for SARS-CoV-2 positive. CSF: transparent appearance, slightly xanthochromic color, coagulation and negative film. Proteins 105 mg/dl, glucose 45 mg/dl, leucocytes 121 mm3, erythrocytes 66 mm3, PMN 8% and MNN 92%. Negative culture, PCR Herpes Virus negative, Viral load for SARS-CoV2 in CSF 3.400 cop/ml and plasma 118,900 cop/ml. Aseptic meningitis is confirmed by SARS-CoV-2. Antiviral and antibiotics are discontinued and Gamma globulin and methylprednisolone are administered. Evolving favorably and afebrile at 6th day to complete oral steroid treatment for 3 more days.

Conclusion. The mechanism by which SARS-CoV-2 affects the CNS is still unknown. This findings suggests direct infection can be possible. Although it is also described vascular affection has been found that the Spike protein of the virus binds to ACE-2 receptor present in the cerebral vascular endothelium. Neurological manifestations have been described even without respiratory symptoms. A novel pediatric case with viral load for SARS-CoV-2 in CSF is demonstrated. Importance of detecting SARS-CoV-2 in children with encephalitis, which can progress satisfactorily.

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362. Saliva as a Reliable Sample Type for Mass SARS-CoV-2 Testing Strategies

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Session: P-15. COVID-19 Diagnostics

Background. Quickly detecting and isolating individuals positive for SARS-CoV-2 is essential for limiting virus spread. Policy makers rely on the number of active cases to make decisions, and individuals use this information to evaluate risk should they return to public spaces. Robust testing strategies have been plagued with limited authorized diagnostic assays and high test prices, with large-scale implementation hampered by worldwide supply chain issues.

Methods. Having identified its potential early in the pandemic, we simplified salivated COVID-19 diagnostic testing by (1) not requiring collection tubes with preservatives, (2) replacing nucleic acid extraction with a simple enzymatic and heating step, and (3) testing specimens for SARS-CoV-2 in duplex RT-qPCR. Moreover, we validated this approach (“SalivaDirect”) with reagents and instruments from multiple vendors to circumvent supply chain disruptions.

Results. SalivaDirect’s simplified protocol does not compromise on sensitivity. In our hospital cohort, we found a high positive agreement (94%) between saliva tested with SalivaDirect and nasopharyngeal swabs tested with a commercial RT-qPCR kit. With the National Basketball Association we tested 3,779 saliva specimens from healthy individuals and detected low rates of invalid (0.3%) and false-positive (< 0.85%) results. Using comparative assays and sample types, we also demonstrated SalivaDirect to efficiently detect SARS-CoV-2 in asymptomatic individuals. SalivaDirect is a simplified method for SARS-CoV-2 detection

(A) Schematic overview of SalivaDirect workflow depicting the main steps of mixing saliva with proteinase K, heat inactivation, and duplex qRT-PCR testing. Figure created with BioRender.com. (B) SARS-CoV-2 is stable in saliva for at least 7 days at 4°C, room temperature (RT), 19°C, and 30°C without addition of stabilizing buffers. Spiked in saliva samples of low virus concentrations (12, 25, and 50 SARS-CoV-2 copies/mL) were kept at the indicated temperature for 7 days and then tested with SalivaDirect. N1 cycle threshold (CT) values were lower when kept for 7 days at 30°C as compared to fresh samples (Krukal-Wallis; p = 0.03). Horizontal bars indicate the medians. (C) Comparing Ct values for saliva treated with proteinase K and heat as compared to nucleic extraction yields higher N1 Ct values without extraction (Wilcoxon; p < 0.01). (D) Testing extracted nucleic acid from saliva with the N1 primer-probe set (singplex) as compared to a multiplex assay showed stronger N1 detection in multiplex (Wilcoxon; p < 0.01). The dotted line in (B)–(D) indicates the limit of detection.

Conclusion. Saliva is a valid alternative to swabs for SARS-CoV-2 screening. Importantly, SalivaDirect enables labs to utilize existing infrastructure, improving test implementation time and requiring limited investment to scale-up to meet mass testing needs. With the safe and reliable self-collection of saliva, our vision is to help provide accessible and equitable testing solutions, especially in low-resource and remote settings.

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363. Characteristics of Envelope and Nuclear Gene Expression Patterns in Asymptomatic SARS-CoV-2 Patients: A Single Center Retrospective Observational Study

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Session: P-15. COVID-19 Diagnostics

Background. Reverse transcription-polymerase chain reaction (RT-PCR) is used for the diagnosis of COVID-19, caused by SARS-CoV-2. RT-PCR is a method that detects the virus by amplifying two regions of the target viral genome, namely the nuclear (N) and envelope (E) encoding sequences. However, it is not known a relationship between the symptoms and the gene expression patterns, especially in asymptomatic patients. Herein, we validated the characteristics of E and N gene expression patterns using RT-PCR on samples obtained from asymptomatic COVID-19 positive patients.

Methods. In this retrospective cohort study, conducted at Juntendo University Nerima Hospital, Tokyo, Japan, SARS-CoV-2 RT-PCR positive patients whose specimens had been obtained and analyzed by our laboratory technicians from September 1, 2020 to December 31, 2020 were enrolled. For RT-PCR, the LightMix Modular SARS-CoV-2 reagent (TIB MOBILIO company) was used. After excluding patients who had symptoms, background, demographic, laboratory, and gene expression pattern data were collected from RT-PCR-positive asymptomatic patients. We also investigated patients who met the release criteria of the Center for Disease Control and prevention. Continuous and categorical variables were analyzed, with p < 0.05 as statistical significance using the student-t test, chi-square test, or Fisher’s exact test, respectively.

Results. Of 92 RT-PCR-positive asymptomatic patients, 57 comprised the expression E only group (Group E) and 35 comprised the E+N group (Group E+N). Significantly more patients in Group E met the release criteria compared to those in Group E+N [41 (71%) vs 10 (28%), p < 0.001]. Among patients who met the release criteria, those in Group E+N had significantly more immunosuppression [7 (70%) vs 8 (8%), p = 0.004].

Moreover, among the patients who underwent RT-PCR screening, no patients in Group E developed symptoms [0 vs 6 (42%), p = 0.02].

Conclusion. The results of this study suggest that RT-PCR-positive asymptomatic patients can be divided into three patterns: pre-symptomatic, gene E positive patients; post-symptomatic covid-19-recovered patients, regardless of gene E and N expression patterns; and false positive, gene E positive patients.

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364. Individualized Prognostics in COVID-19 Facilitated by Computer Recognition of Blood Leukocyte Subsets

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Session: P-15. COVID-19 Diagnostics

Background. To determine whether CBC differentials of COVID+ inpatients can predict, at admission, both maximum oxygen requirements (MOR) and 30-day mortality.

Methods. Based on an approved IRB protocol, CBC differentials from the first 3 days of hospitalization of 12 SARS-CoV-2 infected patients were retrospectively extracted from hospital records and analyzed with a privately owned Pattern Recognition Software (PRS, US Patent 10,429,389 B2) previously validated in sepsis, HIV, and hantavirus infections. PRS partitions the data into subsets immunologically dissimilar from one another, although internally similar.
Results. Regardless of the angle considered, the classic analysis—which measured the percentages of lymphocytes, monocytes, and neutrophils—did not distinguish outcomes (A). In contrast, non-overlapping patterns generated by the PRS differentiated 3 (left, vertical, and right) groups of patients (B). One subset was only composed of survivors (B). The remaining subsets included the highest oxygenation requirements (B). At least two immunologically interpretable, multi-cellular indicators distinguished the 3 data subsets with statistically significant differences (C, p ≤ 0.05). Survivors (the left subset) showed lower N/L and/or higher M/L ratios than non-survivors (the vertical subset, C). Therefore, PRS partitioned the data into subsets that displayed both biological and significant differences. Because it offers visually explicit information, clinicians do not require a specialized training to interpret PRS-generated results.

Conclusion. (1) Analysis of blood leukocyte data predicts MOR and 30-d mortality. (2) Real time PRS analysis facilitates personalized medical decisions. (3) PRS measures two dimensions rarely assessed: multi-cellularity and dynamics. (4) Even with very small datasets, PRS may achieve statistical significance. (5) Larger COVID+ infected cohort is being analyzed for potential commercialization.

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365. Assessing Provider Utilization of COVID-19 Inflammatory Marker Trends in Hospitalized Patients and Implications in Optimizing Value-Based Care During a Pandemic
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Session: P-15. COVID-19 Diagnostics

Background. Numerous inflammatory markers may serve a role in prognostication of patients hospitalized with COVID-19. Early in the pandemic, our health system created an admission order set which included daily d-dimer, c-reactive protein (CRP), lactate dehydrogenase (LDH), and ferritin. Given more available outcomes data, limiting standing order of studies that do not affect daily management could result in significant cost savings to the health system without adverse patient outcomes. The purpose of this study was to determine ordering and utilization patterns of inflammatory markers by physicians caring for patients hospitalized with COVID-19 infections.

Methods. An anonymous 10-question survey was distributed to 125 physicians (Infectious Diseases, Hospitalist, Pulmonary and Critical Care faculty). Responses were tallied and values greater than 50% were identified as the majority of the surveyed group.