CouldDOL/LAM be a validDual-Therapy option evenin pregnancy? Data from a retrospectiveanalysis.

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P005

Background:Numerousdatafromclinicaltrialsandreal-life studieshasshownthatthe2-drugregimen dolutegravir/lamivudinewasnon-inferiorto3-drugregimens[1-2].Regardingpregnancy,whileGuidelinesrecommend regimensincludingdolutegravirplusabackboneoftwoNRTIs (ABC/3TCorTDF/FTC)[3-6],nodataonDTG/3TCuseare available.

MaterialsandMethods:Weconductedaretrospective analysisfromOctober2017toJune2022recruitingpregnant womentreatedwithDTG+2NRTI(TDF/FTCorABC/3TC)or DTG/3TC.Theprimaryefficacyoutcomewasa HIV-RNA<20 copies/mLatdeliveryandtheprimarysafetyoutcomewasthe occurrenceofdrug-relatedadverseeventsinmothersand infantsuntilthepost-partumvisit.Variablesinvestigatedwere maternalandgestationalageatdelivery,timeofARTinitiation, modeofdelivery,birthweight,maternalCD4countandHIV-RNAduringItrimester,IItrimesterandatdeliveryandinfant HIV-1status.

Results:24pregnantwomen,bothnaïvepatientsand patientsalreadyoncARTbeforepregnancy,treatedwith dolutegravir-basedtherapy;13onDTG+2NRTI(4 DTG/TDF/FTC,9DTG/ABC/3TC)and11onDTG/3TCwere enrolled.IntheDTG/2NRTIgroup,4ptswerenaïve;at delivery3ptshadadetectableHIV-RNA(1ptnaïve35 cp/mLwhile2pts>1500cp/mLduetopoortherapeutic compliance),themedianCD4countwas570cells/mcLinthe 1sttrimesterand588cells/mcLatdelivery.Amongthe11pts intheDTG/3TCgroup(tablebelow),3werenaïve;at deliveryonly1pthadadetectableHIV-RNA(1naïve53 cp/mL);1ptexperiencedaviralblipduring3thtrimester probablycausedbytakingvitamin/ironsupplementsand cARTatthesametimebutHIV-RNAreturnednegativeat timeofdelivery;medianCD4countwas554cells/mLinthe 1sttrimesterand555cells/mcLatdelivery.Wefoundno differencesinbirthslessthan37weeks.Allinfantsreceived antiretroviralprophylaxisandhavetestednegativeonfollow-up.Noneonatalmalformationswerefound.

Pt	Age	Race	Yrsof HIV	Yrsof cART	HIV RNA cp/ml I Trim	HIV RNA cp/ml II Trim	HIV RNA cp/ml III Trim	HIV RNA cp/ml Delivery	CD4 I Trim	CD4 II Trim	CD4 III Trim	CD4 Delivery	HIV baby 0-2m	HIV baby 6-12m
1	2	Black	0	0		209577	775	5	NA	10	17	23	0	0
2	3	Black	0	0	0	0	0	3	31	1	0	5	0	0
3	2	Black	0	0		78804	43	2	1	28	35	42	0	0
4	2 32 3	Caucasian	10	5	0	0	0	0 0 2	56 954	2 635 16	4 780 94	5 820 14	0	0
5	3 7	Black	5	5	2	0	0	0 0	54	58	60	62 1	0	0
6	6	Black	5	5	0	0	2	2	0	4	3	5	0	0
7	2	Black	2	3	0	0	0	0	42	43	39	41	0	0
8	8 25 2	Caucasian	4	4	2 0	0	0	0	9 NA 63	6 813 48	3 731 47	2 671 48	0	0
9	4 32	Caucasian	0	0		9795	20	20	3 NA	9 626	5 853	2 861	0	0
10	3	Caucasian	4	4	2	0	20	0	47	50	69	542	0	0
11	4 1	Caucasian	1 8	1 8	0 0	2 0	10 6	0	9 95	8 67	1 90	897	0	0

Conclusions:Inthiscaseseriesreported,DTG/3TCregimenmayrepresentavalidtherapeuticoptionduringpregnancyin patientsinwhom,forvariousreasons,DTG+2NRTIregimenisnotindicated.Furtherdataandstudiesareneededtosupportthe evidenceofefficacyandsafetyofDTG/3TCinpregnancy.

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