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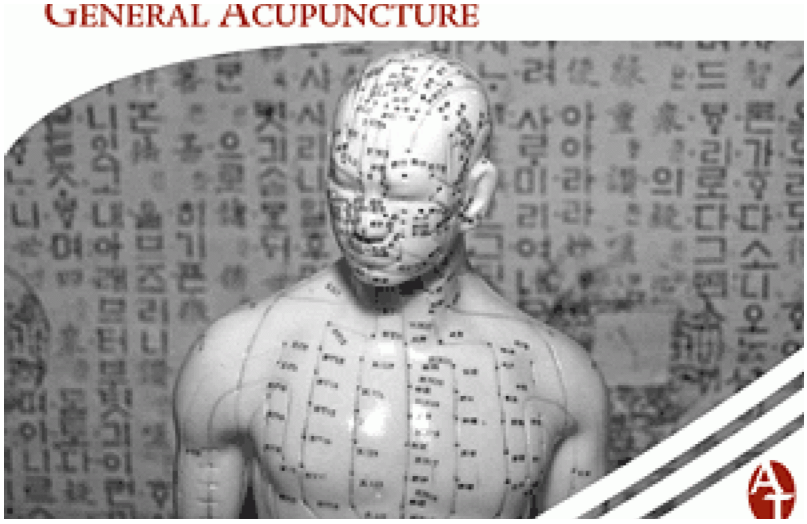

GENERAL ACUPUNCTURE

Our Medicine: What does hypertension really tell us?

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Hypertension is an issue affecting a growing number of people as life becomes more stressful. The problem of hypertension is significant in American society, as well as in primarily, but not exclusively, the "developed" world. According to Dr. W.F. Graettinger, in his article "*Systemic Hypertension*" found in *Current Diagnosis & Treatment in Cardiology* it is estimated that more than 62 million Americans have hypertension, and about half of that number may be aware of their problem. Half again of that group may be receiving some treatment, and only one-third of the group that is aware of their problem will have their blood pressure under control. Mainstream medicine considers hypertension to be a "gateway" disease to other, more serious, heart and/or kidney disease.

In research done in 2006 by this author on Traditional Chinese Medicine (TCM) treatments for hypertension, the results from the search "acupuncture or electroacupuncture and hypertension or high blood pressure," returned 1,846 citations. Among those citations was the review "*Hypertension and Depression*" by Scalco, which had the stated intention to study the literature for the relationship between those two prevalent diseases; it was used then as the basis to frame an 8,500-plus word discussion of TCM and other non-drug treatments for hypertension as well as to examine the interplay of depression and hypertension. The Scalco paper, investigates non-pharmacological treatments for hypertension, and helps to expand the insight into the systemic nature of the issues that combine to produce it; physical de-conditionings, fluid dynamics, sympathetic nervous system (SNS)/bio-electrical, dietary, and lifestyle/emotional imbalances, along with some additional evidence to show that the use of antidepressant drugs may actually enhance conditions for hypertension. When hypertension is understood in this systemic manner as discussed by Scalco then high blood pressure (HBP) can be seen as a condition that is treatable with TCM methods, with the benefit of providing less side effects and better quality of life than the mono-therapy of biochemically specific synthetic drugs used in

standard care.

This present research effort was made to discover what updates on the treatment of hypertension using acupuncture and/or herbs could be found using similar search terms in the PubMed database and this time only 27 references were returned. Again, the results were both prosaic and interesting for what might be learned about our profession and its relationship with mainstream medicine in terms of the various offerings for helping people with hypertension. Out of the 27 papers found investigating the treatment of hypertension with acupuncture several studies have generated a controversial response cascade which is worth looking into for the sake of analyzing our profession in today's world. One of them is the 2006 study called S*top Hypertension With the Acupuncture Research Program (SHARP)* by Macklin, and another is entitled *Randomized Trial of Acupuncture to Lower Blood Pressure* by Flachskampf from 2007. Macklin states the intention of the *SHARP* study is to be "the first large randomized trial" to study acupuncture treatment of hypertension; they found 192 people to participate. Those people were taken off their antihypertensives before starting treatment and were then randomly assigned to one of three arms: an individualized TCM style acupuncture protocol, a pre-standardized acupuncture protocol, or an invasive sham acupuncture protocol. Each person received 12 acupuncture treatments over six to eight weeks.

Their results found that the average blood pressure decrease from the beginning to the end point blood pressure data collection at 10 weeks did not differ statistically in those randomized to active (the individual or standard) groups versus the sham acupuncture group. They felt that even analyzing the data by age, baseline blood pressure, gender, history of antihypertensive use, obesity, primary TCM diagnosis, or race did not reveal any subgroups where the benefits of "active" acupuncture differed largely from "sham" acupuncture. They conclude: "Active acupuncture provided no greater benefit than invasive sham acupuncture in reducing systolic or diastolic blood pressure."

The Flachskampf study starts off a little more altruistically with the statement of intention to study acupuncture's ability to lower blood pressure because, "hypertension is a prime cause of morbidity and mortality in the general population and pharmacological treatment has limitations resulting from drug side effects, costs, and patient compliance." They found 160 people with essential hypertension who were randomized to 22 sessions of either active acupuncture or sham acupuncture over the six-week study. Unlike the SHARP study where antihypertensives were stopped before joining the study, here 78 percent of the participants continued to take their regular antihypertensive medication. Their primary outcome measures were based on average 24-hour ambulatory blood pressure levels measured immediately after the six week treatment course as well as later at three and six months.

After treatment in the active acupuncture group they report that the average 24-hour ambulatory systolic and diastolic blood pressures decreased significantly by 5.4 mm Hg and 3.0 mm Hg respectively. However, at the three and six month follow-up, both systolic and diastolic blood pressures returned to pretreatment levels in the active treatment group. Flachskampf concludes that: "Acupuncture according to traditional Chinese medicine, but not sham acupuncture, after six weeks of treatment significantly lowered mean 24-hour ambulatory blood pressures; the effect disappeared after cessation of acupuncture treatment."

After those two studies were published a commentary entitled "*Acupuncture for Hypertension: a Tale of Two Trials*" was published in a 2007 edition of Forschende Komplementaemedizin which offered three different viewpoints on the studies: the acupuncturist view was provided by Hugh MacPherson; the perspective of the statistician was provided by Andrew Vickers; and the perspective of the

anthropologist was provided by Volker Scheid, also an acupuncturist. Dr. Scheid provided some interesting commentary on the historical precedents of the Flachskampf claim that TCM can treat hypertension based on "thousands of years of experience with it," showing that statement as problematic since HBP is a modern symptom found only with modern allopathic equipment; it's well worth the time spent to read it.

However, rather than going through each of the commentators arguments point by point for the sake of expediency it's simpler to introduce the piece as suggested reading and to summarize that essentially each of the commentators addressed the areas of strength or the specific problems presented by the two individual studies in accordance to their particular viewpoint. Overall each of the comments were generally supportive of the use and ability of the RCT to investigate acupuncture; and none of them appeared too upset that both of the studies found that outcomes weren't much different between the so-called "sham" and "verum" arms or with the fact that BP returned to higher levels after the termination of treatment protocols.

In 2006, after the SHARP study results were published an op-ed letter was written to Hypertension entitled, *Acupuncture for Hypertension: can 2500 Years Come to an End?* by Dr. Norman M. Kaplan, a well-respected hypertension expert in the allopathic community. In it he presents his request for TCM researchers to end all future investigation of acupuncture for hypertension. He based that request upon the self-admitted failure of the SHARP study to produce significant outcomes in lowering blood pressure with acupuncture when compared to "sham" needling and used the conclusion from the study, the "author's own words" against them as the cause for his request that, "all acupuncture research on hypertension come to an end . . . ."

The money and effort expended in this trial should save even more wasted money and ineffectual effort. Acupuncture is receiving a number of proofs of inadequacy, but it may turn out that science cannot trump 2,500 years of Asian tradition.

In July of 2010 I sent a letter-length email to both Hypertension and Dr. Kaplan, pointing out the "unscientific" and low quality nature of his piece due to its basis in the flawed logic of using one single study alone to derive his conclusions; for being generally "unfriendly" to another medicine trying to offer help with a difficult problem; for his basic lack of qualification to comment professionally on acupuncture research; and the misuse of a citation in the Kaplan letter. The email concluded by asking for a public retraction from both of them. A few weeks later the editors of Hypertension declined the offer by saying, "it's an opinion letter from a 'thought leader' which was published nearly four years ago . . . . Thanks for your interest in Hypertension." Another few weeks after that Dr Kaplan replied to the forwarded email from the journal editor saying, "Dr Hall's comment seems satisfactory to settle the issue."

After sending the comments to Kaplan in 2010, further research continued on the trail of articles that had followed the earlier high blood pressure trials and that search found that Dr. Howard H. Moffet, working for Kaiser Permanente's Division of Research, had sent his own response letter to Kaplan's conclusions and it was published in Hypertension in a 2007 Letter to the Editor entitled, "*Hasty Conclusion About Acupuncture for Hypertension?.*" He states that the major problem of the Macklin study was a lack of internal validity due to a lack of variation between treatment arms.

It is unreasonable to expect differences in outcomes if there are no differences among the intervention arms. Each intervention arm used "corporeal acupuncture" (i.e., needles puncturing the body), and

there was no physiological hypothesis to explain how the different maneuvers could have different effects.

Hypertension also carried a brief Kaplan reply to Moffet entitled, "*Response to Hasty Conclusion about Acupuncture for Hypertension*" stating his agreement with Moffet's assertion that there might be effects from acupuncture beyond the lack of effect on blood pressure, again citing the Macklin study as the final "proof" that it doesn't reduce blood pressure any more than placebo. He repeats his belief that even if acupuncture "has a small effect on blood pressure the time and expense to continue treatment render it ineffective . . . ." Finally he states that, "lifestyle changes and drugs remain the only 'proven' therapies and they shouldn't be ignored in pursuing such an 'ineffectual alternative.'" Thus the insights into our medicine from Dr Kaplan end; but his "professional" comments live on in the Pubmed database.

Discussion

In the investigation on the topic of TCM treatments for high blood pressure, this data was discovered that shined a light on the issues produced by the fascination within our medicine for following allopathic medicine as our guiding model and then using, as they do, the RCT for the "proof" that our methods "work." The response(s) of Kaplan to one such effort raises the question of whether we should blithely pursue the RCT as the best standard to support our medicine as has been the push from a large part of the leadership and education within our field? That is, in using the type of data found "robust" in the RCT, i.e., when we adhere to the biochemical reductionist theories used in allopathic RCTs, are we falling prey to a more narrow view of what constitutes holistic health in our medicine? Indeed that is an interesting question, and in looking at the answer perhaps we may have to adjust, in terms of how we see our professional identity and how we can best investigate our medicine.

Professionally, we have the problem of using a classical medicine system in a time dominated by data and the use of data to provide evidence of veracity. Additionally, we have powerful commercial interests that are well versed in creating data streams that show support for their product, and these interests have merged into or are so close to allopathic medicine such that using that data (rather than using the Heart/Shen as we are prescribed to do by the Nei Jing) has even become accepted as medicine itself. That is, the data is used for what could be termed its "placebo" effect on a person's condition, as the treatment--it could be as simple as "our research shows you have a 77 percent chance of recovery if you take this medication." The word "medication" is selected rather than "drug" to enhance the placebo effect.

This situation of practicing "data as medicine" where the problems of using so-called scientific research that has been directed and funded by drug companies with the patently obvious influence of these financial incentives on outcomes, but still accepting that as the "proven" basis for it's inclusion as medicine, has been recognized within the allopathic community. Yet the systemic dysfunction due to the commingling of those influences upon what is considered "medicine" within that community has not only failed to be overcome by them, but its medical model has been adopted by our community in our pursuit of "integration" stemming from our desire to be seen as "medical." Along with that goes the attention for using "evidence based" methods chosen primarily for expediency, perhaps without giving too much understanding to the kind of influences that can enter into making those decisions about what constitutes "evidence"--let alone how all of that effects the very basis of our medicine and its practice. But, in trying to avoid the problem that issues from our thousands of years of empirical evidence being rendered "insubstantial" by the "evidenced based medical" line of thought due to its

being considered "anecdotal" in basis and therefore, providing "no proof" to substantiate the profession--how far is too far--for "evidence"? Then, if we don't use the RCT by what method do we find the ground that we as a profession can agree to stand on, irrespective of how we are perceived by allopathic practitioners or perhaps more importantly, the payor system?

Historically, Oriental Medicine was the only option of its day and so it developed treatments for many serious, life-threatening diseases. Now, in the modern era it may be more expedient to use drugs to save lives. However in the many chronic cases where the combinations of lifestyle and health intersect, for example to get long term benefit for high blood pressure the choice in most cases does require, as even Kaplan acknowledges, more than just "the right medication(s)." Many times in my work as a clinical supervisor in Los Angeles I see people taking the anti-hypertensive drugs, but their blood pressure is still high. Would we assume that that high blood pressure is "better" because "at least they are taking the 'right drugs'"--but how is it really different for that person if we go strictly by the numbers (as Kaplan claims he does) and their blood pressure is still reading high? If we only go by the numbers in our life, the allopathics also have to answer that question, admit that they don't have the only viable solution, and then be more willing to refer serious and difficult cases over to our medicine for our systemic treatment methods.

If we as professionals of a free standing and independent medicine truly believe the TCM theorem that acupuncture/herbs provide systemic homeostasis, then we should not be routinely referring chronic hypertension cases out for treatment by allopathic's emergency medicine approaches. In accepting the idea that we should automatically refer hypertension cases out because of some vague notions that our medicine will de facto increase blood pressure that amounts to a catch-22 for our profession. It is potentially another example of echoing some programming from our allopathic brethern that we should be "complementary" care to them and infers that we have nothing serious to offer for significant medical conditions. Certainly there may be cases where emergency medicine approaches may be appropriate, but having personally seen very positive results from using our methods to treat some rather extreme blood pressure readings, it is my opinion that we should not automatically be deferring to allopathic medicine for essential hypertension. If in fact better results can be obtained from within our own medicine we can apply TCM scientific method and proceed according to individual findings. If we routinely refer out we all lose the chance to help someone with a serious condition, we prematurely devalue the medicine "in house" and that perpetuates the professional low self-esteem we develop, or adopt, when we accept allopathic as the sole "gatekeeper" of "evidence based" medicine. But in review of our major TCM source books, and in review of PubMed searches for acupuncture treatment for hypertension, treatment for hypertension is included. If hypertension is rather a chronic, systemic disorder from the point of view of both medical systems, then it is one for which our medicine is quite adequately designed to provide "care" in the same manner that allopathic provides care without guarantee of cure.

As a profession we need to move forward, with or even ahead of the times. Can we do that without providing evidence against ourselves to those who see their best function as our interlocutor? In review of our efforts to study our own medicine using the tool of the RCT to show how well we are integrating, Kaplan has instead used our desire for professional association as a weapon against us. He uses our self-provided "evidence" as his final proof, and then unscientifically not accepting the arguments from Moffet to help adjust his opinions, he persists in espousing his line of thinking that acupuncture is "ineffectual"-- "because we said so." How can we "integrate" with that kind of "science"? And what does it say about us that we want to? As far as the diffident Dr. Kaplan is concerned, on the topic of integration he provides ample insights for us into the "evidenced based"

mentality; if we look there for professional association it's like extending the glad hand of friendship to Pontius Pilate, yet hoping for a new outcome.

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