2. Transfusion sanguine

Le seuil transfusionnel (taux seuil d'hémoglobine en deçà duquel il est recommandé de proposer une transfusion sanguine au patient) est variable en fonction des facteurs de fragilité du patient, de la chronicité de l'anémie, ainsi que des symptômes liés à l'anémie et à leur tolérance. La commission d'évaluation du collège français d'hématologie a fixé le seuil critique à 8 g/dL. Ce seuil doit être plus élevé chez les patients à risque et notamment, les personnes âgées de plus de 65 ans, les patients coronariens ou présentant une maladie cardio-pulmonaire. Inversement, ce seuil peut être abaissé à 7 g/dL chez les patients sans comorbidités cardiovasculaires (56).

Recommandation

Le seuil transfusionnel est fixé à <8g/dl. Il peut être plus élevé chez des patients présentant des facteurs de risque notamment cardio-vasculaire ; ou abaissé à 7g/dl chez certains patients sans facteurs de risque et asymptomatiques.
Toute anémie symptomatique doit faire l'objet d'une transfusion.

3. Les Agents Stimulant l'Erythropoïèse

L'utilisation de ces molécules en cancérologie fait l'objet de recommandations de l'ESMO actualisées en 2018 (57) et de l'ASCO/ASH (58). Les différents produits commercialisés en France sont présentés dans le Tableau 13. La forme pegylée de l'epoétine bêta n'a pas l'AMM dans le domaine de l'oncologie.

DCI	Nom Commercial	Dose initiale	Augmentation de dose si pas d'augmentation de l'Hb (1 g/dL à 4 sem)
Epoétine alfa	EPREX®	450 UI/kg x1/sem.	Non recommandé
	BINOCRIT®*		
Epoétine bêta	NEORECORMON®	30000 UI /sem (450 UI/kg x1/sem)	Non recommandé
Epoiétine thêta	EPORATIO®*§H	20000 UI x1/sem	40000 UI x1/sem
Epoiétine zêta	RETACRIT®*	450 UI/kg 1 fois/sem	Non recommandé
Darbepoétine alfa	ARANESP®	2,25 µg/kg x1/sem ou 500 µg (6,75 µg/kg) x1/3 sem	Non recommandé

Tableau 13 – Différents ASE disponibles en France et posologies recommandées
*Les * indiquent un produit biosimilaire*

[H] Site de l'EMA, Résumé des Caractéristiques du Produit, http://www.ema.europa.eu/docs/fr_FR/document_library/EPAR_-_Product_Information/human/001033/WC500043300.pdf

L'intérêt des ASE est de réduire les besoins transfusionnels et leurs complications en augmentant le taux d'hémoglobine. En oncologie thoracique, les ASE ont montré qu'ils amélioraient le taux d'hémoglobine de 1,63 g/dL [IC95% 1,46-1,80] en moyenne et réduisaient le risque de transfusion de 42% (RR = 0,58; [IC95%} 0,53 – 0,64]). Les ESA améliorent également la qualité de vie notamment grâce au contrôle des symptômes liés à la fatigue et à l'anémie (59). Les ESA n'ont par contre jamais démontré leur bénéfice en termes de survie globale ou sans progression (47,60). De même, leur ratio coût-efficacité semble peu attractif d'un point de vue économique (50). Il ne semble pas que les ASE augmentent le risque de progression tumorale. Il est désormais bien établi que ces agents sont responsables d'une augmentation du risque thrombotique (RR = 1,51; IC95%, 1,30-1,74) ce qui a conduit à encadrer de manière stricte leur utilisation. L'efficacité et les effets indésirables semblent identiques pour l'époiétine et la darbepoétine dans l'étude groupée de l'agence américaine de recherche et de qualité dans les soins (61).

- Il est recommandé de n'instaurer les ASE **qu'après avoir recherché et corrigé une cause alternative d'anémie** et particulièrement un déficit en fer, en folate et/ou en vitamine B12.
- Les ASE ne doivent être utilisés que pour le traitement des anémies induites au cours d'une chimiothérapie.
- Les ASE ne sont pas recommandés pendant la radiothérapie seule mais peuvent être prescrite au cours de la radio-chimiothérapie.
- Les différentes ASE semblent avoir une efficacité identique et des effets secondaires similaires.
- Il est recommandé **d'associer une supplémentation martiale en cas de carence martiale absolue ou fonctionnelle** (62). De nombreuses données concordent à dire que la voie intraveineuse est plus efficace sur la réponse hématologique et la réduction du nombre de transfusion par rapport à la voie orale (63)(64)(65). L'ESMO suggère que la supplémentation ferrique orale puisse être en option en cas de carence martiale vraie (Ferritinémie < 100ng/mL) ET en l'absence d'inflammation (CRP<5UI) (57). La surveillance de l'efficacité de cette supplémentation peut être réalisée avec des dosages réguliers de la ferritine et du Coefficient de Saturation de la Transferrine (CSAT). Si le taux de ferritine est supérieur à 100 ng/L (1000µg/L), il est conseillé de suspendre le traitement ferrique jusqu'à une valeur de ferritinémie <100 ng/L. Il existe plusieurs options pour l'administration de fer injectable. Elles sont reprises dans le tableau 15.
- Les résultats d'une analyse de 7 études ayant utilisé du fer intraveineux chez des patients atteints de cancer suggèrent une efficacité sur la correction de l'anémie (augmentation du taux d'hémoglobine avec diminution des besoins transfusionnels) même en l'absence d'ASE et quel que soit le mécanisme de l'anémie (il s'agit cependant d'études hétérogènes) (66).
- Les ASE doivent être **initiés pour des taux d'hémoglobine au-dessous de 10 g/dl**. Dans une nouvelle analyse rétrospective de l'un des essais de phase III (promue par Amgen) de la Darbepoeitine alpha, il a été montré qu'il était préférable d'initier les ESA précocement lorsque l'on passe au-dessous du seuil de 10 g/dL : **au-dessus de 9 g/dL idéalement**. Dans le cas contraire, malgré les ESA, le recours aux transfusions sanguines est plus fréquent et les chances de restaurer une hémoglobine optimale (au-dessus de 10 g/dL) sont plus minces (67,68).
- Le **taux cible d'hémoglobine est d'environ 12 g/dl**. L'augmentation au-delà de 13 g/dl doit être évitée.
- Les antécédents personnels de thrombo-embolie, l'état clinique du patient, une chirurgie récente, sont des facteurs à prendre en compte pour évaluer le risque de complications thrombo-emboliques sous ASE.
- Le traitement doit être débuté aux doses figurant dans les résumés des caractéristiques des produits et reprises dans le tableau 14. Le taux d'hémoglobine, le bilan martial (CSAT et Ferritinémie) et le dosage sérique des vitamines B12 et Folates doivent être surveillés toutes les 3-4 semaines.
- Les recommandations concernant l'adaptation posologique des ASE en fonction de l'hémoglobine sont rapportées dans la figure 2. A l'exception de l'époiétine thêta, il n'est plus recommandé d'augmenter les doses à 4 semaines en cas d'inefficacité des ASE (augmentation de l'Hb inférieure à 1g/dL à 4 semaines) et les ESA doivent alors être arrêtées.
- En cas de réponse, le traitement par ASE doit être poursuivi jusque 4 semaines après l'arrêt de la chimiothérapie.

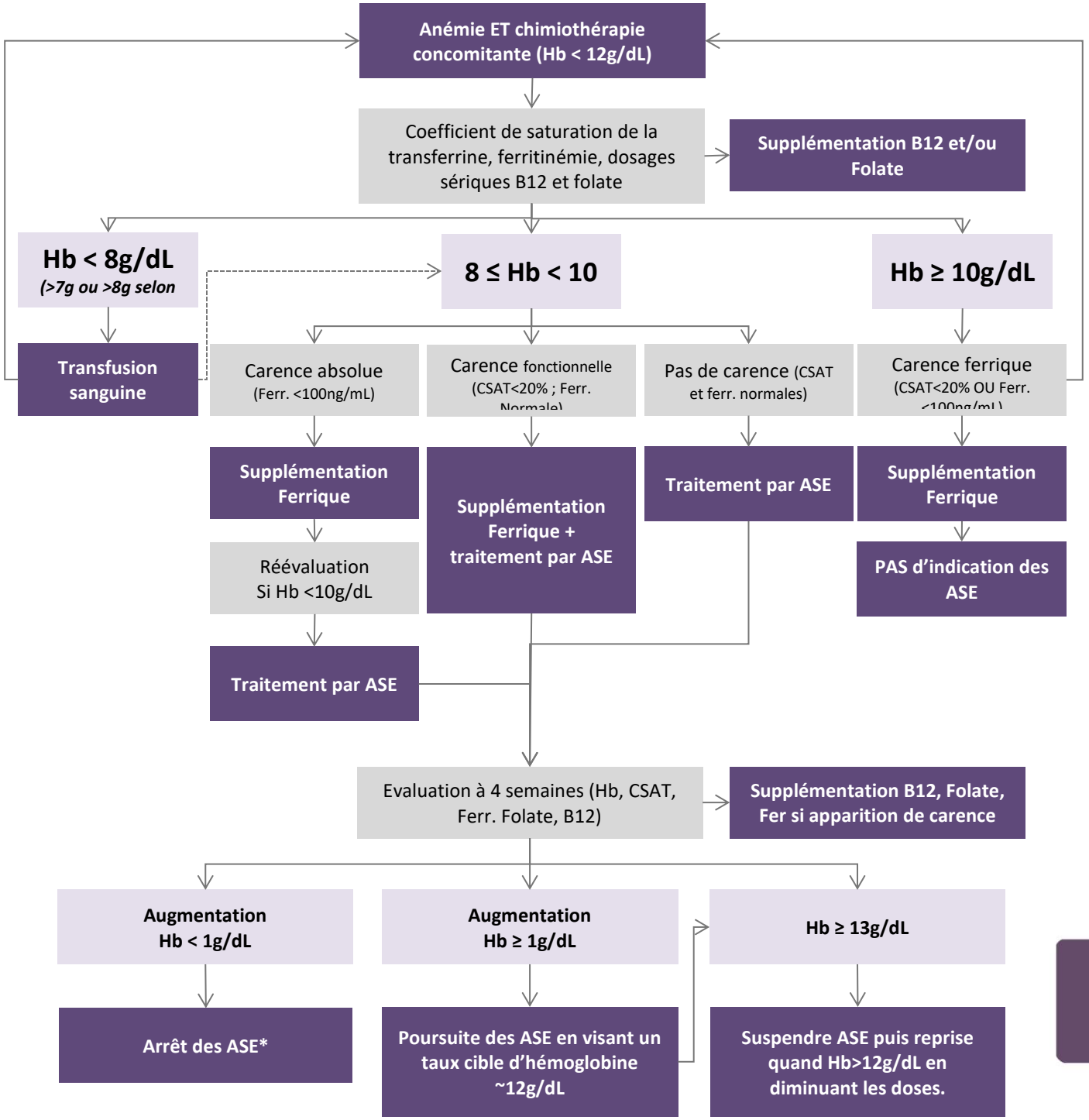
Pour mémoire, et bien que les anémies de grades 1-2 soient fréquentes sous ITK[I], les ASE n'ont pas l'AMM dans cette indication et le traitement repose essentiellement sur une supplémentation martiale si besoin et des soins symptomatiques (69).

DCI et nom commercial	Posologie	Mode d'administration	Disponibilité en ville
Carboxymaltose ferrique FERINJECT® 50 mg	1000mg	La dose unique à ne pas dépasser est de 1000 mg/j. Ne pas administrer 1000 mg plus d'une fois par semaine. Voie intraveineuse[J] : - Bolus : jusqu'à 1000 mg de fer (sans dépasser 15 mg/kg). - Perfusion : dose unique maximale pouvant atteindre 1000 mg de fer (sans dépasser 20 mg/kg de poids corporel).	OUI
Oxyde ferrique VENOFER® 100 mg *Sous surveillance renforcée depuis Mars 2014*	1000mg en plusieurs injection de 100 à 200 mg par injection x 1 à 3/sem, en respectant un intervalle de 48h entre chaque injection	Voie intraveineuse en perfusion lente. La dose par injection ne doit pas dépasser 300 mg	NON

Tableau 14 – Solutions de fer injectable disponibles en France

[I] Inhibiteur des Tyrosines Kinases de l'*Epidermal Growth Factor Receptor*

[J] Se référer au résumé des caractéristiques du produit pour les modalités d'administration



*Sauf epoïetine thêta
Ferr. Ferritinémie – CSAT: Coefficient de Saturation de la Transferinne

Figure 2 – Proposition d'arbre décisionnel pour la prescription et le suivi des ASE (Adapté de (57)**).**

Recommandations

- Il est recommandé de rechercher et traiter une cause alternative d'anémie.
- Les ASE ne doivent être utilisées que pour la correction d'une anémie liée à une chimiothérapie et en dehors de la radiothérapie seule.
- Il est recommandé d'associer une supplémentation martiale en cas de carence ferrique vraie ou fonctionnelle. Il est recommandé d'administrer le fer par voie intraveineuse à la dose de 1000mg/semaine en une ou plusieurs injections jusqu'à correction.
- Les ASE doivent être initiées pour des taux d'hémoglobine en dessous de 10 g/dl.
- Le taux cible d'hémoglobine est d'environ 12 g/dl. L'augmentation au-delà de 13 g/dl doit être évitée.
- Il est recommandé de contrôler l'hémoglobine, le bilan martial, et les dosages des folates/B12 toutes les 3-4 semaines et d'adapter les traitements en fonction de ces dosages.
-Si le taux d'hémoglobine n'est pas augmenté d'au moins 1 g/dL après 4 semaines (sauf epoïétine thêta), il est inutile de poursuivre le traitement par ASE.
-En l'absence de données spécifiques, les ASE ne sont pas recommandés pour le traitement des anémies survenant sous ITK (70)**.**

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