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STUDY PROTOCOL

Analysis of Traditional Chinese Medicine Symptoms in Children with Spastic Cerebral Palsy, a Protocol for Data Mining

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Background: Cerebral palsy (CP) is characterized by abnormal pronunciation, posture, and movement. Clinically, CP can be categorized into various motor syndromes, including spastic hemiplegia, diplegia, quadriplegia, involuntary movement, ataxia, and mixed types. Among these, spastic CP represents over 70–80% of all CP cases. The primary objective of our study is to identify the top and core Traditional Chinese Medicine (TCM) symptoms and analysis their association rules in children with spastic cerebral palsy, thereby enhancing the theoretical foundations of TCM treatment on spastic CP.

Methods: The study will be conducted on children aged 4 to 14 years with spastic CP who are undergoing treatment at Xi'an Encephalopathy Hospital Affiliated to Shaanxi University of Chinese Medicine. Basic information about the patients and their TCM symptoms will be collected on the first day of admission. This information will include age, gender, birth history, family history, disease classification, and TCM symptoms (including symptoms, tongue, and pulse). Once the data is collected, it will be exported from the electronic medical record system for further analysis. Descriptive statistics will be performed using Excel 2019, while exploratory factor analysis and cluster analysis will be conducted using SPSS Statistics 22. Additionally, association rule analysis will be carried out using SPSS Modeler 18.

Results: This study will investigate the most top TCM symptoms in children with spastic CP and explore the association rules between these symptoms, mapping the presentation of spastic CP onto symptoms identified within TCM.

Conclusion: Our findings will provide the distinctive characteristics of TCM symptoms in children with spastic CP, furnishing evidence-based support to clinicians and patients in making well-informed decisions collaboratively.

Keywords: cerebral palsy, TCM symptoms, data mining, descriptive statistics, association rule analysis, exploratory factor analysis, cluster analysis

Introduction

Cerebral Palsy (CP) is a group of permanent movement and posture development disorders attributed to nonprogressive disturbances in the developing fetal or infant brain. CP can lead to limitations in activity and often involves motor issues, sensory, perception, cognition, communication, and behavior disturbances, epilepsy, and secondary musculoskeletal problems.[1] The definition of CP has evolved over time due to its clinical and etiological heterogeneity. Among the various CP subtypes, spastic CP is the most prevalent, accounting for over 70% of all CP cases.[2,3] Global population-based studies have reported a CP prevalence ranging from approximately 1.5 to 4 per 1000 children.[4–8] In low- and middle-income countries, the birth prevalence of pre- and perinatal CP is around 3.4 per 1000 live births, while in high-income countries, it's lower at 1.5 per 1000 live births (1.6 per 1000 when including post neonatal CP),[9] which carrying an increased risk of severe motor impairments, poor nutritional status, and diminished health-related quality of life.[10,11] Children with CP face significant mental burdens and experience poor social adaptability, primarily due to abnormal motor function, especially gross motor function. These challenges not only impact the children themselves but also

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extend to their families. The severity of gross motor difficulties in individuals with CP can vary widely, depending on various factors such as the type and extent of brain damage, access to appropriate interventions, and the level of social support.[12]

There is no record of CP in TCM documentation. This disease is generally grouped under the scope of "five late", "five soft" and "five hard", which is mostly related to insufficient congenital endowment or improper parenting after birth. Many studies[13–15] have shown that TCM plays an important role in the treatment of spastic CP. Especially, the efficacy of acupuncture and tuina for spastic CP has been repeatedly verified by many studies.[16,17] However, according to the characteristics of "TCM syndrome differentiation and treatment", the treatment effectiveness on children is closely related to whether the syndrome differentiation is accurate. TCM clinicians or acupuncturists often decide individualized treatment measures according to the individual symptoms of children with spastic CP in the clinic, which improves the pertinence of treatment to a certain extent, but often makes it difficult to promote treatment experience. Therefore, it is urgent to explore the characteristics of spastic CP TCM symptoms and their association rules. The purpose of this study is to apply data mining technology to map the presentation of spastic CP onto symptoms identified within TCM, then form a standardized treatment protocol based on this knowledge and realize the therapeutic potential of TCM on spastic CP.

Methods and Analysis

Medical Record Selection

We will select medical records of children who have received treatment for spastic cerebral palsy (CP) at Xi'an Encephalopathy Hospital affiliated to Shaanxi University of Chinese Medicine, China. The inclusion period for the study is from October 2021 to March 2023. Ethical approval for the study has been obtained from the Hospital Ethics Committee (Approval No. XN2023-13).

Review Process

Data Screening

Inclusion criteria for medical records included: (1) The age of the patient: 4 ~ 14 years old. (2) The first and second admissions were diagnosed with spastic CP. The diagnostic criteria for CP and the clinical classification criteria for spastic CP have been established according to the committee members' determinations in the Guidelines for Rehabilitation and Treatment of Cerebral Palsy in China.[18] (3) Admission information is complete. (4) The medical records contain complete demographic information and TCM symptoms. (5) The patient does not have other serious organic diseases of the heart, liver, kidney, and other important organs.

Sample Size for Inclusion

In research on data mining of TCM symptoms, achieving a substantial sample size is generally essential to maintain the study's accuracy. Specifically, in Exploratory Factor Analysis, an adequate sample size is essential to enhance reliability and stability, facilitating a robust factor structure and interpretation. For Cluster Analysis, a substantial sample size is imperative to ensure representativeness of resulting clusters. Similarly, in Association Rule Analysis, a sizable sample size is crucial to ensure reasonable support and confidence in generated association rules. Based on historical hospital case volumes and considering the research timeline, we have initially set a target of including 500 (subject to situational considerations) valid medical records as the study subjects for this research.

Database Establishment and Data Normalization Processing

The medical record that meets the research criteria is exported from electronic medical record system to an Excel document to establish the TCM symptoms database and the included medical record data would be cleaned and organized. TCM symptoms should comply with the relevant terminology standards. The principle of data input is that if the patient has the symptom, it is marked as 1, otherwise it is marked as 0. Two senior physicians will review the finished Excel document to ensure that all the data is correct, which will be used for further analysis. The flow chart of the study (Figure 1) will be used to show the research screening process.

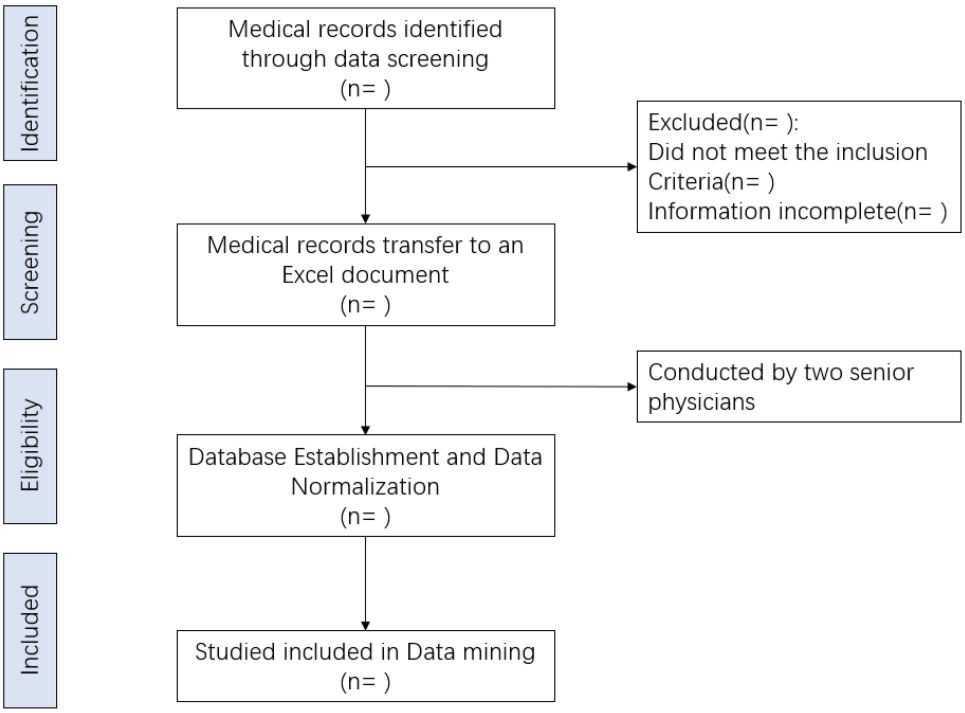

Figure 1 The flow chart of the study.

Managing Missing Data

In order to better evaluate the TCM symptom data, we will contact the patient's guardian and they will then provide any missing information. If detailed information cannot be obtained in this manner, we will proceed to evaluate the presently available data.

Data Analysis

Descriptive Statistics

All of TCM symptoms data extracted from medical records will be input into an Excel 2019 document, which will then be used to create a three-line table for descriptive statistics on the top frequency of symptoms. Specifically, it is divided into the distribution statistics of symptoms (including tongue and pulse symptoms) (Table 1). Top frequency of symptoms will also be presented using Bar charts (Figure 2).

Table 1 Top Frequency of Symptoms

Number	Symptoms	Frequency
1	Symptoms 1	…
2	Symptoms 2	…
3	Symptoms 3	…
4	Symptoms 4	…
5	Symptoms 5	…
6	…	…
7	…	…
…	…	…

Note: "…": Data to be filled in based on research results.

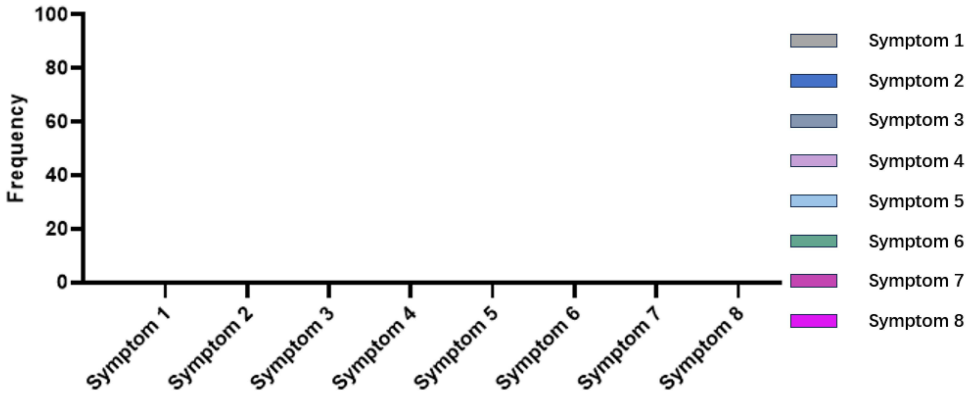

Figure 2 Top frequency of symptoms.

Exploratory Factor Analysis

We will utilize SPSS Statistics 22 software to conduct exploratory factor analysis on the TCM symptoms data. Prior to factor analysis, we will subject the data to Kaiser–Meyer–Olkin (KMO) and Bartlett sphericity tests. Factor analysis will proceed if KMO> 0.5 and P<0.05. In such cases, the factor analysis will be extracted using the maximum variance rotation method. Conversely, if KMO < 0.5 or P > 0.05, factor analysis will not be suitable.

Cluster Analysis

We will utilize SPSS Statistics 22 software to conduct cluster analysis on the TCM symptoms data, followed by the construction of a cluster analysis tree. Subsequently, we will analyze the clustering relationships among various symptoms (including tongue and pulse symptoms).

Association Rule Analysis

We will utilize the Apriori algorithm available in SPSS Modeler 18 software to conduct an analysis of association rules on TCM symptoms data. The probability of occurrence for both previous and posterior items will be expressed through the concept of support, while the degree of confidence will represent the likelihood of the posterior item appearing when the previous item is present. Through iterative experimentation, we will determine the optimal and minimum degree for both support and confidence, which will be illustrated in the specific format presented in Table 2. Subsequently, a complex network diagram will be generated to analyze the correlation among all the symptoms.

Discussion

CP comprises a cluster of enduring central motor and postural developmental disorders, along with limited mobility syndromes,[19] which arise from non-progressive brain damage occurring during the fetal or infantile developmental stages. Among the various clinical types of CP, spastic CP stands as the most prevalent, accounting approximately 70–80% of all cases.[20] Despite the current lack of understanding regarding the exact etiology of CP. Study by Jin SC[21] has revealed that mutations affecting neurite genes can elevate the risk of developing this condition. The currently therapeutic approaches for cerebral palsy encompass diverse modalities, such as physical therapy,[22] occupational therapy,[23]

Table 2 Association Rules of Symptoms

Posterior Item	Previous Item	Support (%)	Confidence (%)
Symptoms 1	Symptoms 2	…	…
…	…	…	…
…	…	…	…
…	…	…	…
…	…	…	…

Note: "…": Data to be filled in based on research results.

medications,[24] surgery,[25] hippotherapy[26] and yoga,[27] etc. TCM[13] has emerged as a significant player in the treatment of CP, particularly through the application of acupuncture and tuina techniques, as elucidated by recent studies.[28]

As an important component of complementary medicine, TCM is widely utilized in the treatment of spastic CP, particularly in East Asian countries like China[13] and South Korea.[29,30] Acupuncture, as a crucial intervention in TCM, has been extensively validated by numerous clinical studies for its effectiveness in managing spastic CP.[31,32] Given that TCM follows the theory of "syndrome differentiation and treatment", the clinical efficacy of TCM are closely associated with the accuracy of syndrome differentiation by the physicians. Therefore, exploring the TCM symptoms in spastic CP and guiding clinicians to implement treatments based on syndrome patterns play an important role in standardizing therapeutic approaches and enhancing TCM treatment efficacy.

To investigate the underlying rules governing the diverse TCM symptoms in spastic CP, we will utilize data mining techniques, which offer a promising and pragmatic methodology.[33] Data mining technology facilitates the establishment of associations between individual data points, computes the frequency of each item within the database, and identifies associations with other things.[34,35] Through descriptive statistical analysis, we can identify the most common top TCM symptoms (including pulse and tongue symptoms) in children with spastic CP. Exploratory Factor Analysis (EFA)[36,37] is a statistical approach used to uncover the underlying structure or latent variables that may explain the correlations among observed variables in a dataset. This technique is commonly employed in multivariate data analysis to simplify complex datasets and identify key factors contributing to the data's variability. EFA proves valuable in revealing the latent structure of data and reducing dimensionality, thus facilitating the interpretation and analysis of intricate datasets. Cluster analysis[38,39] is a statistical method used to group similar objects or data points together based on their similarity or distance in a multidimensional space. The primary goal of cluster analysis is to partition a dataset into clusters, where data points within each cluster exhibit greater similarity compared to data points in other clusters. It is important to note that cluster analysis is an exploratory technique, and the validity and meaningfulness of the resulting clusters need to be carefully evaluated by experts. Association rules are a powerful technique in data mining and machine learning used to discover interesting relationships or associations between different items in a large dataset.[40] The basic form of an association rule is represented as "A > B", where A is the previous item and B is the posterior item. The support and confidence values associated with the rule indicate the significance and reliability of the discovered association. Association rule mining finds widespread use in healthcare research; however, it is crucial to interpret and validate the discovered rules diligently to avoid drawing incorrect or misleading conclusions based on chance occurrences in the data. In this study, the degree of support for the association rule refers to the probability of two TCM symptoms occurring simultaneously, while the confidence degree refers to the probability of symptom 1 and symptom 2 being used in conjunction. It is important to note that terms such as "posterior item" and "previous item" used in our study are used purely for the purpose of the analysis and does not imply a genuine temporal order or causality between symptoms. The study will provide evidence-based support for sorting out the relationship between TCM symptoms in spastic CP, guiding the accuracy and appropriateness of TCM interventions, and potentially enhancing the efficacy of TCM clinical interventions in patients with spastic CP.

Conclusion

Our findings will provide the distinctive characteristics of TCM symptoms in children with spastic cerebral palsy, furnishing evidence-based support to clinicians and patients in making well-informed decisions collaboratively.

Patient and Public Involvement

Patients and/or the public were not engaged in the design, conduct, reporting, or dissemination plans of this research.

Consent to Participate

As a data mining protocol, this study will not involve specific patient information. Hence, an exemption from the requirement of patient parental consent has been granted by the ethics committee. However, the study will strictly adhere to all principles of the Declaration of Helsinki.

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Disclosure

The authors report no conflicts of interest in this work.

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