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Viral suppression in the context of SARS-CoV-2 among children infected with HIV-1 monitored in five health facilities in Benin

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Abstract

Monitoring the effectiveness of antiretroviral treatment by measuring viral load is a strong recommendation from the WHO following the intensification of this therapy, which, if well managed, improves patients' quality of life. In children, treatment options are limited and virological non-suppression is high. Virological suppression among children living with HIV who were followed at care facilities during the SARS-CoV-2 pandemic is poorly documented in countries with intermediate resources, such as Benin.

Methods

A longitudinal study was carried out from November 20, 2020, among children under 15 years of age who had been receiving ART for at least six months in five healthcare facilities. TCD4 lymphocytes (LTCD4) count was performed using the CyFlow counter II (from Partec laboratories). Viral load was performed using the Abbott RealTime HIV-1 assay (Abbott Molecular, Inc.). The linear range of 40–10.000.000 copies/ml and a detection limit of 40 copies/ml were defined by the manufacturers. Virological success was assessed as a suppressed viral load ($VL < 3\log_{10}$). For children whose $VL_1 \geq 3\log_{10}$, WHO 2016 recommendations were applied and therapeutic education sessions were offered for 3 months, after which VL_2 was measured. Children whose (VL_1 and VL_2) $\geq 3\log_{10}$ were considered not suppressed.

Results

The mean age of 305 children enrolled was 110 (SD 41.25) months, with a predominance of girls at 52.8% (161/305). The median LTCD4 at study starting was 814 [IQR 544-1118] cells/µl. Overall, 73.11% (223/305) of children achieved virological success at the first viral load measurement, compared to 79.63% (219/275) at the second (03 months after the first). Between the two measurements, 9.83% (30/305) of children did not keep their medical appointments due to SARS-CoV-2 pandemic restrictions. Also, 20.73% (17/82) of non-suppressed children at VL_1 went undetectable. Among the 17.1% (47/275) of unsuppressed children, 10.64% (5/47) were on integrase strand transfer inhibitors as DTG (Dolutegravir).

Conclusion

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This study, conducted in children on ART during the SARS-CoV-2 pandemic, highlighted a high rate of retention in care and viral suppression. However, there are challenges in achieving the UNAIDS third 95 to ensure sustainable viral suppression in children.

Keywords Pediatric HIV, Viral load, Viral suppression, SARS-CoV-2

Background

Reducing the impact of HIV infection among children is a major global challenge. In 2020, around 1.7 million children aged 0–14 are living with HIV worldwide, and of these 88% are in sub-Saharan Africa. Efforts have been made to improve.

Therapeutic coverage, increased from 21 to 53% between 2010 and 2020 [1]. Regional disparities have nevertheless been noted across the continent. West Africa has the lowest coverage (36%), compared to 57% in East and Southern Africa. To assess treatment efficacy, the WHO recommends monitoring by viral load. This should be done on ART every 6 months, or twice a year in the case of sustained suppression [2]. The main aim of antiretroviral treatment is to reduce virus progression and therefore achieve lasting virological suppression, which will improve quality of life for patients. In the event of non-suppression, it is recommended to repeat the viral load measurement, on a new sample, three months after the first. The WHO recommends adherence support sessions for parents or guardians during this period. In the literature, virological non-suppression can be correlated with several factors, including clinical stage, co-infection, the presence of resistance mutations or failure to adhere to treatment regimens [3].In the case where two consecutive viral load measurements are less than 1000 copies/ml, we speak of therapeutic success [2]. Based on the three UNAIDS (95-95-95) all treatment programs, aim to achieve 95% lasting virological suppression in patients. Overall, the rate of virological suppression in children is much lower [4].

In Benin, the first case of HIV infection was discovered in 1985. Pediatric antiretroviral triple therapy only started in 2005. The prevalence of HIV infection is stable at around 1% in the general population [5, 6]. The goal of antiretroviral therapy is to reduce the progression of the virus to an undetectable level in the blood. The viral load is the best marker of the effectiveness of the treatment. When this objective is not achieved, it results in therapeutic failure, which is defined as the conjunction of clinical, immunological and virological failures. In 2018 in Benin, 2.024 children were living with HIV. Although children living with HIV are a priority of the Fighting Against AIDS Program (PFAA), data on the achievement of 95-95-95 in these children was very poorly documented. As the treatment of the child depends on the person in charge of administering it, if it is poorly conducted, it increases the risk of resistance and therefore therapeutic failure [7].

In 2019, a study carried out at the National University Hospital Center Hubert Koutoukou Maga (CNHU-HKM) in Cotonou revealed a prevalence of antiretroviral treatment failure of 24.4% in a cohort of children under treatment [8]. Another study carried out at the CNHU-HKM care site revealed 71%, 84% and 4% resistance to NRTIs, NNRTIs, and PIs respectively, in children with treatment failure [9]. These rates of antiretroviral treatment failure and resistance are alarming enough for the question of therapeutic efficacy through the assessment of virological suppression to be addressed in order to guarantee optimal care for these children. In addition, the SARS-CoV2 pandemic that began in 2019 has undermined all health systems worldwide. The management of HIV infection, particularly among children, has slowed down due in part to the decrease in funding, but also to other factors [10]. Thus, at the beginning of this crisis, between 2019 and 2020, the number of children followed in care sites in Benin fell from 2.278 to 2.133, a decrease of about 6.37% [7]. As the Littoral department has the highest paediatric active queue in the country, it is necessary to explore the situation of children with regard to the achievement of the third UNAIDS 95 and the implications that the SARS-CoV-2 crisis may have generated in the biological monitoring of children.

This study aims to determine the prevalence of virological suppression in children followed up at HIV infection management sites in Benin, particularly in the context of the SARS-CoV-2 pandemic, which has disrupted all health systems [1].

Methods

Study population

This is a longitudinal study that recruited HIV-1-positive children under 15 years of age who had been on treatment for at least 06 months from September 2020 to December 31, 2021. These were sites of CHUZ Abomey-Calavi (public center) in the Atlantic department; Non-governmental organization (NGO) Racines (private center), Bethesda Hospital (private center), CHU-MEL (mother and child university Hospital/public center), and Suru-Léré Hospital (ambulatory treatment center/decentralized structure of the PFAA) in the Littoral department. Baseline and follow-up data (TCD4 lymphocyte count, hemoglobin level, viral load value) were collected to assess the rate of virological suppression, anemia and

immune restoration during medical follow-up in children. For this purpose, grouped blood samples were taken from eligible children selected based on medical records.

The inclusion criteria were to be on HIV treatment at least 6 months, aged under 15 years of age, having given assent or consent, as the case may be, with parental or guardian consent, and being followed up at one of the five care facilities centers selected for the study.

Biological analyzes

All analyses were performed on a blood sample taken of two Ethylenediaminetetraacetic acid (EDTA) tubes per child (5 ml/tube). The parameters of interest were hemoglobin level (to assess anemia), TCD4, and plasma viral load to assess treatment efficacy. Viral load was measured according to 2016 WHO recommendations in two phases separated by three-month intervals during which all participants received adherence support.

CD4 and HIV viral load measurements

TCD4 lymphocytes were counted using the CyFlow counter II flow cytometer from Partec Gmbh [11]. Plasma viral load was measured using the Abbott m2000RealTime HIV-1 assay (Abbott Molecular) [12].

Variable definitions

Anemia

Anemia was defined as a hemoglobin value less than 11 g/dl of blood [13].

Immunological success (WHO recommendations)

Immunological success was defined as a LTCD4 ≥ 200 cells/µl of blood.

Immunological failure was defined as persistent LTCD4 < 200 cells/µl for children under 05 years of age and < 100 cells/µl of blood for children over 05 years of age throughout follow-up.

Virological suppression (WHO recommendations)

Virological success was defined as two consecutive viral load, three months apart, inferior to 1.6log$_{10}$; Virological suppression was defined as two consecutive values (three months apart) of viral load (VL_1 and VL_2) strictly below 3log10 (1.6 < VL < 3log10); Virological non-suppression was defined as two consecutive viral load (VL_1 and VL_2) measurements greater than or equal to 3log10 within a three-month interval accompanied by intensive adherence support [14].

Statistical analyzes

Data on sociodemographic characteristics and those related to therapeutic history were collected from patients' medical records using a questionnaire. All data were entered and analyzed using Excel 2016. A descriptive analysis was carried out, with data presented as numbers, percentages, mean, standard deviation, median, and IQR with their 95% confidence intervals.

Ethical considerations

The study protocol was approved by the National Ethics Commitee for Health Research (CNERS) under trial number 30 of August 30, 2020 (Reference N°: 111/MS/DRFMT/CNERS/ SA). Informed consent was obtained from parents or legal guardians of the participants involved in the study. Confidentiality and anonymity of the information was also maintained. The study was conducted in accordance with the relevant guidelines and regulations.

Results

Participants characteristics

Of the 512 medical records identified, 369 participants were eligible, of whom 17.34% (64/369) could not be included due to non-compliance with consultation appointments due to health requirements linked to the health crisis SARS-CoV-2. The final sample consisted of 305 children living with HIV followed at the different selected sites (Fig. 1).

The mean age was 110 (SD 41.25) months, with a female predominance of 52.8%. (Table 1).

Biological profile

Overall, 68.85% (210/305) of participants had a hemoglobin above 11 g/dl, 97.38% (297/305) had an absolute LTCD4 value above 200 cells with a median of 814 [544–1118] cells/µl blood. The suppression rate in the first phase of the study was 73.11% (223/305). The control viral load (VL2) was not done in twenty-three (23) patients. The suppression rate in the second phase was 80.14% (226/282). The rate of viral load between 1.6 and 3log$_{10}$ between the first and second measurements fell from 19.02 to 14.18%. Among the participants in the first phase, 11.52% of those who were in virological success returned detectable in the second phase; 12.20% of those who were not deleted came back deleted and 17.07% undetectable. The proportion of participants with virological failure is 16.67%. The summary of biological data is presented in Table 1.

Therapeutic profiles

The treatments used were non-nucleoside reverse transcriptase inhibitors (NNRTIs) in 37.71% of participants, 32.13% integrase strand transfer inhibitors, Dolutegravir

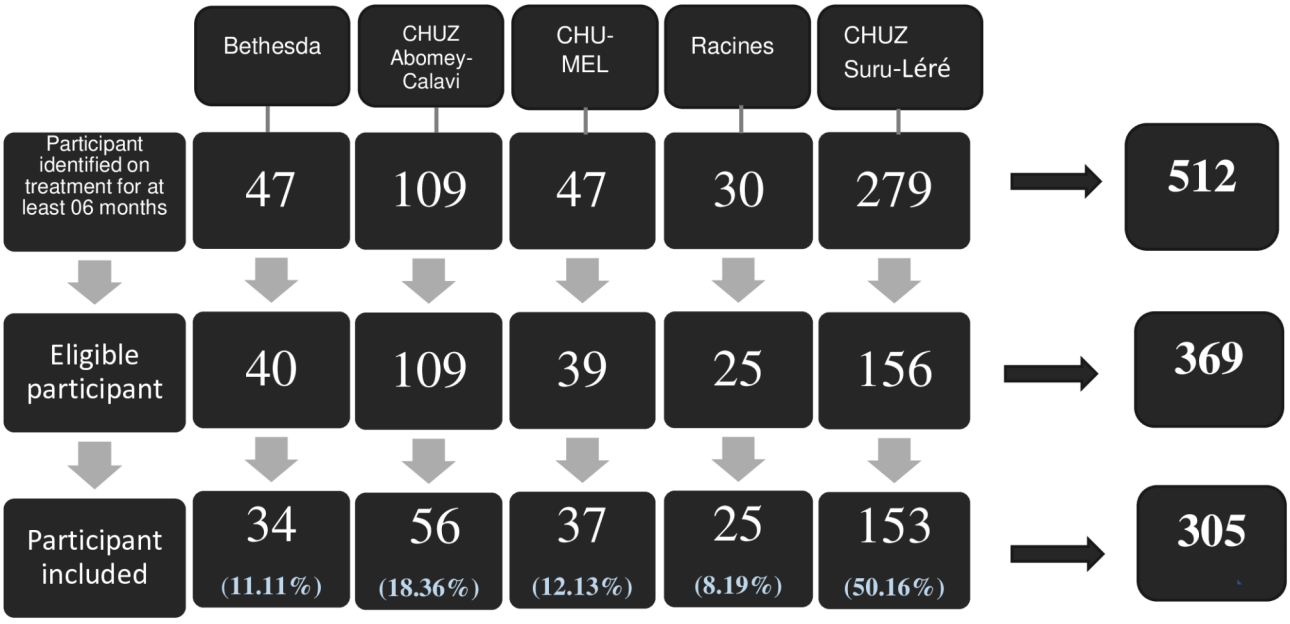

Fig. 1 Participant selection diagram

(INSTIs, DTG) and 29.51% protease inhibitors (PIs). The mean duration of treatment for all protocols combined was 6 years 7 months and 8 days (Table 1).

Treatment profile of virological suppressed patients

About virologically suppressed participants at VL_2, 82/226 (36.28%) were on (DTG). The rate of participants not suppressed under DTG was 8.93% (5/56) (Table 2).

Table 2: summary of viral load results in term of second phase.

Discussion

Sustainable viral suppression, reflected by an undetectable viral load or strictly below $3\log_{10}$, is the main objective of WHO for monitoring the HIV pandemic. In this study of 305 HIV-1-infected children on antiretroviral treatment, the mean age of 110 (SD 41.25) months is in line with the demographic trend at the national level of the population (45.56%) which is made up of children aged 0–14 years old. A female predominance of 52% was observed, which is in agreement with national population data [15].

The average duration of antiretroviral treatment is 06 years 07 months and 08 days, similar to that reported in Tanzania [16]. In our study, the most prescribed treatments are those based on DTG, followed by those based on EFV and LPV/r. This can be explained by the new standards and policies adopted by Benin which recommended the gradual switch of all patients to DTG-based treatment. These data corroborate one of conclusions of the Ugandan study by Adeodata K. et al., which revealed that treatment based on protease inhibitors provides a benefit to children particular under second-line therapy [17]. Furthermore in Ethiopia, the AZT + 3TC + NVP/EFV combination predominance was documented in the north-west, while in the south-west, ABC + 3TC + NVP treatment was in the majority [18, 19].

A large proportion of our participants had hemoglobin levels within normal ranges, probably due to the iron supplementation given to adolescents as part of DTG-based treatment. Although AZT, used in applied treatment regimens, is a molecule prone to anemia, it appears to be well tolerated [20]. In Ethiopia, the proportion (62.5%) of participants with a hemoglobin level greater than 11 g/dl reported by Salomon G et al., is similar to that reported in our study but conversely lower than that found by Tadesse B et al., [18, 21]. In addition, the proportion of children with an episode of anemia (31.15%) is still worrying, although it is much lower than that reported in Burkina Faso where 55% of participants had a hemoglobin of less than 10 g/dl. On the other hand, in Ethiopia, Bayleyegn B et al., documented a much lower prevalence than ours (21.3%). This difference may be explained by the variability between studies in the standards used to define anemia [22, 23].

The vast majority of participants in this study had satisfactory immunity with a high median CD4 count, which reinforces the non-use of CD4 counts in Benin as a marker of the effectiveness of antiretroviral treatment. Indeed, children in this age group have physiologically high CD4 counts and therefore do not reflect the true extent of the infection [24]. Similar results have been obtained in Tanzania and Ethiopia [16, 18]. On the other hand, immunological failure was observed in only

Table 1 Patients socio-demographic and laboratory characteristics

Parameter	*n*	%
Sex		
Male	144	47.21
Female	161	52.79
Age group (Month)		
< 60	37	12.13
≥ 60	268	87.87
Hemoglobin		
Hb < 11 g/dl	95	31.15
Hb > 11 g/dl	210	68.85
CD4 count		
CD4 < 100	7	2.30
CD4 [100–200]	1	0.33
CD4 > 200	297	97.38
CD4 < 100 [≥ 60 months[	2	0.75
CD4 < 200[< 60 months]	0	0.00
Immunological failure	2	0.66
Quantification VL_1		
VL_1 undetectable	165	54.10
$1.6 < VL_1 < 3\ log_{10}$	58	19.02
VL_1suppressed	223	73.11
$VL_1 > 3log_{10}$	82	26.89
Quantification VL_2		
VL_2 undetectable	186	65.96
$1.6 < VL_2 < 3\ log_{10}$	40	14.18
VL_2suppressed	226	80.14
$VL_2 > 3log_{10}$	56	19.86
Global non suppressed		
VL_1&$VL_2 > 3log_{10}$	47	16.67
VL_1 not having VL_2	23	7.54
VL_1 undetectable which are detectable in VL_2	19	11.52
$1.6 < VL_1 < 3log_{10}$ and superior to $3log_{10}$ in VL_2	8	13.79
$VL_1 \geq 3log_{10}$ not having VL_2	11	13.41
$VL_1 > 3log_{10}$ and suppressed in VL_2	10	12.20
$VL_1 > 3log_{10}$and undetectable in VL_2	14	17.07
CD4 > 200 with $VL \geq 3log_{10}$	44	15.60
Treatment		
(ABC /AZT/TDF) + 3TC + LPV/r	90	29.51
(ABC/AZT/TDF) + 3TC + DTG	98	32.13
(ABC/AZT/TDF) + 3TC + EFV	94	30.82
AZT + 3TC + NVP	21	6.89
TDF + 3TC + ATZ	1	0.33
D4T + 3TC + EFV	1	0.33

Hb: Hemoglobin, g: gram, dl: Deciliter, CD: Cluster of differentiation, IQR: Interquartile, VL: Viral Load, ABC: Abacavir, 3TC: Lamivudine, LPV/r: Lopinavir/ritonavir, AZT: Zidovudine, TDF: Tenofovir, EFV: Efavirenz, NVP: Nevirapine, DTG: Dolutegravir, ATZ: Atazanavir, D4T: Stavudine

Table 2 Summary of viral load results

Variables		Suppressed 226 ; 80.14%	Not suppressed 56 ; 19.86%	Total
Age (month)				
	< 60	27 (11.95)	07 (12.5)	34
	[60–108[	90 (39.82)	15 (26.79)	105
	[120–168]	109 (48.23)	34 (60.71)	143
Mean age (SD)		110 (41.25)		
Sex				
	Male	108 (47.79)	26 (46.43)	134
	Female	118 (52.22)	30 (53.57)	148
Therapeutic regimens				
	NNRTIs	76 (33.63)	31 (55.35)	107
	PIs	68 (30.09)	20 (35.71)	88
	INSTI	82 (36.28)	05 (8.93)	87

SD: Standard deviation, NNRTIs: Non-nucleosid reverse transcriptase inhibitors, PIs: Protease inhibitors, INSTI: Integrase strand transfer inhibitors

one participant, contrary to what was described a few years earlier in the cohort of the HKM National University Hospital [24]. The proportion of participants not suppressed decreased over time, from 26.89 to 19.86% between the first and second phases. This result is the result of therapeutic education sessions, which are of paramount importance in the follow-up of patients. The overall rate of non-suppression or virological failure of 16.66% is variously appreciated compared to those obtained in Kenya and Uganda [25, 26]. Although the suppression rate is high, it is important to note that the proportion of viral loads suppressed but not undetectable, between the first and second phases, is quite large, highlighting the efforts required to achieve lasting suppression and thus avoid increasing the risk of resistance [27]. However, higher rates were achieved in the Central African Republic, at 60.1% and 63.6% respectively in children receiving first- and second-line treatment [28].

Similarly, the proportion of participants with virologic suppression increased between the first and second phases, resulting in high overall suppression. This performance is the result of applying different processes on a case-by-case basis. Indeed, the sessions to strengthen compliance (explaining the importance of the treatment and the disadvantages of a poorly administered treatment), the psychological support sessions, the constant follow-up through phone calls of encouragement, and the availability of the nursing staff whose professional contacts are known to the parents or guardians of the children are all actions that have contributed to this accomplishment. In addition, most of our patients come from care sites where the follow-up is complete and regular because it is done on site, thus limiting the movement of patients. In addition, it should be noted that Benin, like some countries, has experienced some difficulties in the care of children. Indeed, as each treatment site is autonomous, it has been observed over time that some treatment sites did better than others in monitoring patients. Thus, to make good practices available to sites in difficulty, it was proposed to initiate meetings between the actors according to the clinical or biological levels to discuss the difficulties encountered and find solutions approaches, in short, a sharing of experience. With the

support of the central level, all the sites help each other, especially with the implementation of WhatsApp forums through which prescribers exchange particular cases and find the best treatment approach for patients with therapeutic difficulties. Studies in Africa and elsewhere support the rationale for these support procedures [29, 30, 31].

These suppression rates obtained are consistent with those obtained in Kenya [27], Ethiopia [32], and Ghana [33]. The SARS-CoV-2 crisis caused a loss of 17.34% of our eligible patients and 7.54% of the patients included due to missed consultation appointments, as access to certain public centers was at that time subject to the presentation of the vaccination pass. The care sites had to carry out an internal reorganization to avoid the loss of their active feed. The "mediators" have therefore been called upon a lot to guarantee retention in care by actively searching for the "lost to follow-up". Despite all its efforts, a decrease was noted in the national active population of children living with HIV from 2.278 in 2019 to 2.133 in 2020 [7]. Indeed, some authors have shown that health or political crises harm the treatment of HIV infection, particularly in children [31, 34, 35]. In addition, worldwide, this crisis has led to a decline in treatment coverage for children [33].

The results of this study show that despite satisfactory immunity and virological suppression, difficulties in achieving undetectability remain in children. This virological success could be described as suboptimal, as it is far from the 3rd objective of UNAIDS. The significant influence of the SARS-CoV-2 pandemic could be observed in children receiving ART at the five sites with the highest active queue in the Atlantic and Littoral departments.

Conclusion

This study, conducted in children on ART during the SARS-CoV-2 pandemic, highlighted a high rate of retention in care and viral suppression. However, there are challenges in achieving the UNAIDS third 95 to ensure sustainable viral suppression in children.

Limits

The main limitation of this study is the unavailability of certain key data, such as the serological statut of siblings, weight at inclusion, biological and therapeutic data at inclusion.

Abbreviations

3TC	Lamivudine
ABC	Abacavir
ART	Antiretroviral Therapy
AZT	Zidovudine
CD 4	Cluster of differentiation
CHU-MEL	University Hospital Center for Mother and Child
CNHU	Koutoukou Maga National University Hospital Center
DTG	Dolutegravir
EDTA	Ethylene diamine tetraacetic acid
EFV	Efavirenz
HIV	Human Immunodeficiency Virus
IQR	Interquartile
PSLS	Reference National Laboratory Fighting Against AIDS in Benin
LPV/r	Lopinavir/Ritonavir
NVP	Nevirapine
NRTI	Nucleoside reverse transcriptase inhibitors
NNRTI	Non- nucleoside reverse transcriptase inhibitors
INSTI	Integrase Strand Transfer Inhibitor
PCR	Polymerase Chain Reaction
PI	Protease inhibitors
PLHIV	People living with HIV
PSLS	Program Fighting Against AIDS of Benin
PMTCT	Mother-to- child transmission prevention program
RNA	Ribonucleic Acid
TDF	Tenofovir
UNAIDS	United Nations Program on HIV/AIDS
VL	Viral load
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1

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Author contributions

EHDG: conceived of the study, participated in it design, data collection, analysis, and statistical analysis and drafted the manuscript.AASO, MKG, RKK, AA, MB: participated in its design and coordination.ASO, LBM: wrote the manuscript and improved the English quality.All authors read and approved the final manuscript.

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Data availability

All data generated and analyzed during this study are not publicly available. Study data is only available to scientific collaborators. Data are available on request from the corresponding author Edwige Hermione DAGBA GBESSIN. Data may also be available upon request. All data sharing is subject to National Ethics Committee for Health Research.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the National Ethics Commitee for Health Research (CNERS) under trial number 30 of August 30, 2020 (Reference N°: 111/MS/DRFMT/CNERS/ SA). Informed consent was obtained from parents or legal guardians of the participants involved in the study. Confidentiality and anonymity of the information was also maintained. The study was conducted in accordance with the relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Clinical trial

Not applicable.

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