

Integrating Traditional Chinese Medicine (TCM) practices into T2 diabetes mellitus treatment: incentives and challenges

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Editorial

Diabetes affects an estimated 29 million people in the United States, and was the seventh leading cause of death as of 2010 [1]. While Type 1 Diabetes Mellitus (T1DM) is largely managed with routine insulin injections, the Type 2 form (T2DM) often requires multi-agent therapies and can lead to a host of burdensome complications in patients as well as high costs for providers and payers.

Traditional Chinese Medicine (TCM) currently occupies a small niche within the western medical canon but is gaining prominence among patients who struggle with the dosing regimens and side effect profiles of conventional pharmaceutical therapies (e.g. military veterans suffering from Post-Traumatic Stress Disorder, or PTSD) [2]. Similar preliminary outcomes have been made in fields such as oncology, where using TCM therapies as complements to chemotherapies and other standard cancer treatments has yielded promising results [3].

Areas such as oncology and mental health have been appealing targets for TCM integration due to the unclear etiology of disease in these spaces, as well as the safety risks found in a number of the available treatments. In such cases, there is no guarantee that standard western medical treatments will be more effective than alternative therapies, which allows TCM practitioners to potentially play a greater role in treatment discussions.

T2DM represents an increasingly attractive opportunity for greater TCM utilization in American health care, as a growing chronic disease population and rising drug prices have spurred interest in holistic patient management as a means of improving care quality and lowering health costs. Chronic care for T2DM patients is costly and inconvenient to patients (as well as to payers and providers), who often present with a range of comorbid conditions and may require combination therapies or routine insulin injections [4]. Moreover, many patients who achieve safe blood glucose levels under conventional diabetes treatments may still experience adverse side effects from their medications in addition to other forms of discomfort.

Perhaps the most immediately relevant niche for TCM practices to occupy in the T2DM treatment paradigm is in comorbid patients who struggle with the dosing or side effects of existing pharmacologic treatments. While metformin monotherapy is still widely administered as a first-line treatment, roughly 75 percent of patients required multiple therapies to reach and maintain target HbA1c levels nine years after initial disease onset [5,6]. Treatments for these patients

can be costly, risks of non-compliance abound, and achieving stable HbA1c levels does not necessarily prevent or alleviate the various secondary complications that stem from the disease. For instance, Thiazolidinediones (a common second or third line therapy) pose considerable risk of heart failure, and sulfonylureas are largely recommended in short-acting form (where dosing is less convenient) because the long-acting compounds carry a risk of hypoglycemia [5]. Moreover, recent clinical studies have attributed increased onset of cardiovascular disease (CVD) in T2DM patients to usage of these compounds [7].

Recently launched T2DM pharmacologics have proven to be reasonably safe and effective, but their costs remain burdensome. AstraZeneca's Farxiga (dapagliflozin) generated \$457 million in 2016 sales and cost over \$3,000 per patient, while Johnson & Johnson's Invokana sales exceeded \$1.2 billion with a per patient cost of over \$4,500 [8]. TCM therapies have demonstrated much stronger safety profiles relative to older T2DM therapies in recent clinical trials, and a full TCM treatment regimen, consisting of herbal therapies and monthly acupuncture sessions, will only cost an average of \$950-1,100 per patient per year [9]. At the very least, providers should be open to investigating the head-to-head efficacy of these alternative therapies against standard pharmacologics, especially in patients whose symptoms are difficult to control.

A second incentive for TCM integration stems from the broader shift toward preventative treatment models that is occurring across the United States. As chronic disease prevalence in the United States quickly approaches the 150 million patient mark, patients are increasing suffering from the secondary symptoms and complications of their illnesses. Millions of T2DM patients remain in a state where their blood glucose levels are not alarmingly high but are still high enough to progress the disease. Preemptively starting these patients on additional treatments for these later-stage symptoms (e.g. diabetic neuropathy) can be burdensome on patients and is clinically unnecessary, given the strength of these agents. In fact, many of the conventional T2DM pharmacologics have been shown to cause hypoglycemia in patients, suggesting that excessive treatment is almost as problematic as a lack

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thereof [10]. With a wide range of agents varying in strength, TCM herbal and acupunctural therapies can help manage these symptoms at an earlier stage without the risk of over-treatment.

Going forward, it is important to note that the attractiveness and potential for TCM integration in the US only go as far as the American health system's willingness to assimilate this little-understood field. It currently operates outside the traditional provider-hospital system as few treatments are FDA-approved, though there is uncertainty whether remedies consisting of herbs or food products even need such approval, given how many herbal agents are available over-the-counter. Moreover, if the US healthcare landscape grows to embrace TCM, the biopharma industry, where diabetes/metabolism is a lucrative therapeutic area, will likely lobby against such practices on the grounds that products have not received the same regulatory scrutiny as conventional pharmacologics have.

On an equally practical note, the availability of TCM treatments (at least for the near future) may be tied to the TCM provider supply across the country, which further slows its integration into the health system. Standard medical institutions do not offer extensive courses in TCM practices and current providers educated in conventional western medicine are unlikely to invest the additional time needed to master these concepts.

Due to the low costs and safe side effect profiles of TCM therapies, payers and providers alike have considerable incentives to experiment with TCM in their respective practices. The potential of TCM to replace costly medications and prevent hospitalizations (even in a fraction of patients) carries strong appeal to all players in the healthcare system. For Medicare, Medicaid, and indigent populations, inpatient stays largely result in net losses for hospitals [11]. For commercially insured

T2DM patients, hospitalizations and prescriptions are costlier for payers. While more clinical research should be conducted to investigate the true efficacy and safety of these alternative therapies, TCM certainly has the potential to be a staple in emerging T2DM treatment paradigms.

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