levels	Strong against	2	8
Only from a certain level of pain (i.e. PASS)	Strong in favour	8	2
As soon as pain occurs again	Strong in favour	9	1
According to the patient's wishes	Moderate in favour	7	3

Re-treatment after success of viscosupplementation

Which of these clinical situations may push you into retreating patients?			
Early stage of OA?	Strongly in favor	9	1
Advanced stage of OA?	Strongly against	2	8
Young age?	Strongly in favor	9	1
Elderly	Moderately against	3	7
Risk factors of rapid progression?	Strongly in favor	9	1
Sports practice (leisure)?	No consensus	5	5
Sports practice (professional)?	Strongly in favor	9	1
Contraindication to arthroplasty?	Moderately in favor	7	3
Severe comorbidities?	Strongly in favor	8	2
Does the chondroprotective properties of HA influence your decision to retreat asymptomatic or little symptomatic patients with HA?	Strongly in favor	8	2

VS = viscosupplementation; OA = osteoarthritis; PASS = Patient's Acceptable Symptom State; HA = hyaluronic acid.

When VS was previously successful, re-treatment can be considered after recurrence or increase in pain. However, in subjects with high risk of disease progression, in young patients, and in professional sportsmen re-treatment could be considered systematically, because of the probability of hyaluronic acid to slow OA progression

Conclusion
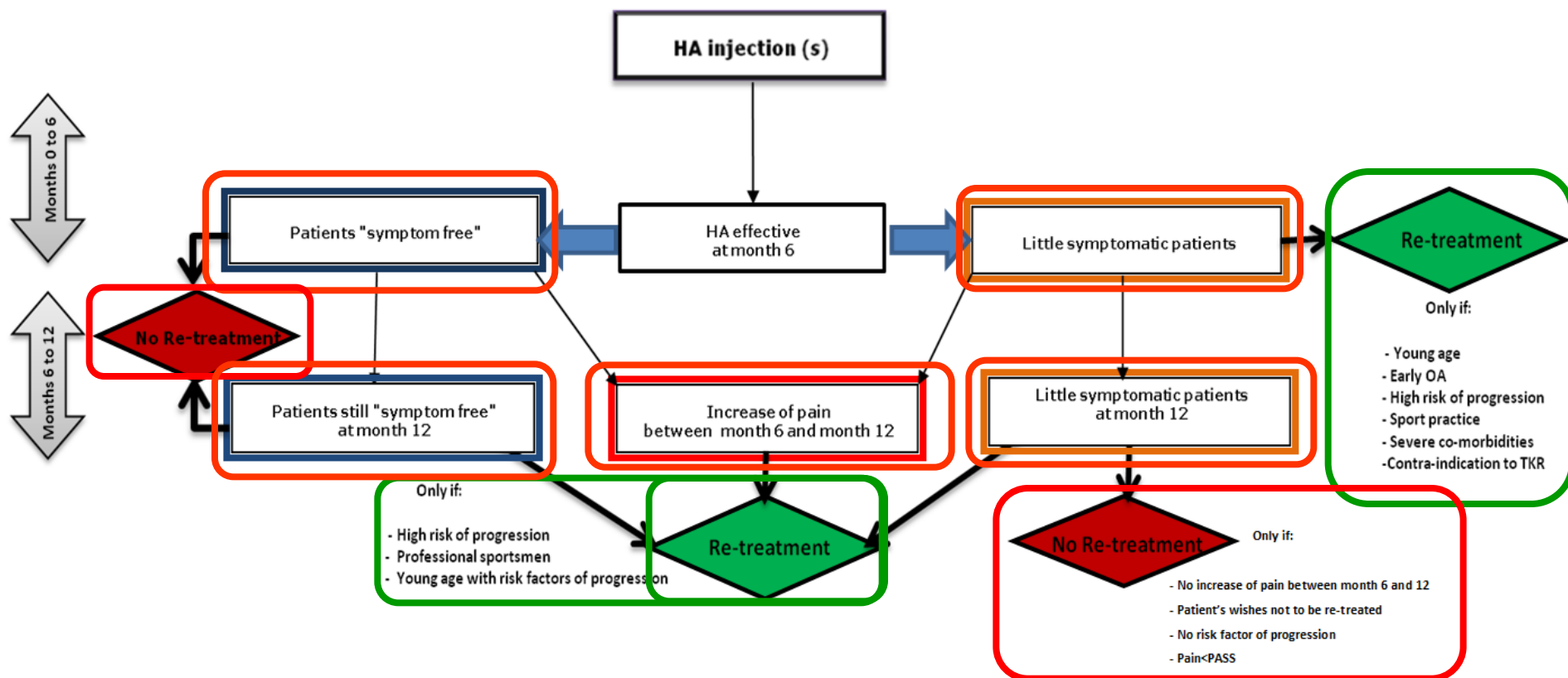
The EUROVISCO working group drew up a set of suggestions aimed to help practitioners in the decision making of re-treatment with VS in patients with knee OA who were previously treated with IA HA injections.

❖ **In case of failure**, the authors draw attention to the necessity of a rigorous clinical and radiological analysis, and to the use of VS in concordance with data from the Evidence-Based-Medicine.

❖ **In patients who previously improved with VS**, re-treatment can be considered as soon as pain recurs or increases again. However, in subjects with a high risk of progression, in young patients, early OA, professional sportsmen, VS re-treatment can be considered systematically even in asymptomatic patients as there is compelling new evidence on HA to retard OA progression

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Thank you for your attention!

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