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An Herbal Remedy Exhibiting Potent Therapeutic Effects Against Respiratory Infectious Diseases in Humans, Including Covid-19 and Influenza

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ABSTRACT

Background: There is no specific evidence-based therapy with proven efficacy for COVID-19. Marecipe AV, an ancient Chinese herbal compound, has been utilized in our clinic for over a decade to treat viral infectious diseases, demonstrating remarkable therapeutic benefits. We hereby present the outcomes of using Marecipe AV herbal therapeutics for the treatment of COVID-19 and influenza at our clinic during the outbreak in China.

Methods: The efficacy of Marecipe AV in treating COVID-19 was assessed through a comparative analysis of the duration of fever, the time to sustained resolution of clinical symptoms, and the incidence of hospitalization due to progression to severe COVID-19 between a treated patient cohort and an untreated control group. The efficacy of Marecipe AV in treating influenza was evaluated by comparing the duration of influenza-associated fever among the treatment group, the preventive treatment group, and the control group.

Results: Data were collected from 524 individuals diagnosed with COVID-19, of whom 159 received Marecipe AV, while 365 did not. All 122 patients treated with Marecipe AV experienced resolution of fever within 24 hours of initiating treatment, with the COVID-19 clinical course concluding within the subsequent 24 hours. The incidence of fever among the 37 individuals exposed to Omicron who were undergoing anti-tumor treatment with Marecipe was 0%, in contrast to 98% among their close contacts. Among 78 individuals at high-risk of progressing to severe COVID-19, the hospitalization rate was 0% for those treated with Marecipe AV, while it was 68% for untreated patients. The Marecipe AV herbal therapy has been shown to provide significant benefits in improving clinical symptoms, particularly by shortening the duration of fever associated with influenza.

Conclusion: Marecipe AV herbal therapy has demonstrated a clear and potent therapeutic effect against COVID-19 and influenza. The use of Marecipe therapeutics has the potential to terminate the clinical course of mild to moderate COVID-19 in all patients treated within a 48-hour window, while also effectively preventing the development of severe cases in all high-risk patients.

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly worldwide, COVID-19 Excess Mortality Collaborators et al. (2022), 2. COVID-19 Cumulative Infection Collaborators et al. (2022) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has evolved into variants with increasing transmissibility and capability of evading human immunity (e.g., the B.1.1.529 [omicron] variant) Cao et al. (2022), Flemming et al. (2022), Viana et al. (2022). In late 2022 to early 2023, following the lifting of COVID-19 containment measures, an Omicron variant infection swept across China. In just a short span of two months, more than 80% of China's urban population was infected simultaneously. Currently, there is no evidence-based specific therapy with proven efficacy for COVID-19. The World Health Organization (WHO) recommends Nirmatrelvir–ritonavir (Paxlovid) for the treatment of mild-to-moderate COVID-19. Silveira et al. (2020), Zhong et al. (2022). Although Paxlovid brings hope for the treatment and prevention of COVID-19, it does not fully meet clinical needs Li et al. (2024). During the recent outbreak of Omicron infections, the vast majority of COVID-19

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patients in China were unable to obtain Paxlovid or even other medications in a timely manner, Fan et al. (2024), Cao et al. (2023), Steve Chaplin et al. (2022), I et al. (2022). Ma Recipe is an ancient herbal formula composed of powders derived from plants and rare freshwater fishes Feng et al. (2022), Feng et al. (2021), Feng. Marecipe AV is a modified version of Ma Recipe, featuring adjusted proportions of the herbs. Although the active ingredients and the mechanisms of action against viral infectious diseases have not been elucidated, it has been utilized in our clinic for over ten years to treat various viral conditions, including influenza, HPV infection, HBV infection, herpes zoster and postherpetic neuralgia Feng et al. (2024). In our clinical practice, we have observed that fever associated with influenza typically resolves within 12 hours following the administration of Marecipe AV, with sustained clinical recovery achieved within the subsequent 24 hours. Furthermore, clinical trials of Marecipe AV for the treatment of various life-threatening viral infections in animals have shown its remarkable efficacy in saving lives threatened by diseases such as African swine fever, avian influenza, canine distemper, and canine parvovirus Feng, Feng et al. (2024).

Based on clinical experience suggesting that Marecipe AV herbal therapeutics may effectively treat influenza within 24 hours, we utilized this therapy to treat COVID-19 patients in our clinic, considering the lack of available treatment options during the COVID-19 pandemic. This study provides a retrospective analysis of the outcomes of Marecipe AV in the management of COVID-19 and human influenza infections.

METHODS

Study Design

This study is a post-hoc analysis of clinical observations, rather than a prospective clinical trial with a robust design. Data on all COVID-19 outpatients at our clinic and their close contacts during the COVID-19 outbreak were collected through telephone interviews. The efficacy of Marecipe AV in addressing these conditions was assessed based on the duration of fever caused by COVID-19, the time to sustained clinical symptom resolution, and the rates of hospitalization for progression to severe COVID-19 in both the treated and untreated groups. The administration of Marecipe AV follows the daily practice of traditional Chinese medicine (TCM). TCM practitioners prescribe herbal formulas for patients who then take these prescriptions to the pharmacy to obtain the herbs. Patients prepare and consume the Marecipe AV extract orally at home. This process is consistent with the ethical principles of TCM and complies with relevant laws and regulations governing TCM practice.

Population

As this study was not a pre-planned clinical trial, there were no specific inclusion or exclusion criteria for selecting patients to receive Marecipe AV herbal therapy. Data were collected from all adult patients who presented to our clinic with fever during the COVID-19 pandemic in 2023 and the seasonal influenza outbreak at the end of 2024 in China. We conducted telephone interviews to gather information about family members who were considered close contacts and lived with the patients treated with Marecipe AV, as well as to collect data from patients with advanced cancer who were receiving treatment with Marecipe in our clinic, along with their close contacts. Additionally, we collected data on the treatment of severe COVID-19 patients who were hospitalized in various hospitals and received Marecipe AV. Given that most Chinese herbal medicines lack indications and that there are no standardized prescriptions for specific diseases, the requirement for additional informed consent is not necessary when prescribing these herbal remedies, even if they have not been previously utilized for treating conditions such as COVID-19. This framework ensures that TCM practices remain within the bounds of legal and ethical standards.

Procedures

Each febrile patient visiting our clinic during the COVID-19 pandemic undergoes COVID-19 dipstick and SARS-CoV-2 nucleic acid tests to confirm SARS-CoV-2 infection. The TCM doctors at the clinic prescribe a treatment regimen for the patient, who then collects the herbs from the TCM pharmacy and prepares the Marecipe AV extract at home according to the preparation method provided by the physician, which is subsequently taken orally. The standard treatment for patients with mild to moderate COVID-19 involves the oral administration of 10 grams of Marecipe AV preparation three times a day, with a reduction to twice daily on the fourth and fifth days. For patients with severe and critical COVID-19, Marecipe AV is administered orally at a dose of 10 grams every four hours for a duration of 3 to 5 days, followed by a dosage adjustment to 10 grams twice daily. For human influenza infections, Marecipe AV is administered orally at a dose of 10 grams every four hours for a duration of three days. Marecipe AV is a formulation composed of Prunella vulgaris, Vitex seeds, red grass, and rare freshwater fish meal. The primary components Betaine, Rosmarinic acid, Isoorientin, and Linolenic acid were identified through mass spectrometry analysis. The preparation method for Marecipe AV involves grinding the herbs into a fine powder, soaking them in water at low temperatures, and subsequently administering the preparation orally. Further details about Marecipe AV can be found in reference 18. Daily telephone interviews were conducted with patients who received Marecipe AV treatment, as well as with their close contacts, starting the day after the patients were

discharged from the clinic. The collected data were entrusted to a third-party statistical professional for analysis.

Outcomes

The primary endpoint included the duration of fever and the time to sustained clinical symptom resolution for two consecutive days. The secondary endpoints focused on hospitalization rates associated with the progression to severe and critical COVID-19. The study endpoints were determined based on the treatment design for the COVID-19 study conducted by Xiaohong Fan et al. The duration of fever is defined as the time from the administration of the initial dose to the absence of fever for two consecutive days. The time for sustained clinical symptom resolution for two consecutive days is defined as the duration from the initial dose to the first of two consecutive days without moderate to severe symptoms. The main criterion for resolution was near-complete, but not total, alleviation of symptoms, allowing patients to return to normal activities such as work and no longer requiring bed rest. The duration of fever was used as the primary endpoint to evaluate the efficacy of Marecipe AV in the treatment of influenza.

Statistical analysis

An analysis of variance (ANOVA) was conducted for each data set. The Kolmogorov-Smirnov test and the Mann-Whitney U rank sum test were employed to compare the observed indicators among the treatment groups. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 27 for Windows.

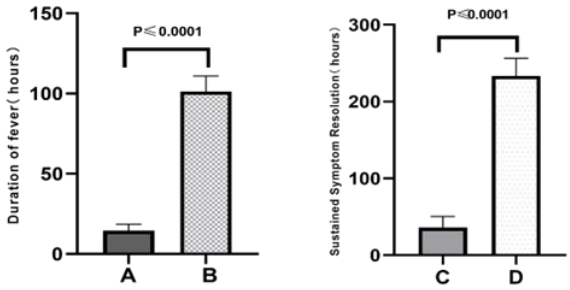
RESULTS

Data were collected from a total of 524 observed individuals, including 122 patients who received Marecipe AV therapy and 365 who did not. Among the 524 patients, 37 individuals with advanced cancer who were undergoing anti-tumor treatment with Ma recipe had been exposed to COVID-19, and there were 102 cases involving their close contacts. In most cases, fever onset occurred within 24 hours before the visit or telephone follow-up. It is important to note that the quality of this data is poor, particularly regarding the reported onset time of fever among the populations. Additionally, 78 individuals aged 75 years or older, deemed to be at high-risk of developing severe COVID-19, were identified and divided into independent subgroups for analytical purposes. Furthermore, 17 critically ill COVID-19 patients admitted to various hospitals received Marecipe AV therapy, while data from 31 untreated COVID-19 inpatients during the same period were used as controls. Each subject was confirmed to be infected with SARS-CoV-2 through either a COVID-19 dipstick test or a SARS-CoV-2 nucleic acid test. All participants in the study were from urban areas in China and presumably had received SARS-CoV-2 vaccinations.

All 122 patients who received treatment stopped experiencing COVID-19-related fever within 24 hours of initiating the dosing regimen. The mean duration of fever was 14.51 hours for the group of 122 treated individuals, compared to 96 hours for the group of 365 untreated individuals. The median duration of fever was also significantly shorter in the Marecipe AV-treated group than in the untreated group (12.00 hours [P25=12, P75=18] vs. 84.00 hours [P25=84, P75=120]; Z value = -16.71, P value < 0.001). The difference between the two groups was statistically significant, as determined by the two independent Mann-Whitney U rank sum test. None of the 37 patients receiving Marecipe intervention for advanced cancer experienced COVID-19-related fever during the COVID-19 wave, while 100 out of 102 close contacts developed COVID-19-related fever. The incidence of fever associated with COVID-19 was 0% in the Marecipe AV intervention group, compared to 98% in the control group without Marecipe AV intervention.

The moderate to severe influenza-like symptoms of COVID-19 decreased or disappeared within 48 hours of initiating treatment with Marecipe AV in all 122 patients. The average duration of COVID-19 symptoms for individuals treated with Marecipe AV was less than 48 hours, compared to 216 hours for untreated individuals. The median time to sustained clinical symptom resolution for two consecutive days was also significantly shorter in the Marecipe AV-treated group than in the untreated group (48.00 hours [P25=24, P75=48] vs. 216.00 hours [P25=216.00, P75=240.00]; Z value = -16.94, P value < 0.001). The difference between the two groups was statistically significant, as determined by two independent Mann-Whitney U rank sum tests. All patients who received the Marecipe AV intervention concluded their OVID-19 course by the 48-hour mark.

Figure 1: Analysis of Fever Duration and Time to Sustained Clinical Symptom Resolution



A: Duration of fever following the first dose of Marecipe AV; B: Duration of fever without Marecipe AV treatment; C: Time to sustained clinical symptom resolution for 2

consecutive days after the first dose of Marecipe AV; D: Time to sustained clinical symptom resolution for 2 consecutive days without Marecipe AV treatment.

There were 78 patients at high-risk for severe COVID-19, of whom 56 received MarecipeAV and 22 did not. In the group of 22 patients who did not receive MarecipeAV, 15 were hospitalized due to progression to severe COVID-19, and 8 died, resulting in a hospitalization rate of 68.18% and a mortality rate of 36.36%. In comparison, the hospitalization and mortality rates for the 56 high-risk COVID-19 patients treated with MarecipeAV were both 0%.

There were no deaths among the 17 in-patients with severe COVID-19 who were treated with Marecipe AV herbal therapeutics. Most of the in-patients treated with Marecipe AV herbal therapeutics experienced a significantly shorter clinical recovery time. All but one critically ill in-patient recovered and was discharged within 8 days after receiving the first dose of Marecipe AV. Three critically ill in-patients with COVID-19 exhibited rapid recovery following Marecipe AV treatment. One patient presented with severe kidney dysfunction, had no urine production, and required hemodialysis to sustain life. The other two in-patients with severe COVID-19 required mechanical ventilation and were in critical condition. All three patients were transferred from the intensive care unit to a general ward within 3 days of receiving their first dose, and they were discharged after rehabilitation within the subsequent 5 days. One patient, who required mechanical ventilation and was in critical condition, showed rapid improvement after Marecipe AV treatment and was discharged on the 22nd day following the initiation of dosing. During the same period, none of the 31 COVID-19 patients who did not receive Marecipe AV treatment in the same intensive care unit survived.

Data on cases of influenza were collected from 469 adult individuals aged 14 to 82 years, among whom 102 influenza outpatients with febrile symptoms received an influenza antigen test and were treated with Marecipe AV. Additionally, 150 individuals identified as close contacts of febrile influenza patients received prophylactic treatment with Marecipe AV for a duration of three days. A total of 217 close contacts served as controls and did not receive Marecipe AV.

Among the 102 febrile patients, 99 exhibited a duration of fever lasting less than 12 hours following the initial administration of Marecipe AV. One patient experienced a fever lasting 168 hours (7 days), while two others had fever durations ranging from 12 to 36 hours. In the cohort of patients treated with Marecipe AV, resolution of influenza symptoms (excluding cough) occurred within 24 hours after the administration of the first dose. Fever was observed in 150 of the 217 individuals exposed to the influenza virus who did not receive Marecipe AV. The median duration of fever among these 150 individuals was 132 hours (5.5 days [P25 = 5.24, P75 =5.79]). None of the 150 individuals exposed to the influenza virus who were treated with Marecipe AV developed a fever.

Adverse Events

There were no adverse events associated with the Marecipe AV treatment throughout the entire course of the study.

DISCUSSION

Given the lack of satisfactory treatments for COVID-19 and our previous clinical experience with Marecipe AV herbal therapeutics, which has demonstrated effectiveness in treating influenza within 24 hours, we administered this treatment to patients with COVID-19 as if they had influenza at our clinic during the COVID-19 pandemic, particularly during the period of drug shortages.

The findings suggest that Marecipe AV has a highly effective therapeutic effect on fever induced by SARS-CoV-2. Fever in all 122 COVID-19 patients returned to the normal range within 24 hours after the administration of Marecipe AV herbal therapeutics. The incidence of fever attributed to COVID-19 among patients receiving the Ma recipe intervention for cancer therapy was 0%, in contrast to 98% among their close contacts who did not receive the Marecipe AV intervention.

The moderate to severe COVID-19 symptoms were alleviated or completely resolved within 48 hours for all treated patients, significantly reducing the duration of the COVID-19 clinical course from an average of 214 hours to 48 hours. The most notable improvement was the complete restoration of appetite in patients, who no longer required bed rest. The use of Marecipe AV herbal therapeutics can substantially shorten the time to sustained clinical symptom resolution of COVID-19. These data suggest that the clinical course of mild to moderate COVID-19 concluded for all patients within 48 hours following the Marecipe AV intervention.

In the subgroup of individuals at high-risk COVID-19, the hospitalization and mortality rates for patients treated with Marecipe AV were 0%, compared to 68.18% and 36.36% for untreated patients, respectively. Based on this data, it is hypothesized that Marecipe AV herbal therapeutics may prevent the progression of mild-to-moderate COVID-19 to severe COVID-19 in all treated cases.

The use of Marecipe AV herbal therapeutics resulted in a significant reduction in the time to sustained clinical symptom resolution, the duration of fever associated with COVID-19, and completely prevented hospitalizations that progressed too severe COVID-19.

The differences in these indicators between the Marecipe AV treatment group and the untreated group were substantial, suggesting that Marecipe AV therapy has a significant therapeutic effect on COVID-19. However, given that there has never been an effective treatment for fatal acute viral infectious diseases, and considering that Marecipe AV is an herbal therapy that has not been extensively studied, the results of this study should be interpreted with caution. Regardless, a definitive evaluation of the clinical efficacy of Marecipe AV in the treatment of COVID-19 cannot be established from these data, as this study constitutes a retrospective clinical summary rather than a controlled clinical trial. Some research has provided evidence supporting the efficacy of Marecipe AV herbal therapeutics in treating COVID-19. In real-world animal trials, Marecipe AV has been utilized to treat severe and fatal acute viral infectious diseases, including African swine fever, avian influenza, canine distemper and canine parvovirus. It has successfully saved the lives of animals infected with these lethal viruses, reducing mortality rates from nearly 100% to zero and rapidly curing these deadly viral infectious diseases within three to five days Feng et al. (2024).

It is not appropriate to evaluate the effectiveness of Marecipe AV herbal therapeutics in treating severe COVID-19 due to the limited number of casese treated by Marecipe AV available. However, among the 17 critically ill COVID-19 patients treated with Marecipe AV, there were no fatalities, whereas all 31 control patients did not survive. This observation suggests that Marecipe AV may provide potential benefits for severe cases.

The study was retrospective rather than a clinical trial of a new drug. Pre-selection of treatment subjects was not feasible; consequently, the quality of the data may have been compromised. We conducted timely telephone interviews with patients undergoing treatment to provide guidance for the subsequent management of COVID-19 patients, as the efficacy of Marrecipe AV for treating COVID-19 was unknown at that time.

Marecipe AV therapy demonstrates significant advantages over other approved influenza treatments Hayden et al. (1997), Koszalka et al. (2022), Batool et al. (2023). The ability of Marecipe AV to terminate influenza fever within 12 hours after the initial intervention is particularly noteworthy. None of the individuals exposed to influenza who received Marecipe AV prophylaxis developed fever, whereas 69% of those who were not treated experienced fever. This finding suggests that Marecipe AV provides rapid and complete relief from influenza symptoms, including fever, headache, and muscle aches, rather than merely reducing symptom severity or slightly shortening the duration of symptoms, as seen with other influenza medications. Furthermore, prophylactic treatment with Marecipe AV may provide substantial benefits to individuals exposed to the influenza virus and could offer complete protection against influenza infection in these individuals.

During the ongoing influenza pandemic in China in 2024, a significant proportion of influenza patients experienced cough, with approximately 15% of these patients having a cough that lasted for up to 45 days. Since cough is a subjective symptom that cannot be easily quantified, these factors compromised the quality of the data obtained through telephone interviews. Consequently, the statistical analyses based on these data are inherently prone to significant bias, which is why we did not perform a statistical analysis of the time to clinical resolution to assess the treatment effect.

The mechanism of action of Marecipe AV herbal therapeutics remains unclear. Several unpublished in vitro studies have demonstrated that the Marecipe AV extract exhibits limited inhibitory effects on SARS-CoV-2, while also showing the ability to inhibit and eliminate various other viruses, including HBV, influenza virus, rabies virus, and herpes simplex virus. Marecipe AV has demonstrated in vitro antiviral activity against various types of viruses. Both Hepatitis B virus (HBV) and Influenza A (H1N1) can be rapidly cleared in vitro (data not shown). An in vivo study indicates that Feline Calicivirus in infected cats can be eliminated after 10 days of treatment with Ma Recipe AV (data not shown); however, this virus is not cleared naturally or by other antiviral drugs. The antiviral effects and viral clearance may represent the therapeutic mechanisms of Marecipe AV, although its extract exhibits limited inhibitory effects on SARS-CoV-2 in vitro. The primary chemical components of MarecipeAV, including betaine, rosmarinic acid, isoorientin, and linolenic acid, were identified using mass spectrometry. According to the literature, these components are not associated with viral suppression. In several trials involving Marecipe AV for the treatment of fatal viral infectious diseases in animals, it was observed that the pathogenic virus remained detectable in the animals' bodies even three days after they had fully recovered. A significant number of COVID-19 patients experienced complete resolution of fever and influenza-like symptoms within 24 hours after the administration of Marecipe AV. This suggests that the effects of Marecipe AV may extend beyond mere viral clearance, as the process of clearing a virus typically requires time, and symptom relief should not occur so rapidly. In conclusion, the primary mechanism of action of Marecipe AV may be more closely associated with inflammatory or immune responses rather than solely with viral inhibition or clearance.

LIMITATIONS

The study is a retrospective analysis rather than a rigorously designed prospective clinical trial. The number of treatment cases is insufficient, and the quality of the data is suboptimal. Due to these limitations, the efficacy

assessments based on the outcomes lack credibility. Consequently, the results of this study should be regarded as a reference for initial exploration rather than a definitive assessment of efficacy. All patients with COVID-19 treated at our clinic received Marecipe AV, which precluded the possibility of selecting participants for enrollment based on their clinical conditions. Furthermore, the limited number of untreated cases in the high-risk COVID-19 control group significantly impacted the outcomes related to hospitalization and mortality, introducing substantial statistical bias.

CONCLUSION

Marecipe AV herbal therapy has shown a clear and potent therapeutic effect against COVID-19 and human influenza infections. The oral administration of MarecipeAV effectively alleviates fever in patients with mild to moderate COVID-19 within 24 hours, reduces the COVID-19 clinical course to less than 48 hours. Marecipe AV herbal therapeutics can effectively prevent the progression from mild to moderate COVID-19 to severe illness. Marecipe AV therapeutics may hold potential for the treatment of severe COVID-19 cases.

DECLARATIONS

Ethics

Although the study treatment and pharmaceutical preparations adhere to the established norms and ethical standards of TCM, we have submitted an ethics application to expand the indications for the use of Marecipe AV to include COVID-19. The Traditional Chinese Medicine Ethics Committee of Tongrun Tang Clinic approved the study (Ethics Committee File Number: 202101).

Role of the funding source

All aspects of this study were no funder.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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