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Effectiveness of Traditional Chinese Medicine in Primary Care

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1. Introduction

This chapter first describes the role of Traditional Chinese Medicine (TCM) in health care. It then reviews the literature on the effectiveness of TCM with a special focus on primary care. An appraisal of the outcome measures in the context of TCM is made. The relationship between TCM and the concept of health-related quality of life (HRQOL) is discussed. The current applications and limitations of the HRQOL measures derived from Western culture to TCM are identified. The chapter ends with an overview of Chinese culture specific measures for evaluating the effectiveness of TCM in primary care.

2. The role of Traditional Chinese Medicine (TCM) in health services

In China, it was estimated that there were 3.1 billion TCM outpatient visits per year for the 1.3 billion population [1]. Currently, TCM accounts for 40% of all health services delivered in China, and it has been part of the formal Chinese healthcare system since 1950 under the political directives of Mao Tse Tung [2]. However, the development of TCM in Hong Kong followed a different path as it was not recognized by the Government as part of the formal healthcare system until 1997 when Hong Kong was reunited with China. The Hong Kong Special Administrative Region (SAR) government tried to re-integrate TCM into the health care system in the past decade by the establishment of the Chinese Medicine Council of Hong Kong (CMCHK) as a statutory body under the Chinese Medicine Ordinance to regulate and register Chinese Medicine Practitioners (CMP) in 1999 [3]. Although TCM in Hong Kong is still mostly a private service, piloting outpatient TCM clinics and limited inpatient services have started in public hospitals. Subsidized TCM primary care outpatient services have been provided by the Tung Wah Group Hospitals for nearly half a century in Hong Kong [4].

Even though Western Medicine consultation is the most commonly used type of primary care, 50 to 60% of people have consulted TCM in Hong Kong and 13.5% of the people have consulted TCM frequently or occasionally [5, 6]. There are 5604 registered CMP serving a

population of 6.8 million in Hong Kong [3] and most of them provide primary care. A recent survey found that 19% of all private outpatient services were provided by Chinese Medicine Practitioners (CMP) [7] suggesting that many people find TCM helpful enough to be willing to pay for the service. Users of TCM were found to be more likely to be women, older persons, chronic disease patients with lower quality of life, and the lower socioeconomic group [8]. With its whole person approach, TCM may have a role in primary care to enhance the quality of life and health of people especially the elderly and those with chronic diseases.

TCM is regarded as a form of complementary and alternative medicines (CAM) in most countries other than China. CAM refers to a broad set of health practices that are not part of the country's own tradition and are not integrated into the dominant health care system [9]. The number of CAM visits exceeded the number of visits to all primary care physicians, and the estimated total out-of-pocket expenditure on CAM was US\$27 billions in 1997 which was comparable to that for all primary care physician services for the same year [10]. TCM, especially acupuncture and bone-setting, is one of the most popular CAM globally being practiced widely in Asia, the United States (US), Canada, Europe and Australia [10]. TCM makes up a major proportion of the CAM services in the US [10] increasing from 34% in 1989 to 42% in 1997 [11]. Many of these patients reported improvement with their illnesses that Western Medicine failed to help [12]. In Denmark, the proportion of patients who had used TCM at least once annually increased from 23% in 1987 to 43.7% in 2007 [13]. TCM consultations accounts for a total expenditure of £580 million in the United Kingdom (UK) [14].

The increasing use of TCM has caused a profound impact on the global health care services. The National Centre of Complementary and Alternative Medicine (NCCAM) and the National Health Service (NHS) have been established in the US and the UK respectively, to allocate national budget for TCM services in primary care. Other European countries also have provided public financing for TCM [10]. The global increase use of TCM has called for more information on its function and outcomes to guide medical resource allocation.

3. Effectiveness of Traditional Chinese Medicine

The effectiveness of acupuncture in pain control was first demonstrated by an expert panel systematic review in the NIH conference in 1997 [15], which attracted the world's attention to TCM. This has established the place of TCM in health care. *Artemisia annua* was proved to be effective in against resistant malaria and gave hope of preventing more than 800 thousand deaths from malaria among children each year [16, 17]. In Geriatrics, TCM has been shown to not only improve health-related quality of life (HRQOL) in the treatment of illnesses, but also to promote healthy aging [18]. Wesnes and Ward et al. found Panax ginseng significantly improved an index of memory quality by 7.5% and this effect persisted for the whole treatment period until 2 weeks after washout [19]. TCM has also been studied for the prevention of acute severe respiratory syndrome (SARS) in hospital workers [20]. None of the health workers who took the supplement had contracted SARS compared to 0.4% of health care workers who did not ($p=0.014$). Improvement in influenza-like symptoms and quality of life were also observed among herbal supplement users. A remarkable effectiveness of TCM was found in patients with irritable bowel syndrome in a randomized controlled trial that showed an improvement measured by the total bowel symptoms scale and global improvement scores assessed by both patients and

gastroenterologists [21]. Many studies in Europe were carried out in recent years to evaluate TCM treatments for specific conditions with variable results. In the UK, a daily decoction containing 10 herbs was found to be more effective than placebo in improving patients with chronic atopic dermatitis in erythema, surface damage, patients' subjective feeling on itching and sleep in a randomized, double-blind placebo-controlled trial [22, 23]. In Netherlands, the effectiveness of Chinese herbal medicine (CHM) integrated with TCM diagnosis was confirmed for the treatment of postmenopausal symptoms when compared with hormone replacement therapy (HRT) or placebo in a randomized placebo-controlled trial [24]. It was found that CHM could significantly improve the amount of hot flushes than placebo. In addition, quality of care research in a TCM hospital in Germany found that TCM care could reduce the intensity of complaints, improve quality of life (in terms of both mental and physical-related HRQOL scores of SF-36) and subjective and objective global rating of conditions of inpatients subjects [25]. However, there were few research data on the effectiveness of TCM in primary care even though it is most commonly used for this purpose.

The National Health Service (NHS) of the UK conducted 4 large-scale population studies on the impact of CAM in reorganization of primary care services in 1999 [14, 26, 27]. Results showed that patients not only had their health outcomes significantly improved or expectation met after the consultation but also had significantly decreased in the use of medication and general practitioner time. A limitation of these surveys was that they did not differentiate between the different types of CAM.

A study by the Swiss Federal Department of Home Affairs evaluated and compared the health status and health care utilization rates of users of complementary and alternative medicine (CAM) clinics found that patients attending CAM clinics had higher consultation rates and more severe illnesses than patients in conventional primary care clinics [28]. This study gave evidence on poorer self-perceived health status of CAM patients which need for a more physician-based medical services provided by CAM practitioners in primary care. The need for evaluating Chinese medicine and assure the quality of care was revealed by a population survey in Beijing [29] and a qualitative study in the UK [30]. Before this study, there were no data available on the effectiveness of TCM in primary care yet. The effectiveness of TCM primary care service as a whole remained unknown and that for the treatment of common problems were limited. Such information is needed to inform policy makers and the public how TCM is best utilized in our health care system [31, 32].

3.1 Evaluating the effectiveness of Traditional Chinese Medicine (TCM)

Despite the fact that TCM is popular globally and national institutes have been established for the integration of TCM into their health care systems, scientific evidence to support its use is not sufficient. The effectiveness of a highly individualized treatment made by a Chinese Medicine Practitioner (CMP) is usually subject to only the CMP's assessment and patients' subjective perception. The lack of a standardized outcome measurement method limits its scientific evaluation and generalizability of the results. The requirement of the paradigm of evidence based practice in using randomized controlled trials (RCT) as the 'gold standard' for the evaluation of treatment effectiveness has led to the denigration of non-experimental studies. A major conference held in 1993 concluded that only RCT was capable to confirm the benefit brought by TCM, and recommendation should not be made from evidence gathered in observational or case-control studies. However, only a few

Chinese herbal remedies and acupuncture have been proven by RCT [15]. Most claims on the effectiveness of TCM were based on empirical experience, leading to some people concluding that TCM was mostly not effective or even harmful [33]. Nevertheless, the debate on the most appropriate study designs for evaluating the effectiveness of TCM continues.

Unfortunately, most randomized controlled trials (RCT) conducted on TCM were rated to be poor in quality [34, 35] but RCT is not the only research study design and has its limitation. Classical RCT enforced the evaluation of TCM by the conventional Western medicine model, which can be impractical and inappropriate [36]. Black pointed out that not every intervention can be evaluated by a randomized trial and most importantly the rigorous random allocation may reduce the effectiveness of the intervention by not considering the subject's active participation, beliefs and preference [37]. We need observational or cohort studies to evaluate some interventions while others should be tested by RCT. Studies conducted by Thomas and Fitter showed the impossibilities of blinding Chinese Medicine Practitioners or patients during acupuncture interventions or giving individualized TCM treatments according to patients preference [38]. The realization of the inappropriateness of classical RCT to evaluate TCM led to the development of two alternative clinical trial methods: (1) the partial randomization design; and (2) the pragmatic design with prior randomization by Fitter [39] to evaluate the effectiveness of TCM. The partial randomization design takes patients' preference into account before they are randomized into treatment or placebo groups. Upon recruitment, patients are asked whether they have a preference for certain treatments, and if they do, they are assigned to the preferred treatment. If not, they are randomly assigned into either the study or the control treatments. The pragmatic design with prior randomization classifies eligible patients into syndrome groups by TCM practitioners before they are randomized to receive the appropriate treatment or placebo.

The study by Zaslavshi showed the pragmatic design with the integration of the CMP's syndrome differentiation based on TCM theory into a randomized controlled trial was feasible in an acupuncture clinical trial [40]. This model was also used successfully in a RCT on the treatment of Irritable bowel syndrome (IBS) with Chinese herbal medicine showing better improvement in patients treated with individualized Chinese herbal formulae than standard TCM treatment and placebo groups [21].

The Medical Research Council in the UK [41], the NIH in the US [42] and WHO [43] have established guidelines on the research methodology for evaluating the effectiveness of CAM. All these recognize that conventional research methodology may not be applicable and recommended syndrome differentiation in clinical trials. The pragmatic design of applying TCM syndrome differentiation to guide the formulation of the treatment before randomization is recommended to be a clinical trial model for attaining evidence-based TCM [44, 45].

4. Health outcome measures in the context of Traditional Chinese Medicine

Clinical outcomes can be categorized into four types (1) clinician-reported outcomes; (2) physiological outcomes; (3) caregiver-reported outcomes and (4) patient-reported outcomes (PROs) [46]. Clinician-reported outcomes are the observation, global impression or functional assessment made by professionals including doctors and nurses. Physiological outcomes include results from different laboratory tests (e.g. blood test, ultrasonic

examination, X-ray etc). Caregiver-reported outcomes include the patient's behavior dependency and functional status observed by the caregiver. Patient reported outcomes (PROs) represent the patients' own perception of the changes in their own health condition, response to treatment and feelings, which include but not limited to general health status, symptoms, functional status and health-related quality of life (HRQOL). The first two types of outcomes used to be the main measures of efficacy or effectiveness of treatments but they are no longer adequate or sensitive enough for modern health care that aims at improving quality of life [47]. PROs started to gain popularity especially in the field of oncology. WHO defined the concept of 'health' as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.' [48]. This definition has changed the conventional use of morbidity and mortality to measure health outcomes. Health care has become more concerned with the impact of health on social behavior and psychological well-being. In 1970s, quality of life began to be applied as an outcome to the medical field [49-53]. In 1975, the word 'quality of life' started to be used as a keyword in medical journals such as *Annals of Surgery* or *Health Education* [54]. In 1977, 'quality of life' became indexed in the Index Medicus (Medline) database. In 1966, only four quality of life related articles published in Medline, 511 articles were published in 1998 and 4872 were published in 2008. The number of articles increased to a total of 72989 from 1966 to 2008 reflecting the increasing applications of QOL in medicine. The Oncologic Drugs Advisory Committee of the Food and Drug Administration (FDA) announced the beneficial effects on quality of life (QOL) as an endpoint and it could serve as the basis for approval of new oncology drugs [55]. Health-related quality of life (HRQOL) has become a standard outcome indicator in many clinical trials, population studies and health services in Western Medicine. There is potential for it to be used as a primary outcome measure for TCM.

5. The philosophy and conceptual base of Traditional Chinese Medicine

To evaluate the effectiveness of Traditional Chinese Medicine (TCM) its underlying philosophy and concepts of health must be defined. Dating back to the 8th century BC, Chinese defined the health by the concepts of the Yin and Yang which formed the theoretical base of TCM. Chinese Medicine practitioners (CMP) consider patients' symptoms in the context of an imbalance between Yin and Yang, In TCM, the equilibrium of Yin and Yang is best described in the earliest book on TCM, *Internal Classic of Medicine* [56].

"If the Yin and Yang energies of a man are kept in a state of equilibrium, his body will be strong and his spirit sound, if his Yin and Yang energies are dissociated, his vital energy will be declined and finally exhausted." and "A healthy man is one whose physique, muscle, blood and Qi are harmonious and appropriate with each other."

A perfect equilibrium between Yin and Yang indicates a perfect health state and implies good life quality. Disease is the result of a break down of the equilibrium between Yin and Yang with an excess or deficiency of either Yin or Yang. Symptoms develop as a result of the imbalance between Yin and Yang, which can be assessed by Chinese Medicine Practitioners (CMP) with the four diagnostic methods which are "Inspection", "auscultation-olfaction", "inquiry" and "palpation". A TCM treatment regimen aims at regulating and re-establishing the balance between Yin and Yang within the individual. This may involve reducing the redundancy of Yin or Yang or reinforcing the deficiency of Yin or Yang through the process of "planning treatment according to the individualized diagnosis called *Bianzheng* and *lunzhi*". By this principle, even though two patients presenting different symptoms/

illnesses, if the underlying TCM syndrome differentiation is the same, the treatments are still the same. This is known as different illnesses same treatment. On the other hand, two patients with the same presentation of symptoms/illness, if the underlying TCM syndrome differentiations are different, the treatments should be different. The main TCM treatments modalities include herbal medicines, acupuncture, moxibustion, exercises, breathing techniques and diets.

The health concept in TCM also emphasizes the importance of diet, daily activities, physical functioning and emotion, which coincides with that defined by the World Health Organization. In promoting health, Internal Classic of Medicine [56] described that:

“Those who knew the way of keeping good health in ancient times lived in accordance with nature, followed the principle of Yin and Yang, conformed with the art of prophecy, modulated their food and drinks, worked and rested in regular times and avoided overwork; therefore, they could maintain both the body and spirit to live to the natural old age of more than one hundred years.”

6. Outcome indicators of TCM

As mentioned above, Traditional Chinese Medicine (TCM) has long been criticized for the lack of standardized outcome measures. The individualized prescription made by the Chinese Medicine Practitioner (CMP) is usually based on the CMP's subjective assessment. Particularly, the assessments between different CMP for the same patient can be greatly different, a lack of consistency in the assessment methods and outcome limits the generalizability of TCM and makes its evaluation difficult. Some researchers have tried to develop measures to standardize TCM syndrome differentiation diagnosis but it has been criticized that this method is limiting the strength of TCM in individualized treatment [57] and forcing TCM to adopt the classification of Western Medicine. In fact, the evaluation of TCM has little about measuring outcomes [58]. To evaluate the effectiveness of TCM, conventional outcome indicators such as laboratory or physical examination developed from Western Medicine have been applied in TCM research but there are great doubts on their appropriateness in the context of TCM. Some aspects such as complexion, spirit and vitality improvement cannot be captured by these indicators but they are very important indicators of health in TCM.

7. Traditional Chinese Medicine (TCM) and Health-related Quality of Life (HRQOL)

Health-related quality of life shares the same concepts and objectives as TCM. It should theoretically be the most appropriate outcome measure of the effectiveness of TCM. A paper by Lai et al [59] published in 2000 discussed and established the relationship between TCM and HRQOL. They pointed out that Chinese Medicine Practitioners (CMP) mainly rely on patients' reported symptoms and daily activities in their diagnostic process. The assessment of disease progression greatly depends on patients' feedback. Patients' subjective perception of the effect of their illness and treatment could be captured more scientifically by standardized HRQOL measures. To evaluate the effectiveness of TCM more scientifically, they suggested three directions: (1) Applying international generic HRQOL measures to evaluate the clinical effect of TCM; (2) Using standard methods to develop generic HRQOL measures for TCM, and (3) Developing TCM-condition specific HRQOL measures. Many

other practitioners and researchers also agreed that HRQOL should be used as an important outcome of TCM because it can capture the latter's emphasis on the balance in physical, social and psychological well being [60, 61]. This outcome measure should complement conventional methods such as CMP assessment or laboratory results in the evaluation of TCM.

7.1 The concepts of health-related quality of life

The term Quality of life (QOL) is difficult to be defined. It summarizes a wide range of life events [62] and is a subjective appraisal of an individual of his/her life as a whole in various aspects. These aspects may range from the perception of well-being, satisfaction with one's life, achievement of personal goal, social usefulness, normalcy to duration of life, impairment, functional status (social, psychological, and physical), health perceptions, and opportunity. The definition of quality of life in fact depends on subjective perception which is greatly influenced by the environment, social, political and economic situations and cultures. Cummins had identified more than 100 definitions of QOL in the literature [63]. In general, QOL refers to a global state of satisfaction with life as a whole and the presence of positive feelings and the absence of negative ones. The broad and inclusive definitions of QOL go far beyond the medical model and only those aspects related to health are relevant to Medicine.

The term Health-related quality of life (HRQOL) is an attempt to quantify the net consequence of a disease and its treatment on the patients' perception of his ability to live a useful and fulfilling life [64]. It aims at measuring the effect of health by using a defined number of dimensions that are relevant to the person. These dimensions are structured firstly according to the WHO definitions of health to include the physical, psychological and social well-being [48]. Some authors extended the dimensions by adding spirituality. The purpose of HRQOL assessment is not only on measuring the presence and severity of illnesses but also on showing how an illness or treatment is experienced by an individual [65]. It has been used extensively in clinical trials [66-68], health economic research [69-72] and quality of care evaluations [73-76].

Although HRQOL has been criticized as too 'soft' or less reliable than conventional physiologic indicators, HRQOL can detect important clinical changes in many chronic conditions that other clinical outcome measures cannot. HRQOL differentiated patient adherence between three anti-hypertensive agents (captopril, methyldopa, and propranolol) that had similar efficacy in lowering blood pressure but different effects on quality of life [77]. Brown et al. found that a SF-36 physical functioning score and role limitation score lower than the UK norm by 20 and 23, respectively, predicted a need for coronary revascularisation, the use of anxiolytics and the need for two or more angina drugs in patients who had acute myocardial infarctions [78]. Spertus et al. was able to show the benefit of a special angina clinic in that patients had greater improvements in quality of life measured by the Seattle Angina Questionnaire (SAQ) than those receiving usual care from a general medicine clinic [79]. Goodwin et al's systematic review concluded that HRQOL targeting specific symptoms could guide treatment decisions and was often the only significant outcome measure in breast cancer drug trials [80]. HRQOL is now regarded as the most important outcome indicator to guide medical decisions on the optimal treatment for breast cancer in the US [80].

7.2 HRQOL in measuring effectiveness of primary care

If HRQOL is to be used as an outcome measure of the effectiveness of TCM in primary care, it has to be valid and applicable to this setting. Primary care practitioners have always relied very much on patients' subjective symptoms in making diagnoses and evaluating treatment outcomes. A recent review on outcome measures for primary care showed the evolution and recognition of the importance of function and health-related quality of life as indicators of subjective health [81]. The accumulating evidence that HRQOL measures are valid and reliable has facilitated its increasing use in clinical service and research in primary care [82-84]. Before a HRQOL measure can be considered as applicable to primary care, it should [85],

- *Measure the aspects and effects of the illness that the patient decides are most important (relevant)*
- *Enable the patient to score the chosen variables (subjective)*
- *Be a sensitive measure of within person change over time (responsive)*
- *Be applicable to the whole spectrum of illness seen in primary care (generic)*
- *Be capable of measuring the effects of a wide variety of care (generic)*
- *Be brief and simple enough to complete in a 7-10 minute consultation.*

The first HRQOL that was applied to primary care was the COOP Charts, which was later adopted by the World Organization of Family Doctors (WONCA) and modified into the COOP/WONCA Charts for international application in primary care [86]. It was translated and validated for the Chinese population in Hong Kong in 1994 [87, 88]. It demonstrated the negative impacts on the life of patients from common chronic diseases such as depression, diabetes mellitus, osteoarthritis and asthma in primary care (Lam and Lauder 2000). The MOS Short-form 36-item (SF-36) Health Survey has become a popular HRQOL measure worldwide since its first publication in 1992. Studies have shown that SF-36 can predict the utilization of primary care services [89], and low HRQOL in community-dwelling elderly had higher mortality rates [90]. Patients with gout were found to have poorer HRQOL (lower functional limitation scores of the SF-36 Health Survey) and higher rates of inpatient utilization and mortality among all US veterans [91]. The Chinese (HK) version of the SF-36 Health Survey was validated and normed on the Hong Kong population in 1998. It was found to be a sensitive measure of the impact of chronic disease and determinant of primary care service utilization in the Chinese adult population in Hong Kong [88, 89, 92].

7.3 Application of health-related quality of life measures in Traditional Chinese Medicine

Since health-related quality of life (HRQOL) measures were recommended as an important outcome measures in clinical research by the World Health Organization and China Department of Health [93, 94], there has been a surge of HRQOL studies in TCM in the last two decades. Most of the applications were in the fields of cancer, cardiovascular diseases, pain management, geriatrics and respiratory diseases, but very few in primary care.

7.4 Application of HRQOL measures in TCM for the treatment of cancer

The first paper applying HRQOL measurement to TCM was published in 1986 on liver cancer patients [95]. The Karnofsky Performance Scale Index (KPSI) [96] was used as a pre-treatment assessment tool to predict the prognosis of liver cancer patients treated by Chinese herbs and radio-therapy. After this publication, HRQOL measures were used more

often to assess the effectiveness of TCM after chemo- or radio therapy in liver and lung cancer patients [97-100]. The KPSI was the most commonly used in these early studies.

The KPSI was found to be responsive to improvement after TCM interventions. It was reported that 67.7% of stage II or III liver cancer patients [98] and 32 liver cancer patients who did not respond to chemo-therapy [99] had improved KPSI scores after TCM treatment. The KPSI scores was able to show in a cohort study on gastric, liver and esophagus cancer patients that the combination of Chinese herbs with chemotherapy was better than chemotherapy alone [101]. Ma et al's meta-analysis further confirmed the sensitivity of KPSI in 7 randomized controlled clinical trials in showing TCM integrated with chemo-therapy was better than chemotherapy alone (OR = 3.4; 95% CI = 2.5 - 4.6, $p < 0.05$) in the treatment of non-small cell lung cancer [102].

In recent years, more HRQOL measures have become available and being used in clinical trials on TCM. The European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) questionnaire [103] was applied to evaluate the effect of medical qigong in cancer patients with or without chemotherapy [104]. It was found that EORTC QLQ-C 30 scores were significantly improved in both groups and medical qigong could also reduce the side effects of patients who underwent chemotherapy. Other HRQOL measures specific for cancer like Functional Assessment of Cancer Therapy-Prostate (FACT) have also been used. FACT-Prostate (FACT-P) [105] was used in assessing the effect of a dietary supplement containing eight herbal extracts (PC-SPES) on prostate cancer patients and reported a significant improvement in functional, emotional and physical well-being in the treatment group [106]. The FACT-Lung (FACT-L) [107] was used to assess the benefit of Chinese herbal medicine treatment on non-small cell lung cancer patient showing that integration of TCM with Western Medicine (WM) or TCM treatment alone were associated with better improvement in terms of total, physical and emotional status than WM alone [108].

7.5 Applications of HRQOL measures in TCM treatments of other conditions

Other than oncology, HRQOL measures have been applied to many studies on cardiovascular disease, pain management, geriatrics and respiratory diseases. A number of widely used international generic and disease-specific HRQOL measures have been used to assess the effectiveness of TCM treatment of cardiovascular diseases. The quality of life index (QLI) [109] and the Activities Daily Living Scale (ADL) [110] had been applied to cerebral hemorrhage patients to show that TCM was more beneficial than Western medicine in improving the cognitive function and the activities of daily living [111]. Wang et al. and Siu et al. found that TCM was equally effective as an antihypertensive drug, Norvasc, in improving all domains of SF-36 Health Survey in patients with hypertension [61, 112]. The Seattle Angina Questionnaire (SAQ) [113] was used in coronary artery bypass grafting patients and found that combining TCM with conventional Western care can significantly improve the domains of angina stability, angina frequency, treatment satisfaction and disease perception measured by the SAQ when compared with conventional Western care [114].

In evaluating the effectiveness of TCM treatment on patients with osteoarthritis, the SF-36 Health Survey, SF-12 Health Survey, Visual Analog Scale (VAS), Western Ontario and McMaster University osteoarthritis index (WOMAC), Lequesne Index and Global Satisfaction Scale have all been used [115-117]. The effectiveness of Complementary and Alternative Medicine (CAM) clinic in relieving pain of OA patients by the combination

usage of herbs, chiropractic and acupuncture was detected by the SF-12v2 Health Survey [117]. Another study using the SF-36 v2 Health Survey showed that TCM could enhance social functioning and mental health in the elderly population [118]. The efficacy of willow bark extract was confirmed by a statistically significant difference of 14% in the WOMAC pain dimension between the treatment and placebo groups [116]. Ginger extracts were associated with a reduction of pain on a VAS and the Lequesne Index in a randomized placebo-controlled clinical trial [115, 119].

In evaluating the effectiveness of TCM in respiratory diseases [120], Xue et al. used a combination of symptoms scores diaries, the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (RQLQ), patient's global evaluations of improvement and physician's objective evaluation in a multi-center randomized double-blind, placebo-controlled clinical trials on allergic rhinitis. The RQLQ indicated significant beneficial effects of TCM treatment with an improvement in categorical items by 60.7% against an improvement by 29.6% from placebo. Their study also cross-validated improvement in quality of life by patients' global evaluation and practitioners' objective assessments.

HRQOL assessment of the effectiveness and efficacy of TCM have also been applied to studies on HIV[121], hepatitis C virus [122, 123], vomiting and nausea in pregnant women [124], chronic alcoholism [125] and somatoform disorders [126].

7.6 Limitation of existing health-related quality of life measures in evaluation of Traditional Chinese Medicine

Despite the increasing applications of HRQOL measures developed from Western culture to the evaluation of TCM, their validity has been questioned. Song et al. stressed out that such applications should be only a transitional state [127] since the cultural context of Western HRQOL measures may not fully match the health concepts in the Chinese culture. Wu et al. pointed out that health concept from the Western culture may neglect the important Chinese concepts of the relationship between health and the seasonal changes or the importance of syndrome differentiation in TCM, which may hinder the development of TCM [128, 129].

Outcome measures of TCM should be coherent with its underlying philosophy and theory so that they could be sensitive and responsive to the changes brought about by TCM treatments [45, 130, 131]. For example, the commonly used Karnofsky Performance Scale Index (KPSI) [96] only focuses on objective assessment of the patient's ability to perform daily activities, work or self-care, it is not sufficient in describing other changes brought by TCM intervention such as the abilities to adapt to climatic changes or diurnal changes [132]. The domains measured by Western HRQOL measures may not be valid to TCM. Therefore it is uncertain whether the results truly reflect those related to TCM. This had called for the development of HRQOL measures specific for TCM.

7.7 Development of Chinese culture specific HRQOL measure for TCM

To develop HRQOL measures applicable to TCM, the Chinese health concepts must be first explored [133]. Cheung et al conducted a qualitative survey on TCM experts in their study on the content validity of a liver syndrome measure commented that the importance of meaning of health from the Chinese culture is unique and need further investigation [134].

Several TCM condition-specific HRQOL measures have been developed. The Emotion scale for Ganzangxiang of TCM was developed to measure HRQOL specific to the anxiety and depression syndrome that are classified under the liver-syndrome by the TCM theory [135,

136]. PiWei-syndrome differentiation measure [137] and the Liver-Fire Ascending Syndrome Scale [138, 139] were developed with similar principles to capture specific physical symptoms, psychological states changes related to specific TCM diagnosis. TCM syndrome differentiation indicators were included in the IBS-TCM differentiation measure for patients with irritable bowel syndrome [140].

While TCM-syndrome specific measures may be relevant and sensitive for a particular condition, there is doubt on the rationale and feasibility of developing a measure for each of the thousands TCM syndromes [141]. Others have urged the need for a generic TCM measure that should include the basic principles of TCM such as the balance of Yin and Yang or cold and heat, deficiency and excess. A generic HRQOL measure not only can evaluate the clinical effectiveness of different TCM treatments, it can also allow evaluation of health of the general population and comparison of patients with different illnesses [142]. A generic HRQOL measure applicable to TCM could also provide a common standard tool for the validation of the TCM syndromes specific measures to enhance research of TCM in clinical practice [143].

The Yin and Yang Scale was the first generic TCM measure developed based on the Yin and Yang principles. Although it was originally intended only for research purpose and not for clinical assessment, it was found that yin and yang scores could be used to differentiate groups of patients effectively in clinical practice. The Yin and Yang scale was also found to be easier to endorse than the detailed syndrome evaluation making it more useful in the research setting [144]. The Yin and Yang Scales served as a preliminary model of generic TCM measures, but it does not really measure HRQOL.

8. The Chinese Quality of Life instrument (ChQOL)

Leung et al. developed the first and probably the only generic TCM HRQOL measure, the Chinese Quality of Life (ChQOL) instrument in Mainland China in 2005 [145]. The initial model was developed from a review of the literature on TCM, which included the equilibrium of Yin Yang in four dimensions: (1) Physical form and Vitality & Spirit, (2) harmonization of man and society and (3) harmonization of man and nature and (4) Seven emotions. Based on these 4 dimensions, four TCM scholars generated 13 facets that were grouped into two domains: 1. Physical form and Vitality & Spirit, and 2. emotion. No facet could be identified for the dimensions on harmonization of man and society or the harmonization of man and nature because CMP rarely ask patients about these two dimensions, which were then excluded from the final Chinese Quality of Life instrument.

Items were then generated for the 13 identified facets and drafted in wordings that were used in the communication between Chinese Medicine Practitioners (CMP) and patients. Response options on intensity, frequency or capacity appropriate to the items were adopted from previously validated response options of the WHOQOL-100, The initial draft Chinese Quality of Life Instrument (ChQOL) had a 3-domain structure with 69 items. Each item was rated on a 5-point Likert scale and the scale scores were transformed to a range of 100, with higher scores indicating better HRQOL. The draft was reviewed by 100 CMP who added more items resulting in an 80-item instrument. The second draft was evaluated by a convenient sample of 15 subjects including both healthy and patients consulting a TCM clinic by cognitive debriefing interviews to confirm the linguistic and semantic clarity of the items. Two items were dropped and revisions were made to 78 items. These 78 items were then field tested on 273 subjects including in-patients and out-patients of a TCM hospital

and healthy subjects conveniently recruited from the community of Southern Mainland China. Psychometric testing and factor analyses eliminated items that were below the standards of the respective psychometric properties resulting in the final ChQOL with a 3-domain structure and 50 items. The domains are namely physical form (20 items), vitality and spirit (12 items) and emotion (18 items). The three domain scores can be summarized into an overall score. The conceptual structure and the ChQOL are described in other published journal [146].

8.1 Validity and psychometric properties of the ChQOL

Construct validity of the 50-item ChQOL was confirmed by factor analysis and item-scale correlations. The facet-domain correlations ranged from 0.71-0.89 and domain-overall score correlations ranged from 0.56-0.78, supporting the scaling structure. Factor analysis also confirmed the 3-domain structure. The reliability of the ChQOL was supported by internal consistency with Cronbach's alpha ranging from 0.71-0.90 at the facet level and 0.80-0.89 at the domain level. Test-retest reliability was tested on 56 healthy subjects at 2-day interval, giving an intra-class correlations (ICC) ranging from 0.68-0.84 at the facet level and 0.83-0.87 at the domain level. Convergent construct validity was confirmed by moderate correlations between ChQOL scores and SF-36 or WHOQOL-100 scores. Responsiveness of the ChQOL had been examined on 32 subjects with congenital heart diseases showing effect size changes in the three ChQOL domain scores ranging from 0.25 to 0.93.

The ChQOL was adapted into a HK version and pilot tested on 122 Cantonese speaking people (69 patients with chronic diseases who consulted TCM clinic and 53 healthy subjects conveniently recruited in the community) in Hong Kong [132]. The ChQOL (HK version) scales showed good construct validity with the facet-domain correlations ranging from 0.64-0.89 and domain-overall score correlations ranging from 0.79-0.81. Internal consistency was supported by Cronbach's alpha ranged from 0.73-0.90 at the facet level and 0.73-0.83 at the domain level. Test-retest reliability tested in a 2-day interval was good with intra-class correlations (ICC) ranging from 0.77-0.88 at the facet level and 0.89-0.90 at the domain level. Convergent construct validity was confirmed by moderate correlations between the ChQOL (HK version) and the Hong Kong WHOQOL-100. In addition, the ChQOL (HK version) scores were able to discriminate between patients and healthy subjects.

Results from these pilot studies of the ChQOL and its HK version are encouraging. It can become a standard HRQOL measure for the evaluation of the effectiveness of TCM if further studies can confirm its acceptability, feasibility, validity, reliability, sensitivity and responsiveness in different Chinese populations and clinical settings.

8.2 Potential applications of the ChQOL

Over the past 50 years, molecular, cellular and pharmacological research have dominated the research in TCM, but clinical trials on effectiveness have been largely neglected [147]. The few TCM clinical studies evaluated effectiveness of TCM by conventional physical examination or laboratory tests [148] often showed only modest benefits. The use of a validated HRQOL measure can expand the scientific evidence on the effectiveness of TCM by capturing the improvement in HRQOL of patients. The Chinese Quality of Life instrument (ChQOL), if further proven to be responsive to changes related to TCM, can help to solve a major deficiency in evidence-based TCM practice. The ChQOL is generic so that it can be applied to people with different health status or illnesses. This is most suitable for

evaluating the effectiveness of primary care that manages a wide spectrum of patients and conditions. Evidence on the effectiveness of TCM in primary care is important to establish its role in our health care system and to inform the public in their choice of service.

9. Summary

There is evidence supporting the role of Traditional Chinese Medicine (TCM) in primary care with increasing use, resources allocation, regulations, research and education. This trend is not only limited to China but also occurring in Western countries. Health-related quality of life (HRQOL) shares the same concepts and objectives as TCM, which should be a most appropriate outcome measure for assessing the effectiveness of TCM. As HRQOL has already been established as a standard outcome measure in Western medical care, it could be used for scientific evaluation of the effectiveness of TCM in primary care. HRQOL measures developed in the Western culture have been applied to oncology and other areas such as cardiovascular disease, pain management, and geriatrics with variable success. However, these Western measures cannot capture all the health benefits of TCM, which hinders further development and clinical research of TCM. The Chinese quality of life instrument (ChQOL), based on the Chinese cultural concepts of health, is a promising HRQOL measure that can become a scientific outcome measurement tool for TCM. The ChQOL is generic making it applicable to all types of patients and particularly suitable for primary care that manages a wide spectrum of illnesses.

10. References

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During the recent years, traditional Chinese medicine (TCM) has attracted the attention of researchers all over the world. It is looked upon not only as a bright pearl, but also a treasure house of ancient Chinese culture. Nowadays, TCM has become a subject area with high potential and the possibility for original innovation. This book titled *Recent Advances in Theories and Practice of Chinese Medicine* provides an authoritative and cutting-edge insight into TCM research, including its basic theories, diagnostic approach, current clinical applications, latest advances, and more. It discusses many often neglected important issues, such as the theory of TCM property, and how to carry out TCM research in the direction of TCM property theory using modern scientific technology. The authors of this book comprise an international group of recognized researchers who possess abundant clinical knowledge and research background due to their years of practicing TCM. Hopefully, this book will help our readers gain a deeper understanding of the unique characteristics of Chinese medicine.

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