

Original Research Article

Nadifit, data-driven diagnosis: a clinical study for evaluating the significance of traditional Chinese medicine organ patterns through pulse diagnosis (nadi pariksha) for accurate pathology predictions

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ABSTRACT

Background: Pulse diagnosis or nadipariksha, is a traditional diagnostic technique utilized in ayurveda and traditional Chinese medicine, analyzing various pulse characteristics such as force, patterns, rate, and rhythm to discern underlying health conditions. This method integrates TCM's five-element energy levels and Ayurveda's Tridosha levels to accurately identify the root cause of diseases, enabling practitioners to tailor treatments accordingly. In today's fast-paced world, the need for efficient health monitoring is imperative. However, finding expert practitioners proficient in pulse diagnosis is becoming increasingly challenging, necessitating the development of systems capable of providing personalized health insights based on accurate root-cause analysis.

Methods: In this study, we compared predicted symptoms derived from objective TCM organ pattern analysis using the Nadifit pulse diagnosis system with subjective clinical assessments of patients' symptoms. TCM organ patterns were determined based on the combination of five elements and their Yin/Yang energy levels. Pulse signals were collected from 105 individuals and compared with clinical evaluations of patients' symptoms.

Results: The analysis revealed a high level of agreement between the clinical assessment of symptoms and the predicted organ patterns, with a Kappa coefficient of 0.82. This suggests that objective pulse analysis effectively identifies root causes, aligning with subjective assessments.

Conclusions: The findings of this study underscore the validity and reliability of objective pulse analysis in diagnosing health conditions. By demonstrating significant agreement with subjective clinical assessments, this method provides a promising avenue for enhancing diagnostic accuracy and facilitating personalized treatment strategies based on individual health profiles.

Keywords: Nadifit, Single position pulse measurement, Traditional Chinese medicine, Ayurveda, Pulse waveform

INTRODUCTION

Traditional Chinese medicine (TCM) and Ayurveda are the diagnostic tools that can be used to identify the root cause of any issue. It's crucial to emphasize that the definition of health in these approaches is distinct from the biomedical concept. According to TCM and

Ayurveda, health is defined as the equilibrium among various biological components such as dosha (body constitution), digestive fluids, enzymes, hormones (agni), body tissues (dhatu), and the regular elimination of waste products (mala). Additionally, it encompasses peaceful state of the soul (atma), sensory and motor organs (indriya), and mind (manas). This equilibrium is typically

disturbed by a number of unhealthy factors, including irregular eating habits, stress, and variations in the weather.¹ The core approaches in TCM involve employing four diagnostic techniques: observation, listening and smelling, questioning, and pulse examination. Consequently, the treatment based on syndrome differentiation may possess a subjective nature. TCM utilizes eight overarching principles to describe the conditions of the patients, namely Yin, Yang, external, internal, cold, heat, deficiency, and excess. Among these, Yin and Yang are considered pivotal in guiding TCM syndrome differentiation.²⁻⁵ To achieve positive results, it's crucial to accurately identify the syndrome and provide suitable treatment. According to TCM theory, pulse signals gather at the Cun-Guan-Chi segment of the radial artery. This specific area is believed to hold substantial physiological and pathological data regarding the human body.^{6,7} Examining the pulse is paramount in pulse diagnosis, and the diagnostic aspect of the pulse in Traditional Chinese Medicine is formed by integrating the three components of Cun-Guan-Chi. When diagnosing a patient with a disease, a traditional Chinese physician will typically feel the pulse by placing the index finger, middle finger, and ring finger on the radial artery at the Cun-Guan-Chi part.^{8,9} However, it is extremely challenging for medical professionals to become proficient in the technology that is used to take a patient's pulse. But, due to advancements in sensors, signal processing technology, and artificial intelligence, pulse diagnosis has been standardized and made more objective.¹⁰

TCM organ patterns

The theories of TCM and the Ayurvedic system are based on the concept of five elements (Panchamahabhootas) namely Ether (space) (Aakash), Fire (Teja), Water (Jala), Air (Vayu), and Earth (Prithvi). These five elements represent the body organs. Wind corresponds to the Liver and Gallbladder, representing movement and change. Humidity is linked to the Spleen and Stomach, symbolizing nourishment and digestion. Cold is associated with the Kidney and Bladder, representing preservation and fluid regulation. Dryness is related to the Lungs and Large Intestine, signifying inspiration and elimination. Heat corresponds to the Heart and Small Intestine, representing warmth and transformation. According to TCM, the imbalance between Yin and Yang is considered to be the primary root cause of a disease. It is crucial to understand historical background of traditional diagnosis with regard to the physical manifestation of Yin and Yang for its clinical significance. In order to determine a particular treatment plan, a TCM practitioner needs to first identify the precise nature of the YIN/YANG energy imbalance and the particular substratum in which the imbalance is manifested. Through careful examination of clinical symptoms and signs, it is possible to gain a significant understanding of the YIN/YANG imbalance. However, in many situations determining the imbalance in terms of the

dominance and subsequent increase or decrease in YIN/YANG energy levels can prove challenging in numerous scenarios. The characteristics like heat, movement, activity, and light are connected with Yang, whereas the features like cold, rest, passivity, and darkness are associated with Yin. Yang is related with these traits. Specifically, a deficiency in Yang causes cold syndrome, while a deficiency in Yin causes heat syndrome. In other words, heat syndrome is caused by Yin deficiency, whereas cold syndrome is caused by Yang deficiency. In the past, TCM practitioners devised methods for conducting in-depth examinations of the tongue, eyes, urine, stools, skin, and other areas in order to determine the degree of Yin/Yang imbalance. In addition, researchers have suggested the inclusion of a Chinese Medicine Questionnaire (CCMQ) in order to identify the body constitution of different patients.¹¹ Through the examination of the pulse or nadi, it is possible to derive five organ elements, which is of vital significance in terms of research and has practical utility in terms of clinical diagnosis. An individual's heart, kidney, liver, spleen and lungs are considered to be the five yin organs, while the gallbladder, stomach, large intestine, small intestine, and urinary bladder are considered to be the five yang organs. Organ patterns can be derived from combination of five elements and the YIN/YANG energy associated with each organ. This objective method of predicting pathological factors based on the detected organ patterns are compared with subjective method patient's pathological information obtained based on the CCMQ method were evaluated in order to make sure that the two approaches are congruence, in this study.

METHODS

Study description

One hundred and five patients with different kinds of health conditions and body compositions were chosen at random for the purpose of this research. All of the patients' pulses were taken in Manipal Hospitals, and they completed a voluntary informed consent form to take part in the research project. The research was conducted extensively from the December 2023 to February 2024.

The study excluded participants who were taking medications for cardiac conditions, had experienced multiple heart rhythm abnormalities, suffered from irregular heartbeats or arrhythmias, and had pulse recordings with numerous artifacts. The comprehensive compilation of the patient's clinical symptomatology was accomplished using a checklist derived from the classical texts, specifically the CCMQ, aimed at identifying the dominance of YIN/YANG excess or deficiency symptoms. The patients were then examined by a group of clinical specialists who conducted an independent clinical evaluation of each patient in order to determine if the patient had an excess of Yin or Yang or a deficiency of Yin or Yang. The study excluded fourteen participants

who exhibited incongruence in excess or deficiency dominance of YIN/YANG, as determined by both the checklist and clinical assessment. On the other hand, one hundred and five participants, who exhibited congruence in YIN/YANG excess or deficiency dominance according to both the checklist and clinical assessment, were selected for diagnostic evaluation.

Researchers who recorded pulse or nadi data, clinical experts and researchers who filled out the YIN/YANG excess or deficiency dominance checklist, were all blinded to the outcomes of the independent assessments. This was done in order to maintain confidentiality. Nadifit hardware and software system, which was manufactured by Neubotz Technologies, India, was utilized for the purpose of conducting an objective quantitative assessment of pulse. The system implements Artificial Intelligence (AI) algorithms to find TCM organ patterns from the raw pulse. These algorithms were developed with inputs from practitioners in TCM and Ayurveda who demonstrated experience in pulse diagnosis, in addition to testing investigations conducted on a number of individuals. Obtaining TCM organ patterns required a series of sequential activities, such as: recording a pulse or nadi signal at a single place over a period of 20 seconds at a sampling rate of 100Hz.¹² The signal from the sensor is first filtered and then Amplified, and then it is digitally converted so that it can be processed further. It is difficult to define the pulse signal using a mathematical function since it is an uncertain process. The general structure of each single-period sample is comparable, but the level of detail changes depending on the cycle used. Therefore, it is necessary for us to extract pulse features from a single-cycle pulse signal. Analysis in the time domain and analysis in the frequency domain are two approaches on signal analysis that are interrelated and necessary. By analyzing pulse signals from both of these perspectives, we were able to extract more than 27-time domain and 8 wavelet packet energy features.

Time-domain features

Based on the pulse signal's shape, duration, and amplitude, we have retrieved 27 time-domain features. We categorize time-domain features into four groups: peak- valley features, time features, dimensionless features, and dimensionality features.

Wavelet packet energy features

In order to extract the pulse frequency domain features, we choose for wavelet packet decomposition. Right after the three layers of wavelet packet decomposition, the third layer of the wavelet tree contains 8 nodes that correspond to various frequency bands of 4Hz. These nodes represent various information regarding the pulse signal. For the purpose of participating in the subsequent analysis, we make use of the wavelet packet energy feature of 8 nodes in the third

layer as the frequency domain feature of the single-cycle pulse signal.

The obtained features are trained and quantified to get five elements and their associated YIN/YANG energy levels (Organ patterns). Clinical experts assessed study participants for excess or deficiency in YIN/YANG, which was then compared with Organ Patterns derived from the pattern analysis from nadi signals. The (Figure 1) shows the acquired nadi pulse signal for the duration of 20 seconds. The (Figure 2), shows the organ pattern derived from the input pulse signal. It is clearly shows that the organ identified as spleen/stomach and the energy associated is deficient YIN and excess Yang. The (Figure 3) shows the AI predicted diagnostic information for the same organ pattern pulse. Algorithms based on machine learning and artificial intelligence were used to assess organ.

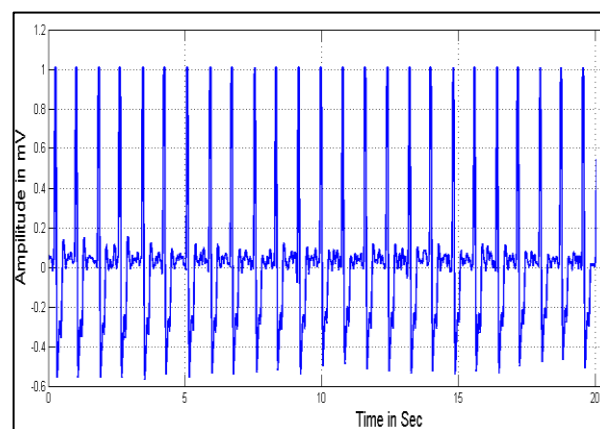


Figure 1: Acquired nadi pulse signal for the duration of 20 seconds.

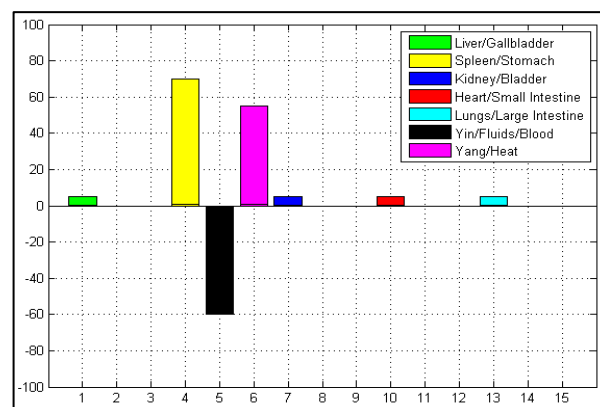


Figure 2: TCM Organ pattern derived from the input pulse signal.

RESULTS

The (Table 1) illustrates the distribution of study participants by gender, revealing that 60 percent of them were male. also shows the distribution of study participants according to age groups.

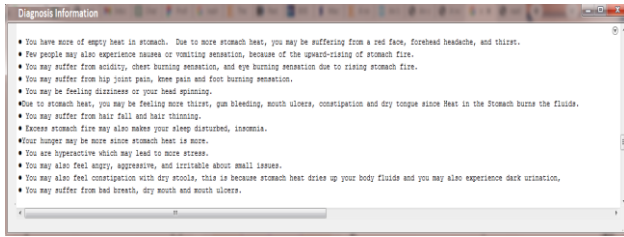


Figure 3: AI predicted diagnostic information for the same organ pattern.

It shows that the majority of patients were over the age of 40, and the highest number of participants fell within the

41-50 age group. The numerical values in the tables represent the frequency of individuals belonging to a particular category. It is observed from the (Table 2) that, except the Yin excess, all energy levels have more than 80 percent accuracy when compared between objective and subjective methods. The (Table 3) shows the random four patients symptoms correlation between Organ pattern's YIN/YANG analysis obtained from the pulse with Clinical method CCMQ's YIN/YANG analysis. It is observed the results obtained from both methods are in correlation. To evaluate the level of agreement in diagnosis between the pulse-based organ pattern analysis and the clinical assessment, the Kappa coefficient was computed using four distinct categories (Table 4).

Table 1: Distribution of study participants based on gender.

| Age group (years) | 11-20 | 21-30 | 31-40 | 41-50 | 51-60 | > 60 | Total |
|-------------------|-------|-------|-------|-------|-------|------|-------|
| Male | 2 | 8 | 12 | 25 | 10 | 5 | 62 |
| Female | 3 | 7 | 9 | 13 | 8 | 3 | 43 |
| Total | 5 | 15 | 21 | 38 | 18 | 8 | 105 |

Table 2: Diagnostic agreement between subjective clinical method and objective pulse analysis method.

| Clinical method | Pulse analysis | | | |
|-----------------|----------------|-----------------|------------|----------------|
| | Yang excess | Yang deficiency | Yin excess | Yin deficiency |
| Yang excess | 20 | 0 | 0 | 6 |
| Yang deficiency | 0 | 27 | 1 | 1 |
| Yin excess | 0 | 3 | 10 | 2 |
| Yin deficiency | 4 | 0 | 1 | 30 |

Table 3: Diagnostic agreement between organ pattern's YIN/YANG analysis obtained from the pulse with clinical method CCMQ's YIN/YANG analysis.

| Organ detected | Organ pattern analysis derived from pulse | | Clinical method CCMQ analysis | |
|-------------------|---|--|-------------------------------|---|
| | Energy level | Predicted symptoms | Energy level | Patients' symptoms |
| Spleen/Stomach | Yin deficient and Yang excess | More hunger, less sleep, constipation, Acidity, Stomach burning. | Yang excess | Hungry, insomnia, throat and stomach burning sensation |
| Liver/Gallbladder | Yin excess and Yang normal | Feeling sleepy, lazy, lethargy, phlegm accumulation, Fatty liver. | Yin excess | Muscular weakness, tiredness, work postponing, procrastination. |
| Kidney/Bladder | Yin deficient and Yang excess | Insomnia, back pain, knee and joints pain, arthritis, hair fall | Yin deficient | Blood pressure variation, less sleep, sciatica pain. |
| Kidney/Bladder | Yang deficient and Yin excess | Body coldness, low back soreness, swelling of legs, water retention in the body. | Yang deficient | Weak digestion, edema, skin issues, blood pressure variation, Diabetes, Sinusitis |

The Kappa coefficient is a statistical measure that provides a more precise assessment of inter-rater agreement compared to a basic percentage analysis. Evaluating diagnostic tests that require viewers to make subjective interpretations can be beneficial. The reliability of the system is based on its capacity to consider the occurrence of chance agreement. A Kappa score of 1 signifies perfect agreement, whereas a score of 0 signifies total disagreement. A score between 0.41 and 0.60

suggests a moderate level of agreement, whereas a score between 0.61 and 0.80 shows a high level of agreement. A score ranging from 0.81 to 0.99 signifies perfect agreement.¹³ The data analysis yielded a Kappa statistic score of 0.82, indicating a complete agreement between the pulse-based organ pattern analysis and the clinical approach to evaluating imbalances in pathological conditions.

Table 4: Yin/Yang excess or deficiency variations of study participants.

| Parameters | Pulse based analysis | Clinical assessment |
|-----------------|----------------------|---------------------|
| Yang excess | 24 | 26 |
| Yang deficiency | 30 | 29 |
| Yin excess | 12 | 15 |
| Yin deficiency | 39 | 35 |

DISCUSSION

This study investigates the feasibility of using the Nadifit system, a novel device employing artificial intelligence (AI), for objective pulse assessment in traditional medicine practices like TCM and Ayurveda (TAM). Both systems heavily rely on pulse diagnosis, a technique where a practitioner palpates the radial pulse to glean insights into a patient's health. The research team recruited 105 participants with diverse health conditions, meticulously excluding individuals with factors impacting pulse readings (e.g., specific medications, cardiac arrhythmias). To establish a baseline for Yin/Yang dominance, a cornerstone concept in both TCM and TAM, the study employed a two-fold approach: Standardized Checklist: A validated questionnaire based on classical medical texts identified signs of Yin or Yang excess/deficiency. Specialists independently assessed each participant to confirm the Yin/Yang dominance identified by the checklist. Independent Evaluation using Machine intelligence software: An Objective assessment of check listed patient's body and symptoms-based Yin or Yang excess/deficiency through real time pulse diagnosis.¹² This rigorous approach ensured consistency and minimized potential bias and yields a substantial agreement as indicated by the Kappa statistic score of 0.82 when compared to 0.78.¹³ Examination of objective pulse analysis is expected to give deeper insights into the state of Yin or Yang imbalance than mere clinical assessment. Further, organ patterns derived from five elements and the Yin/Yang provides specific predictions of patient's symptoms. In conclusion, the Nadifit system demonstrates potential as an objective tool for pulse assessment within traditional medicine frameworks. Future studies should explore its ability to accurately replicate the diagnostic capabilities of experienced TCM and Ayurveda practitioners.

Future directions and limitations

This research lays the groundwork for exploring Nadifit's potential as a tool for TCM and Ayurvedic practitioners. Future research directions could involve: Expanding participant pools, implementing longitudinal studies, Comparing Nadifit's findings with established diagnostic tools, Refining the AI algorithms for improved accuracy. Limitations could involve: limited sample size: The study only included 105 participants, which might not fully represent all health conditions and variations in pulse readings. Exclusion criteria: some individuals were

excluded from the study due to factors like specific medications or heart irregularities, which could limit the system's applicability to a broader range of patients.

CONCLUSION

Preliminary study to assess the diagnostic agreement (pathology prediction) in assessment of Yin/Yang energy imbalances by clinical approach and the pulse-based organ pattern analysis yielded a substantial agreement as indicated by the Kappa statistic score of 0.82. Further, through clinical examination and analysis of patient symptoms, the pulse-organ pattern analysis demonstrates specificity towards identifying health issues. However, use of validated questionnaires for Yin/Yang energy analysis is recommended for future studies to assess diagnostic accuracy of pulse-based organ pattern analysis.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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