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IMPACT OF ANOSMIA TEST AS A TRIAGE DEVICE IN IDENTIFYING COVID-19 PATIENTS

Anaesthesiology

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ABSTRACT

***Background*:**COVID-19 infection is a result ofSARS-CoV-2, which transmitted promptly all over the worldcausingglobal pandemic with significant toll on lives and economy. Sudden loss of smell or anosmia / hyposmia has been proclaimed as a key marker of COVID-19. Virocule's ANOSMIC COVID-19 Smell Tester is the only olfactory testing device forcoronavirus SARS-CoV-2 screening that has been approved by Health Canada.

***Method*:** Two pilotstudies were conducted at the Rajasthan University of Health Sciences and SMS Hospital, Jaipur, India. The first one was retrospective study with 156 (n=156) and the second was prospective study with 50 (n=50) randomly selected subjects to evaluate the sensitivity and specificity of ANOSMIC COVID-19 Smell Tester for screening COVID-19 patients.

***Result*:** The first pilot study demonstrated that 98% of COVID-19 patients had either anosmia or hyposmia, and ANOSMIC test achieved sensitivity of 91% and specificity of 96%. The result of the second trialdemonstrated that 90% of COVID-19 subjects had either anosmia or hyposmia, and ANOSMIC test achieved sensitivity of 90% and specificity of 100% with 95% confidence level.

***Conclusions*:** These Pilot Clinical Studies successfully demonstrated the ability of ANOSMIC COVID-19 Smell Tester to detect COVID-19 patients with over 90% accuracy.

KEYWORDS

COVID-19, SARS-CoV-2, Olfactory Dysfunction, Anosmia, Hyposmia, Medical Device, Smell Tester

INTRODUCTION

COVID-19 pandemic is a global catastrophe with over 98 million patients 2 million deaths in 192 countries(World Health Organization; **Worldometer, January 24, 2021**), despite preventive measures impacting millions of people and jobs, education, businesses, sports, and industries. Many businesses have shut down, others are operating with limited capability with fear of legal liabilities in case of infection at workplace.

Anosmia (Loss of Smell) is usually severe and sudden in onset but transient in most COVID-19 patients, (Hopkins et al 2020). Sudden loss of smell is one of the key symptoms of coronavirus as recognized by WHO, CDC and Canadian Government.

American scientific studies using smell quantitative assessment demonstrated that 98% of COVID-19 patients exhibited at least some smell dysfunction (Moein, et al 2020). It was recommended by Public Health England and the National Health Service (UK) if a person is experiencing abrupt onset smell loss then that person should quarantine immediately for a minimum of 10 days. In South Korea, China, Italy and Germany, there is a significantnumber of patients with proven COVID-19 infectiondevelop anosmia/hyposmia has been reported. The anosmia (loss of smell) has been broadly proclaimed as a marker of SARS-CoV-2/Covid-19 disease and, in a huge extent of cases, its occurrence is reportedly higher than other related symptoms (Cherry et al., 2020).

A large retrospective cohort of European centers (n=417) found that 86% of patients lost their sense of smell (Lechien et al., 2020). A Spanish case-control study (case n=79, control n=40) showed that among COVID-19 patients with new-onset smell/taste disorders, 81% exhibited with smell disorders (Beltran-Corbellini et al., 2020). On average, the loss of smell and taste lasted 7.5±3.2 days but was also seen to prevail the resolution of other symptoms in the majority (63%) of cases (Lechien et al., 2020). The symptom of recovery was observed within 8 days subsequent to the disease resolution in 73% of patients. Although it may seem trivial, the loss of smell and taste substantially affects the patient's life (Lechien et al., 2020).

Currently, RT-PCR tests for detecting the virus take too long to give results, are expensive and inaccurate in initial stages of infection and cannot be effectively used for mass testing. ANOSMIC COVID-19 Smell Tester is the only device approved by an international regulatory agency which works effectively in mass screening for COVID-19.ANOSMIC COVID-19 smell tester can be routinelyused as a first line of defense in evaluating COVID-19patients on a mass scale followed by more robust clinicalassays. This test can help us in prioritizing and segregatingpossible COVID-19 positive cases from general population.The current study aimed to evaluate the unique product(s) that provide low cost and rapid diagnosis of COVID-19 olfactory dysfunction in Rajasthan University of Health Sciences and SMS Hospitals.

MATERIALAND METHODS

ANOSMIC Covid-19 Smell Tester is a screening tool approved by Health Canada for early detection of COVID-19 infection for symptomatic and asymptomatic patients. The device gives off a particular odor derived from a specially engineered combination of all-natural organic ingredients. This product is 100 % plant based and does not contain any animal, poultry, dairy, nuts, chemicals, or CBD. To test for the loss of smell, spray a small amount on to wrist or a tissue and inhale vapor.If a distinct smell is not evident, then there is a good possibility of COVID-19 infection.

Figure – 1 ANOSMIC COVID-19 Smell Tester

The first study was conducted on 156 (n=156) randomly selected subjects at the Rajasthan University of Health Sciences and SMS Hospital, Jaipur, India, in September 2020 in order to evaluate sensitivity and specificity of ANOSMIC COVID-19 Smell Tester for screening COVID-19 patients as a result of olfactory dysfunction causing anosmia (complete loss of smell) or hyposmia (partial loss of smell).In this study, 56 subjects (n=56) had been previously tested as COVID-19 positive, 50 subjects (n=50) asCOVID-19negative with RT-PCR and digital X-Rays, and another50 subjects (n=50) were healthyand not previously tested. The odorant from ANOSMIC tester was sprayed on the back of the wristof the subjects. The test method included verifying the intensity of smell from 0-10 (where 0 is no smell

and 10 is maximum smell), reaction of the subjects to smell, and odorant identification. We also conducted a placebo test on these patients, where one hand was sprayed with ANOSMIC odorant and the other hand with water.

The second study was prospective with 50 randomly selected subjects (n=50) with various COVID-19 symptoms such as fever, cough, diarrhea, and were not previously tested by the RT-PCR/Antibody based assay nor by the CT Scan/X-Ray. The odorant from ANOSMIC tester was sprayed on the back of the wrist of the subjects. Test method included verifying of the intensity of smell on a range of 0-10, the reaction of subjects to smell, and odorant identification. These patients were tested with the RT-PCR based assay and X-Rays after four days. The placebo test was not used in this study.

RESULTS

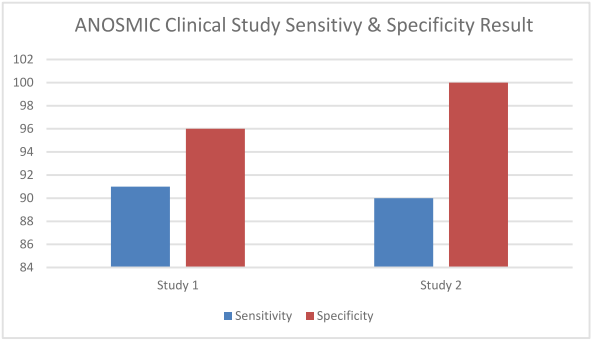

Figure – 2 ANOSMIC Sensitivity and Specificity

The result of the first trial in India demonstrated that 98% of COVID-19 patients had either anosmia or hyposmia, and the ANOSMIC test achieved sensitivity of 91% and specificity of 96%. The result of the second study demonstrated that 90% of COVID-19 patients has anosmia or hyposmia, and the ANOSMIC test achieved sensitivity of 90% and specificity of 100% with95% confidence level. The accuracy of ANOSMIC COVID-19 Smell Tester in both cases was greater than 90%. The second trial demonstrated that our ANOSMIC COVID-19 Smell Tester was able to identify asymptomatic patients as well asthose with early infection that RT-PCR test was not able to identify initially, after four days it identified them as COVID-19 positive. These trials proved very useful in resolving the optimum thresholds for identifying COVID-19 positive and negative subjects, and those that necessitate isolation and further monitoring and testing with 95% confidence level. The product was found to be of low risk with no allergic or adverse reaction in any subject tested in these studies.

DISCUSSION

Rapid and mass screening of viral infection is critical for preventing the spread of the coronavirus. It is observed that about 90% of COVID-19 patients have olfactory dysfunction, by which they lose the sense of smell. Olfactory dysfunction is key indicator for COVID-19 infection and generally happens before fever and coughetc. In light of the pandemic environment and the widespread evidence of smell dysfunction in COVID-19, testing the olfaction of persons who may be at risk or have subtle COVID- 19 signs may facilitate in identifying COVID-19 patients. Cumulative indications showed the symptoms of anosmia/hyposmia and dysgeusia associated to COVID-19, and on April 17, 2020, WHO listed it as symptom and recently the United States Centers for Disease Control and Prevention (CDC) has also identified anosmia as one of the symptoms of COVID-19. Until now, only fever and cough were triggers for people to isolate to prevent the spread the infection.

The objective of this study was to test unique ANOSMIC product that providesfast, low-cost, accurateand non-invasive diagnosis of COVID-19 using olfactory dysfunction test which are developed using all-natural products. ANOSMIC COVID-19 Smell Tester could be used potentially by any person as self-test or to gain admittance to public places, such as airports, offices, industries, parks, schools, restaurants, shopping malls, social gatherings, and subway stations etc. If a person tests positive, they are encouragedto get further confirmatory test for COVID-19 by RT-PCR. As a result, it has immense potential for mass testing which can further significantlyreduce community acquired transmission. Further, the patient can be isolated and treated medically at an early stage, and also reduce stress on health care system.

CONCLUSIONS

These pilot clinical studies were immensely effective in successfully demonstrating the ability of ANOSMIC COVID-19 Smell Tester to detect COVID-19 patients with over 90% accuracy. In our opinion, this device would be awonderful screening tool for earlier detection of COVID-19 symptomatic and asymptomatic patients with high confidence level.

This patent pending screening device is accurate, fast, low-cost, non-intrusive and easy-to-use for everyone for daily test to prevent the spread of coronavirus. This effective and economical technology was prepared with 100% natural ingredients and manufactured in aseptic facility that is Health Canada and FDA approved in Ontario, Canada. It can be used as a triage tool in identifying and segregating COVID-19 positive subjects. Furthermore, if any subject exhibits loss of smell, it is recommended tofollow country-specific quarantine practices, get tested by diagnostic confirmatory tests such as RT-PCR/Antibody based tests, and get appropriate medical treatment. This early detection device can be used by schools, colleges, offices, airports, restaurants, subways, train and bus stations, medical clinics, churches, and general public to not only help in saving lives, jobs, and reduce health care costs but also facilitate safe opening of the economic business sectors in accordance with safety regulatory guidelines.

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