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Sessions on

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Session Introduction

Title: **Update on comparative analysis of Immune reconstitution in HIV-positive recipients of Allogeneic and Autologous stem cell transplant on the BMT CTN 0903/AMC-080 and BMT CTN 0803/AMC-071 trials**

Polina Shindiapina, Ohio State University, USA

Title: **Development of new strategies against SARS-CoV-2/COVID-19**

Iskra V Sainova, Bulgarian Academy of Sciences (BAS), Bulgaria

Title: **Governmental communication during the first months of the Coronavirus in Bolivia**

Ingrid Steinbach Mendez, Alvaro M Hurtado Calderon, Private University of Santa Cruz de la Sierra, Higher University of San Andrés, Bolivia

Update on Comparative Analysis of Immune Reconstitution in HIV-Positive Recipients of Allogeneic and Autologous Stem Cell Transplant on the BMT CTN 0903/AMC-080 and BMT CTN 0803/AMC-071 trials

Polina Shindiapina
Ohio State University, USA

Statement of the Problem: HIV-positive (HIV(+)) individuals demonstrate chronic changes in cellular immunity, including depletion of CD4+ T cells, elevation in CD8+ T cells, increased markers of senescence and activation. We hypothesized that HIV profoundly impacts immune reconstitution after treatment of hematologic malignancies. We performed a detailed assessment of immune reconstitution in HIV(+) recipients of autologous (auto-SCT) and allogeneic (allo-SCT) hematopoietic stem cell transplant on the BMT CTN 0803/AMC 071 (n=38) and BMT CTN 0903/AMC (n=17) prospective clinical trials. These were compared to HIV(-) auto-SCT recipients (n=30) and healthy controls (n=71).

Methodology & Theoretical Orientation: 5-color flow cytometry of whole blood was performed at days 56, 180 and 365 post-transplant (transplant-recipient cohorts) or at a single time point (healthy controls). Results were analyzed by principal component analysis (PCA), Wilcoxon rank-sum test and feature importance score analysis (FIS).

Findings: PCA showed that HIV(+) auto-SCT and allo-SCT recipient immune profiles segregated together and away from HIV(-) auto-SCT recipients and healthy controls. HIV(+) auto-SCT and allo-SCT recipients showed significant differences in 38 and 60 immune cell populations compared to healthy controls on day 56, and 39 and 55 immune cell populations at day 365 post-transplant, respectively ($p<0.031$). In contrast, 7 immune cell populations were identified as significantly different between HIV(+) auto- and allo-SCT recipients on day 56, and none at 1 year post-transplant ($p<0.031$). FIS identified activated T cells, cytotoxic T cells (total, naïve, memory, effector higher in HIV(+) cohorts), and naïve, central and effector memory T helper subsets (lower in HIV(+) cohorts) as significantly impacting the difference between HIV(+) cohorts and healthy controls.

Conclusion & Significance: HIV(+) auto-SCT and allo-SCT recipients demonstrate features of immune activation and converging immune reconstitution trajectories during the post-transplant year, distinct from HIV(-) auto-SCT recipients and healthy controls, suggesting that controlled HIV status significantly impacts post-SCT immune reconstitution. Clinical significance of these findings requires further study.

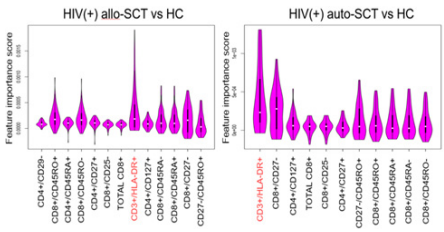

Figure 1. Feature importance score analysis identified immune cell populations with the highest impact on the differences between HIV(+) stem cell transplant recipients and healthy controls (HC) at 1 year post-transplant.

Biography

Shindiapina is an Assistant Professor at the Division of Hematology, Department of Internal Medicine at the Ohio State University, OH, USA. Dr. Shindiapina is a member of the translational lymphoma research group, together with Dr. Robert Baiocchi. Dr. Shindiapina's laboratory focuses on immune reconstitution studies in immunocompromised patients with hematologic malignancies and virus-driven lymphomas. Dr. Shindiapina and Dr. Baiocchi are members of the AIDS Malignancy Consortium.

polina.shindiapina@osumc.edu

Development of new strategies against SARS-CoV-2/COVID-19

Iskra V Sainova
Bulgarian Academy of Sciences (BAS), Bulgaria

The main goal is connected with suppression of the cellular penetration and/or replication of *SARS-CoV-2*/COVID-19, as well as with generation of adequate anti-virus immune reaction, both in vitro and in vivo. For this goal, molecular vaccines against other virus protein(s), as for instance, against gene, coding virus membrane (M) protein or against virus gene, coding viral envelope (E) protein, but also specific siRNAs against the virus gene, coding viral Spike (S) protein, should be developed and tested. Additionally, taking in consideration the eventual changes in many physical and chemical properties of the viral particle after its connection with respective generated antibodies against any of the mentioned proteins, probability for connection of the virion with the cellular receptor by viral S protein would eventually also be prevented. In this connection, the main idea is directed to application of strategies of priming with molecular vaccine against any of the viral genes, coding the mentioned above proteins, and boosting with specific siRNAs against virus gene, coding viral S protein. Both siRNAs and molecular vaccines should be constructed and applied by ways, by which maximal safety for the cell and the organism to be achieved. So, in vitro-incubated cells should be inoculated with viral strain with RNA-genome (if is possible, belonging to *Coronaviridae* family), which should then be treated with appropriate siRNAs against the virus gene, coding viral S protein, necessary about viral penetration in the cell. Molecular vaccines against other virus protein(s) should also be designed. Subsequent evaluation on the in vivo-influence of the tested siRNAs against virus S protein and molecular vaccines against other viral protein(s) on appropriate experimental animals, both non-infected and previously infected with the same RNA-viral strain, should be performed. After performance of all steps, evaluation on the in vivo-influence of the tested siRNAs against virus S protein and molecular vaccines against other viral protein(s) on appropriate immunodeficiency rodents as NOD or SCID mice is necessary, among which should also be available sub-groups, previously infected with the same RNA-virus strain.

Biography

The main goal in the work of Iskra Sainova is directed to balanced activity between oncogenes and tumor-suppressor genes, but also between the protein products of both gene types, on cellular and organism levels. The first step was made during the preparation of her PhD-thesis, and it was connected with development new methods for application of viral strains for production of gene-engineering vaccines, but also as vectors for transfer of nucleotide sequences. She works in the same field to present. In the current time period, in connection with the situation with *SARS-CoV-2*/COVID-19, the same idea is directed to suppression of virus genes in the virus RNA-genome by appropriate siRNAs, as well as with development of appropriate anti-virus molecular vaccines. Iskra Sainova has 1 monography, over 100 research and revies publications, over 100 reviewers of research and review papers and over 180 citations.

iskrasainova@gmail.com

Governmental communication during the first months of the Coronavirus in Bolivia

Ingrid Steinbach Mendez, Alvaro M Hurtado Calderon
Private University of Santa Cruz de la Sierra, Higher University of San Andrés, Bolivia

The research describes the communication actions implemented by the Government of Bolivia to inform and communicate with the population between March and June 2020, when the Covid-19 pandemic arrived. Seventy press conferences, 21 messages to the nation, two web pages and six social networks of governmental institutions and of the president of the Plurinational State of Bolivia were analyzed.

The results show a communication that is not very strategic and rather intuitive, based on fear and contaminated by electoral politics. It was a mixture of political communication and health risk communication, where a diversity of political spokespersons or leaders stood out over professional spokespersons or leaders in the health area, and where the population preferred to turn to alternative (virtual) sources of information and not necessarily to the official media and tools created to inform the population about Covid-19.

Biography

Ph.D Ingrid Steinbach Mendez, is a doctor in Education and Social Communicator. For 32 years she was Dean of the Faculty of Humanities and Communication at the Private University of Santa Cruz de la Sierra, Bolivia. He has experience in academic management, curriculum design, and teaching in social and communicational research methodology. He has investigated in areas of intercultural communication, communication and the city and has advised more than 150 investigations of undergraduate students in corporate communication. She has been director of the Academic Magazine Contributions of Communication and Culture for 30 years.

ingridsteinbach@upsa.edu.bo

Magister Álvaro Hurtado Calderón, has specialized in Social Communication with a mention in “Political Studies” and communication strategies for private companies and the public sector.He has been a professor for more than 30 years at Bolivian universities focusing on image, corporate and communication strategies.In recent years, he has been a communication consultant for WHO / PAHO Bolivia (2021) in the Covid-19 information and communications to the people through the Health an epidemiologic SurveillanceViceministery of the Bolivian country; also, for the Transportation Departure of BID-Bolivia; and NGOs about education, gender and communication for people with HIV, among others.

ahurtadoacademic@gmail.com

Sessions on

Pharmaceutical Sciences | Vaccines and Immunization | Immune disorders | Pharmacy Practice

Session Introduction

Title: **Efficacy and safety of polyherbal formulation as an add-on to the standard of care in mild to moderate COVID-19: a randomized, double-blind, placebo-controlled trial**

Suresh Patankar, ACE Hospital & Research Center, India

Title: **Cytokine profiles of School-Aged Children Infected with Schistosomiasis before and after Praziquantel Treatment**

Edward Okonjo, Technical University of kenya, Republic of Kenya

Efficacy and safety of polyherbal formulation as an add-on to the standard of care in mild to moderate COVID-19: A randomized, double-blind, placebo-controlled trial

Suresh Patankar
ACE Hospital & Research Center, India

Background: Novel corona virus disease 2019 (COVID-19) pandemic is a significant contributor to morbidity and mortality in affected individuals. Modulating the immune response in COVID-19 is now an established treatment approach. Herbal formulations have long been assessed for their potential immune modulating effects. As the search for potential antiviral and immune modulating therapy for COVID-19 is ongoing,this polyherbal formulation could be potentially beneficial. Referenced evidences for using these formulations in humans as justification are as hereunder;

Objective: To assess the efficacy and safety of polyherbal formulation (designated as IP) in comparison to placebo as add on to the standard of care (SoC) among patients with mild to moderate novel corona virus disease 2019 (COVID-19)

Methods: Hospitalized RT-PCR positive patients of mild to moderate COVID-19 disease were randomized to either placebo or IP as an add-on to SoC. The polyherbal formulation (IP) was standardized as per Guidelines for Drug Development of Ayurvedic formulations (CCRAS, AYUSH Govt.of India) and Consort guidelines for reporting randomized controlled trials for Herbal medicine intervention. Using validated quantitative reverse transcription-polymerase chain reaction (qRT-PCR), we assessed the effect on viral load (VL). Changes in immunological parameters such as blood lymphocyte subset and serum immunoglobulin were determined. The clinical improvement was assessed using a numerical rating scale (NRS) and WHO ordinal scale. Patients were followed for 30 days after randomization.

Results: In total, 72 patients were randomized to either placebo (n=33) and IP (n=39). Fifty-two patients (n=21 in placebo and n=31 in IP arm) had qRT-PCR on day 0 and day 4. There was significant reduction in VL in IP arm (from 662081 copies/mL on day 0 to 48963 copies/mL on day 4; p=0.002)) but not in the placebo arm (from 385670 copies/mL on day 0 to 66845 copies/mL on day 4, p=0.106). Change in the NRS score and WHO ordinal scale score was significant in both treatment arms. However, the difference between the two arms was statistically significant in favour of drug arm. The increase in Th1 response was significant in the IP arm (p=0.023) but not in the placebo arm (p=0.098), thus implying immunomodulatory activity in the drug. The Covid specific antibodies were seen in either arm, though there was no statistical difference, numerical values were higher in the IP arm. No safety concerns were observed in any of the trial participants.

Conclusion: This study finds that polyherbal formulation significantly reduces viral load and contributes to immunomodulation and improvement in clinical conditions and early recovery when used as add-on to the standard care in patients with mild to moderate COVID-19 without any side effects. It reflects that the polyherbal formulation has enhancing effect on SoC.

Biography

Suresh Patankar has a long and sustained record of research in both modern and traditional systems of medicine. His extensive clinical work has leveraged the continued research and innovations that he has so tirelessly conducted during more than last three decades. His interest in the domain of herbal or phytoformulations has resulted in several newer herbal formulations useful in disorders which have little help in the modern medicine. His interests in technological innovations have lead to the development of surgical instruments for laparoscopy that have the potential to change the modalities of laparoscopy in future. Apart from research activities he has immensely contributed to the state medical education system and effected noteworthy reforms in it. He is a strong advocate and promoter of holistic health through the integrative application of several systems of medicine apart from being a well known surgeon reputed for his extensive skills.

sureshpatankarace@gmail.com

Cytokine profiles of School-Aged Children Infected with Schistosomiasis before and after Praziquantel treatment

Edward Okonjo
Technical University of kenya, Republic of Kenya

Statement of problem: Schistosomiasis is a parasitic disease that affects millions of people in 78 countries globally. Children under the age of 14, who have the chronic disease may suffer from anemia and malnutrition that contribute to lost days at school and pervasive learning disabilities. The infection is prevalent in Kenya, especially in endemic areas, contributing to significant morbidity. The cellular response pattern is associated with both the acute and chronic phases of the disease, in which cytokines play a critical role. The objective of this study was to evaluate the cytokine profiles of IL-4, IL-2, IL-10, IL-5, IFN-α, and TNF in serum samples of infected school-aged children by using flow cytometry before and after treatment.

Findings: The analysis indicated a shift in the expression of the cytokines after treatment with all the cytokines being downregulated, except TNF. There was a general trend of decrease in the expression of the cytokines at six and twelve weeks after treatment as compared to the pretreatment levels. There were statistically significant differences in the expression in IL-2 (P= 0.001**), IL-4 (P= 0.033*), IL-10 (P=0.001***), IFN-α (P= 0.023*), and IL-5 (P= 0.0001***), except in TNF (P= 0.095).

Conclusion and Significance: The reduction in the cytokine levels can be directly related to the influence of the drug praziquantel, modulating the cytokine response by elimination of adult worms, decline in parasitic load, and reduction of morbidity. Therefore, cytokine response is directly related with the influence of treatment in the variation of the immune response.

Biography

Edward Okonjo is a Lecturer at the Department of Applied and Technical Biology at the Technical University of Kenya. He has a PhD in Parasitology from Technical University of Kenya. Dr Okonjo's research interest is in the immunology of parasitic organisms with an emphasis on Schistosomiasis and Soil Transmitted Helminthes (STHs). More specifically on understanding cellular responses and how these responses influence transmission dynamics. Dr Okonjo is a member of the Kenya Society of Immunology (KSI).

Edward.Okonjo@tukenya.c.ke

Accepted Abstracts

COVID-19 and Vitamin D (Co-VIVID Study): A meta-analysis of randomized controlled trials

Seshadri Reddy Varikasuvu
All India Institute of Medical Sciences, India

Background: Vitamin D levels have been reported to be associated with COVID-19 susceptibility, severity and mortality events. We performed a meta-analysis of randomized controlled trials (RCTs) to evaluate the use of vitamin D intervention on COVID-19 outcomes.

Methods: Literature search was conducted using PubMed, Cochrane library, and ClinicalTrials.gov databases (latest search on August 5, 2021). We included RCTs reporting the use of vitamin D intervention to control/placebo group in COVID-19. Two independent researchers did literature search, abstracted data, and the risk of bias assessment.

Results: A total of 6 RCTs with 551 COVID-19 patients were included. The overall collective evidence pooling all the outcomes across all RCTs indicated the beneficial use of vitamin D intervention in COVID-19 (relative risk, RR = 0.60, 95% CI 0.40 to 0.92, Z=2.33, p=0.02, I2 = 48%). However, no statistical significance was observed for individual outcomes of ICU care (RR = 0.11, 95% CI 0.15 to 1.30, Z=1.48, p=0.14, I2 = 66%) and mortality (RR = 0.78, 95% CI 0.25 to 2.40, Z=0.66, p=0.02, I2 = 33%), though decreased rates were noted. The rates of RT-CR positivity was significantly decreased in the intervention group as compared to the non-vitamin D groups (RR = 0.46, 95% CI 0.24 to 0.89, Z=2.31, p=0.02, I2 = 0%).

Conclusion: COVID-19 patients supplemented with vitamin D are more likely to demonstrate fewer rates of ICU admission, mortality events and RT-PCR positivity. Completion of ongoing trials is largely needed to precisely establish the association between vitamin D use and COVID-19 mortality.

lifeschemistry@gmail.com

Immediately available Prophylaxis against emerging respiratory Viral Infections

Amos Chungwon Lee
Seoul National University, Republic of Korea

Statement of the Problem: In addition to SARS-CoV-2, its variants, and more emerging viral infections to come, prophylaxis methods must be immediately available to prevent devastations that we are currently seeing throughout the world. The heterogeneous clinical phenotype following COVID-19 and other respiratory viral infections varies widely, but many patients become critically ill and die. Despite laudable progress in treating respiratory viruses that has been accelerated by COVID-19, shortages of beds, equipment, drugs, human resources, and specific vaccines will still and, unfortunately, again contribute to poor patient outcomes when new viral pandemics emerge. We anticipate a need for safe, prophylactic therapeutic strategies that can prevent or blunt the initial progression of COVID-19 and future viral infections when existing improved therapies and vaccines may not provide complete, enduring, specific, and/or readily accessible protection.

Methodology & Theoretical Orientation: Herein, we propose testing prophylactic nasopharyngeal administration of type I interferon (IFN-I) for individuals at higher risk to COVID-19 and other respiratory viral infections. IFN-Is (IFN-α and IFN-β) are critical components of innate immunity and the initial cytokines produced by cells during viral infection.

Conclusion & Significance: It is reasonable to forecast that new respiratory infectious diseases will come in the future and, accordingly, developing antiviral prophylaxis strategies now would be prudent and immediately position a more favorable course of action while new specific vaccines and better therapies are being developed. Based on the COVID-19 experience, protecting first-line health care workers against a new respiratory virus would be paramount and well advised.

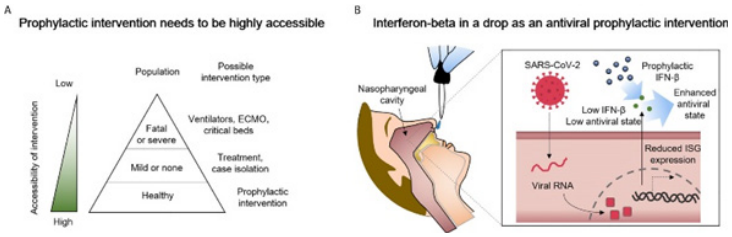

Figure 1 Delivery of type I interferon-beta (IFN-β) to the nasopharyngeal cavity is a candidate prophylactic and early intervention measure against COVID-19 that has high potential for success. (A) A greater accessibility of the intervention can prevent shortages of ventilators, extracorporeal membrane oxygenation (ECMO) machines, and/or critical care beds. (B) Suggested in this perspective is the highly accessible delivery of IFN-β to the nasopharyngeal cavity. The administered IFN-β can partially compensate for reduced interferon-stimulated gene (ISG) expression in SARS-CoV-2-infected cells as way to enhance antiviral immunity

amoslee89@gmail.com