LIGNES DIRECTRICES CANADIENNES SUR LA PPrE ET LA PPE AU VIH

## APPENDICE 4 – TABLEAUX SOMMAIRES DES CONCLUSIONS

**Tableau D1. Régimes de PPrE[ab]**

| Régime | Population | PPrE | Contrôle (placébo ou sans PPrE) | Ampleur de l'effet (intervalle de confiance 95 %)[c] | Qualité de la preuve | Commentaires | Nombre de participants (études) |
|---|---|---|---|---|---|---|---|
| **Résultat : Infection par le VIH** | | | | | | | |
| TDF/FTC quotidiens | HARSAH et FTG | 39/1 487 | 84/1 477 | RR=0,31 (0,08, 1,21) | Élevée | Inclut seulement 339 FTG | 2 964 (3) |
| | | 1,8/100 AP | 2,6/100 AP | HR=0,51 (0,21, 1,01) | Faible | Inclut seulement 140 FTG | 1 225 (1) |
| | HARSAH[d] | 0,26/100 AP | s.o. | s.o. | Faible | Les quatre infections sont survenues chez des personnes qui ne suivaient pas de PPrE, n'y étaient pas fidèles ou venaient de la commencer | 1 985 (4) |
| | Femmes hétérosexuelles | 124/3 671 | 165/3 554 | RR=0,63 (0,39, 1,00) | Élevée | | 7 225 (6)[e] |
| | Hommes hétérosexuels | 13/2 757 | 58/2 253 | RR=0,18 (0,10, 0,34) | Élevée | | 5 010 (4)[e] |
| | Hommes et femmes hétérosexuels | 0,2/100 AP | 5,2/100 AP | RR=0,04 (0,01, 0,19) | Faible | La valeur de contrôle est un résultat contrefactuel simulé | 1 013 (1) |
| TDF/FTC à la demande | HARSAH | 2/199 | 14/201 | RR=0,14 (0,02, 0,60) | Élevée | La valeur de contrôle est le placébo | 400 (1) |
| | | 0,19/100 AP | 6,60/100 AP | RR=0,03 (0,00, 0,19) | Faible | La valeur de contrôle est le groupe placébo de la | 361 (1) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | phase randomisée de l'essai | |
| TDF | HARSAH | 0/101 | 7/299 | RR=0,20 (0,01, 3,40) | Élevée | | 400 (1) |
| | Femmes hétérosexuelles | 77/2 847 | 97/2 669 | RR=0,53 (0,21, 1,37) | Élevée | | 5 516 (4)[e] |
| | Hommes hétérosexuels | 25/2 359 | 48/1 918 | RR=0,42 (0,26, 0,68) | Élevée | | 4 277 (2)[e] |
| | PID | 17/1 204 | 33/1 207 | RR=0,51 (0,28, 0,90) | Élevée | | 2 411 (1) |
| | PID | 0,21/100 AP | s.o. | s.o. | Faible | | 573 (1) |
| **Régime** | **Population** | **PPrE** | **Contrôle (placébo ou sans PPrE)** | **Ampleur de l'effet (intervalle de confiance 95 %)[c]** | **Qualité de la preuve** | **Commentaires** | **Nombre de participants (études)** |
| **Résultat : Tout événement indésirable** | | | | | | | |
| TDF/FTC quotidiens | Toutes populations | 3 634/5 537 (65,6 %) | 3 590/5 525 (65,0 %) | RR=1,01 (0,99, 1,03) | Élevée | | 11 062 (8) |
| TDF/FTC à la demande | HARSAH | 186/199 (93,5 %) | 181/201 (90,0 %) | RR=1,58 (0,76, 3,27) | Élevée | | 400 (1) |
| TDF quotidien | Toutes populations | 2 785/4 222 (66,0 %) | 2 800/4 234 (66,1 %) | RR=0,98 (0,86, 1,13) | Élevée | | 8 456 (4) |
| **Résultat : Résistance au(x) médicament(s) de la PPrE parmi les participants contractant l'infection à VIH** | | | | | | | |
| TDF/FTC quotidiens | Toutes populations | 13/219 | 2/242 | RR=7,18 (1,64, 31,47) | Élevée | | 461 (17) |
| TDF/FTC à la demande | HARSAH | 0/3 | 0/14 | Non estimable | Élevée | | 17 (2) |
| TDF quotidien | Toutes populations | 1/121 | 0/157 | RR=3,89 (0,16, 94,54) | Élevée | | 278 (7) |

[a] FTC=emtricitabine, HR=rapport des risques, HARSAH=hommes ayant des rapports sexuels avec d'autres hommes, s.o.=sans objet, AP=années-personnes, RR=risque relatif, TDF=fumarate de ténofovir disoproxil.

[b] Les données sont tirées de 14 essais contrôlés randomisés[1-14] et de neuf études de cohorte[15-23].

[c] Lorsqu'une seule étude était disponible, la valeur indiquée représente l'ampleur de l'effet déclaré dans l'étude originale. Lorsque plusieurs études randomisées étaient disponibles, les valeurs indiquées ont été estimées par méta-analyse à partir de modèles à effets aléatoires, avec pondération des études selon la méthode de la variance inversée.

[d] Inclut deux études[18,19] ayant inscrit de petits nombres de non-HARSAH.
[e] Le nombre de participants ci-indiqué est une surestimation, car les données du groupe placébo de l'étude Partners sur la PPrE ont également été utilisées comme comparateur pour la prolongation de l'étude Partners.

**Tableau D2. Régimes recommandés de PPEn[ab]**

| Régime | N (%) avec ce régime | N (%) avec comparateur : TDF/FTC/LPV/r | Risque relatif (intervalle de confiance de 95 %) | Qualité de la preuve | Commentaires | Nombre de participants (études) |
|---|---|---|---|---|---|---|
| **Résultat : Complétion du régime comme prescrit** | | | | | | |
| TDF/FTC/RAL | 75/122 (64,1 %) | 63/121 (52,1 %) | 1,18 (0,95, 1,47) | Élevée | Les principales raisons du non-achèvement étaient d'avoir manqué la 2e dose quotidienne de RAL, effets secondaires du LPV/r | 243 (1 étude) |
| | 121/205 (59,0 %) | 274/474 (57,8 %)[b] | 1,02 (0,89, 1,17) | Faible | - | 679 (6 études) |
| TDF/FTC/DTG | 90/100 (90 %) | 274/474 (57,8 %)[b] | 1,56 (1,41, 1,72) | Faible | - | 574 (4 études) |
| TDF/FTC/DRV/r | 145/155 (94 %) | 135/150 (90,0 %)[c] | 1,04 (0,97, 1,11) | Élevée | 21 % étaient des PPEprofessionnelles | 305 (1 étude) |
| **Résultat : Événements indésirables conduisant à l'interruption de la PPE ou à un changement de régime** | | | | | | |
| TDF/FTC/RAL | 2/122 (1,6 %) | 4/121 (3,3%) | 0,50 (0,09, 2,66) | Élevée | - | 243 (1 étude) |
| | 8/424 (1,9 %) | 101/2 511 (4,0 %)[b] | 0,47 (0,23, 0,96) | Faible | - | 2 935 (8 études) |
| TDF/FTC/DTG | 1/100 (1,0 %) | 101/2 511 (4,0 %)[b] | 0,25 (0,04, 1,76) | Faible | - | 2 611 (5 études) |
| TDF/FTC/DRV/r | 1/155 (0,6 %) | 5/150 (3,3 %)[c] | 0,19 (0,02, 1,64) | Élevée | 21 % étaient des PPEprofessionnelles | 305 (1 étude) |
| **Résultat : Infection à VIH au suivi 3 mois** | | | | | | |
| TDF/FTC/RAL | 1/55 (1,8 %) | 0/38 (0 %) | 2,09 (0,09, 49,96) | Modérée[d] | Toutes les infections observées sont survenues chez des patients ayant une exposition continue, excepté un patient sur TDF/FTC/LPV/r | 93 (1 étude) |
| | 1/404 (0,2 %) | 7/2 399 (2,9 %)[b] | 0,85 (0,10, 6,88) | Très faible[d] | | 2 803 (8 études) |
| TDF/FTC/DTG | 0/77 (0 %) | 7/2 399 (2,9 %)[b] | 2,05 (0,12, 35,60) | Très faible[d] | | 2 476 (5 études) |
| TDF/FTC/DRV/r | 0/155 (0 %) | 0/150 (0 %) | Non estimable | Élevée | 21 % étaient des PPEprofessionnelles | 305 (1 étude) |

[a] DRV/r=darunavir + ritonavir, DTG=dolutégravir, FTC=emtricitabine, LPV/r=lopinavir/ritonavir, RAL=raltégravir, TDF=fumarate de ténofovir disoproxil.

[b] Les données sont tirées de deux essais randomisés[24,25] et de sept études de cohorte[26-32].

[c] Estimation groupée de trois études observationnelles[30-32] et groupe TDF/FTC/LPV/r d'un essai randomisé[33].

[d] Le dénominateur inclut six patients recevant de la zidovudine/lamivudine + LPV/r et un patient recevant de l'abacavir/lamivudine + LPV/r.

[e] La qualité des preuves a été déclassée en raison de facteurs de confusion (expositions continues chez des patients séroconvertis) et d'incohérences.

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