inclus dans l'étude étaient PS 0-1 lors de la randomisation (après chirurgie et chimiothérapie), et atteint d'un CBNPC avec une mutation *EGFR* L858R ou Del19 (seules ou associées à une autre mutation *EGFR*). L'objectif principal était la survie sans maladie (*disease free survival*) chez les patients de stades II et IIIA. Au total 682 patients ont été inclus dont 470 de stades II et IIIA (TNM7)[11]. Lors de la publication des résultats, les données étaient matures à 33%. A 2 ans, 90% [IC95% 84%-93%] des patients du bras osimertinib et 44% [37%-51%] du bras placebo étaient en vie et sans maladie. Ainsi, la médiane de survie sans maladie n'était pas atteinte dans le groupe osimertinib (38.8-NC) et de 19,6 mois (16,6-24,5) dans le bras placebo (HR 0,17 [IC 99.06% 0,11-0,26]). Le bénéfice dans les stades IB (IIA dans la TNM 8) (objectif secondaire) semble moins important numériquement mais reste significatif (HR=0.39 [IC95% 0.18-0.76]). Il existe en outre un bénéfice sur les progression au niveau du système nerveux central (médiane de survie-sans maladie au SNC HR 0.18 [0.10-0.33]) (78). Des données actualisées à 4 ans, allant dans le même sens, ont été présentés à l'ESMO 2022[12]. Concernant la survie globale, un communiqué de presse de la société Astra Zeneca vient d'annoncer qu'elle était positive et « cliniquement significative ». Les données complètes n'ont toutefois ni été présentées, ni publiées.

Recommandations

L'osimertinib est recommandé pendant 3 ans, en cas de mutation *EGFR* L858R ou Del19, chez les patients de stades IB, II et IIIA (plus les T4N2 dans la classification TNM8), réséqués, après chimiothérapie adjuvante lorsqu'elle est indiquée ou réalisable, et restant PS 0-1.

4. Formes localement avancées (stades IIIA non opérables, IIIB, IIIC)

Les stades IIIB et IIIC sont jugés inopérables sauf quelques cas particuliers (*cf*. infra). Les limites de la résécabilité concernent les stades IIIA, en fonction de l'envahissement ganglionnaire homolatéral (N2).

Tous les dossiers doivent être discutés en RCP pour déterminer la stratégie optimale (séquence traitement systémique et traitement local).

4.1 Stades IIIA non résécable, IIIB et IIIC ou patients non médicalement opérables

Il y a lieu de réaliser une association de chimiothérapie et de radiothérapie suivie d'une immunothérapie si l'état du patient le permet. La chimiothérapie doit comporter 2 à 4 cures à base de sels de platine, associées à une radiothérapie à une dose comprise entre 60 et 66Gy en fractions de 2 Gy par fraction, 5 fractions par semaine (79). En cas de chimiothérapie d'induction, le volume cible macroscopique tumoral (GTVT) doit être fondé sur l'imagerie post chimiothérapie mais l'imagerie pré-chimiothérapie doit tout de même être prise en compte. Le volume cible macroscopique ganglionnaire doit inclure les ganglions envahis avant la chimiothérapie. Seuls les structures ou volumes anatomiques considérés comme tumoraux sont irradiés (80). Le volume cible anatomoclinique CTV inclut le volume tumoral macroscopique augmenté de la maladie infraclinique (CTVT = GTVT + 5 à 8mm et CTVN = GTVN + 3 à 8 mm selon la taille du ganglion (<2 cm ou > 2 cm)). Le volume cible prévisionnel PTV doit être déterminé par chaque centre selon ses techniques de traitement et de repositionnement ; le plus souvent PTV = CTV + 5 mm. Les mouvement internes de la tumeurs peuvent être pris en compte soit avec un

[11] Les différences sont minimes toutefois pour la séléction des patients. Tous les stades IB de la TNM7 étaient éligibles (soit les tumeurs de 3 à 5cm correspondant désormais aux stades IB (Tde 3 à 4cm) et IIA (T de 4 à 5cm). Deplus,les patients atteints de tumeur ex-T3 (de moins de 7cm mais envahissant la paroie, ou le diaphragme, ou le nerf phrénique, ou la plèvre, ou la bronche souche (<2cm de la carène), ou associé à une atéléctasie ou une pneumopathie obstructive de tout le poumon ou avec des nodules tumoraux dans le même lobe) et N2 étaient classés IIIA dans la précédente classification TNM et sont désormais catégorisés IIIB. De même, les

[12] Tsuboi M, Osimertinib as adjuvant therapy in patients with resected EGFRm stage IB-IIIA NSCLC : updated results from ADAURA. ESMO 2022, Paris, #LBA47.

volume additionnel (ITV, obtenu sur un scanner dosimétrique 4D) soit en diminuant ces mouvements grace aux techniques d'asservissement respiratoire. L'ensemble des organes à risque et les contraintes de doses pour l'irradiation thoracique sont disponibles dans le RECORAD (81). Des études sont en cours pour ajuster la planification dosimétrique en cours d'irradiation.

La dosimétrie doit être réalisée avec un système de planification du traitement qui prend en compte les hétérogénéités de dose dans le thorax (type B ou C), des photons de 6 à 10 MV au maximum doivent être recommandés. La radiothérapie avec modulation d'intensité doit être privilégiée lorsque la technique est disponible car elle apporte un bénéfice dosimétrique, notamment au niveau des doses cardiaques, ainsi qu'un taux plus faible de pneumopathie radique et une amélioration de la qualité de vie.

Un schéma hypofractionné (en séquentiel) peut se discuter.

- **L'association chimio-radiothérapie concomitante** est recommandée chez les patients avec PS 0 ou 1, sans comorbidité, de moins de 70 ans (peut être discutée au-delà) compte tenu de ses meilleurs résultats (82). Une technique de radiothérapie de conformation est indispensable avec évaluation précise des volumes pulmonaires irradiés. La chimiothérapie doit être à base de sel de platine, mais sans gemcitabine. Il n'y a pas de différence entre une chimiothérapie d'induction de 2 cycles ou de consolidation de 2 cycles autour de la phase d'association chimio-radiothérapie.
- Après la phase de radio-chimiothérapie concomitante l'utilisation de durvalumab 10 mg/kg toutes les deux semaines ou 1500 mg toutes les 4 semaines pendant 12 mois est recommandée. L'AMM est disponible quel que soit le niveau d'expression de PDL1. Une RTU est en cours pour les patients avec un PDL1<1% ou inconnu (83,84).
- **L'association chimiothérapie-radiothérapie séquentielle** est préconisée chez les patients PS > 1 et/ou âgés et/ou fragiles. On notera que l'AMM européenne du durvalumab ne précise pas le type de schéma de radiothérapie préalable[13]. En outre, des études rétrospectives montrent une effcicacité similaire de cette immunothérapie après radiothérapie séquentielle comparée à une radiothérapie concommitante (85,86) [14] . L'immunothérapie adjuvante après radiochimiothérapie séquentielle est donc possible (dans les mêmes conditions que ci-dessus).

-**La radio sensibilisation** par sel de platine (cisplatine ou carboplatine) ou autre drogue, hebdomadaire, à faible dose, dans le but unique de radio sensibilisation sans action systémique n'est pas recommandée.

Recommandations

Les 2 schémas de chimiothérapie les plus utilisés en concomitant de la radiothérapie sont :

- **cisplatine 80 mg/m² J1 et vinorelbine 15 mg/m² J1, 8 avec une intercure de 21j**
- **carboplatine AUC 2, J1,8,15 et paclitaxel 45 mg/m² J1,8,15 avec une intercure de 21j.**

Après la phase de radio-chimiothérapie, l'utilisation de durvalumab 10 mg/kg toutes les deux semaines ou 1500 mg toutes les 4 semaines pendant 12 mois et débutant dans les 42 jours suivant la fin de la radiothérapie est recommandée, en l'absence de progression et de contre-indication (dans le cadre d'une RTU pour les PDL1<1% ou inconnus).

[13] Extrait du résumé des caractéristiques du produit : durvalumab « as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy ». AMM européenne du 30/10/2018 disponible sur https://www.ema.europa.eu/en/medicines/human/EPAR/imfinzi (consulté le 07/01/2019).

[14] PACIFIC-R real-world study: Treatment duration and interim analysis of progression-free survival in unresectable stage III NSCLC patients treated with durvalumab after chemoradiotherapy. ESMO 2021 congress, #1171MO.

OPTION : cisplatine (75 mg/m²) – pemetrexed (500 mg/m²) J1-J22 (87) **uniquement pour les cancers non-épidermoïdes (en cas de contre-indication au cisplatine, il pourra être remplacé par du carboplatine).**

4.2 Cas particulier des tumeurs de l'apex (syndrome de PANCOAST TOBIAS « pur » ou « assimilé »)

-Il est recommandé de réaliser d'emblée une association concomitante de chimiothérapie et de radiothérapie jusqu'à 44-46 Gy, avec une réévaluation en vue d'une chirurgie et/ou poursuite de la radiothérapie jusqu'à une dose de 66 Gy (88).

-Chez les patients **fragiles**, non opérables, une association radio-chimiothérapie est réalisée, voire une radiothérapie seule pour les patients douloureux en mauvais état général.

-En cas de N2 prouvé (médiastinoscopie ou ponction), les patients ne tirent aucun bénéfice d'un acte chirurgical.

Recommandations

Dans le cas des tumeurs de l'apex, il est recommandé de réaliser d'emblée une association concomitante de chimiothérapie et de radiothérapie jusqu'à 46 Gy, avec une réévaluation en vue d'une chirurgie (hors N2) et/ou poursuite de la radiothérapie jusqu'à une dose de 66 Gy. Les protocoles de chimiothérapie à utiliser sont ceux des stades IIIB/C.

OPTION : Association radiothérapie préopératoire, chirurgie puis chimiothérapie post-opératoire.

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