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EFEITOS IMEDIATOS DA ACUPUNTURA MANUAL SOBRE A FUNÇÃO MUSCULAR DO BÍCEPS BRAQUIAL DE INDIVÍDUOS SAUDÁVEIS E HEMIPARÉTICOS ESPÁSTICOS CRÔNICOS

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Ana Paula de Sousa Fragoso. **Efeitos imediatos da acupuntura manual sobre a função muscular do bíceps braquial de indivíduos saudáveis e hemiparéticos espásticos crônicos.** Dissertação de Mestrado em Ciências da Reabilitação. Rio de Janeiro, 2011.

Resumo

Introdução: Este estudo segue as recomendações dos organismos internacionais para pesquisas clínicas com acupuntura (STRICTA e CONSORT), tendo como referência, autores antigos, modernos e contemporâneos da Medicina Chinesa, para lançar um olhar mais atento sobre sua seqüela motora mais grave e prevalente do AVC: A hemiparesia espástica crônica do membro superior, com a finalidade de avaliar os efeitos imediatos da estimulação manual de acupontos sobre a função muscular (atividade elétrica e força) do bíceps braquial de indivíduos saudáveis e pacientes, através de uma visão ampla e histórica de sua fisiopatologia e tratamento: **Métodos:** Este ensaio clínico, randomizado, cego com 4 grupos paralelos teve como ponto de partida uma revisão sobre as questões metodológicas e bioéticas inerentes às pesquisas com acupuntura em seres humanos, seguido de um aprofundamento teórico médico oriental e ocidental sobre a etiopatogênia e fisiopatologia do AVC. A prescrição dos acupontos utilizados nas intervenções nos grupos de aagulhamento local (sobre o bíceps – CS2) e tradicional para hemiparesia (IG11) foi guiada por um levantamento estatístico de distribuição e de frequencia temporal de descrição na literatura. Antes de sua execução, o protocolo eleito para o ensaio, teve sua metodologia detalhada e publicada em um artigo à parte. **Resultados:** As questões metodológicas e éticas levantadas por estudos clínicos com acupuntura apontam incongruências que vão desde a eleição da intervenção, aos métodos de avaliação e suas variáveis, bem como a ausência de critérios de randomização e controle e o uso de procedimentos placebo questionáveis. No que tange a etiopatogenia da hemiparesia, observamos que as causas atribuídas ao AVC e suas sequelas não diferem significativamente desde os relatos clássicos chineses até os dias de hoje, e que os padrões sindrômicos achados com maior frequencia na população de hemiplégicos foram o de Fogo e Fleuma. Os meridianos dos sistemas Yangs dos membros são os estimulados com maior frequencia e o IG4 o ponto mais citado entre os 85 autores pré-modernos e modernos. Por fim, observamos que a acupuntura manual (IG11 e CS2) promove uma estimulação neuromuscular suficiente para gerar significativa redução do sinal de recrutamento eletromiográfico de unidades motoras do bíceps em indivíduos sadios, mas o mesmo não aconteceu nos voluntários portadores de hemiparesia espástica crônica. **Conclusões:** Muito embora não haja nenhuma explicação fisiológica conclusiva para os resultados neuromusculares observados ao EMGs, este estudo propõe um modelo mais claro, que pormenoriza os mecanismos e estruturas da conhecida teoria reflexa medular, proposta anteriormente para os mesmo achados em adultos saudáveis, que é ao mesmo tempo compatível com as mudanças adaptativas descritas na fisiologia muscular de hemiparéticos e não deixa de considerar a técnica acupuntural.

Descritores: Hemiparesia Espástica – Acupuntura Clássica – Eletromiografia de Superfície.

Ana Paula de Sousa Fragoso. **Immediate effects of manual acupuncture on biceps brachii muscle function of healthy subjects and patients with chronic spastic hemiparesy.** Dissertation for the Master in Rehabilitation Science. Rio de Janeiro, 2011.

Abstract

Introduction: A large number of studies have focused on important functional and neuropsychological outcomes involving various acupuncture interventions in hemiparetic stroke victim. The lack of success in the production of evidence, not just the results and hypotheses, which mostly comes from badly formulated questions, theoretical framework superficial, disjointed study designs or serious failures of implementation and interpretation. This study follows the recommendations of international organizations in clinical trials on acupuncture (STRICTA and CONSORT), by reference, authors, ancient, modern and contemporary Chinese medicine, in order to assess the immediate effects of manual stimulation of acupoints on the muscle function (electrical activity and strength) of the brachial biceps of healthy individuals and patients. **Methods:** This clinical trial, randomized, single-blinded, with 4-parallel groups was conceived, designed and executed over two years, taking as a starting point a review about the methodological issues and bioethical concerns inherent in acupuncture research in humans, followed by a deepening medical theorist on Eastern and Western pathophysiology of stroke. The prescription of acupoints classical acupuncture for interventions with hemiparesis was guided by a statistical distribution and temporal frequency of use. And even before his execution had his detailed methodology and published in a separate article. **Results:** Methodological and ethical issues raised by clinical studies with acupuncture point incongruities ranging from the election of the intervention, the valuation methods and their variables, as well as the lack of randomization and control criteria and the use of placebo questionable procedures. Regarding the etiopathology hemiparesis, we observe that the causes attributed to AVC and their sequel do not differ significantly from the Chinese classic reports until the present day, and that patterns findings in the population of patients were the Fire Heat and Phlegm. The meridians of yang systems of limbs are stimulated with greater frequency, and the IG4 point most cited among modern and pre-modern authors. Finally, we note that acupuncture manual (LI11 and PC2) promotes a neuromuscular stimulation sufficient to generate significant reduction of motor units recruitment of biceps in individuals, but the same didn't happen in chronic spastic hemiparesis volunteers. **Conclusions:** Currently, there is no physiologic explanation for the observed neuromuscular parameters. Previous studies reported a “reflex loop” but without clear explanations on physiologic mechanisms and structures enrolled. Based on the current results and along with consideration on the sEMG signal characteristics and neurophysiology, a theoretical model was proposed for explanation of the results observed in healthy subjects that is compatible to the adaptive changes observed in post-stroke subjects and considers acupuncture technique.

Keywords: Spastic hemiparesis – Classical Acupuncture – Surface Electromyography.

Sumário

Introdução

1.1 Justificativa

Em 2004, dos 17 milhões de óbitos atribuídos a Doenças Cardiovasculares (DCV) no mundo, seis milhões foram causados por Acidentes Vasculares Cerebrais (AVC). Dados da Organização Mundial de Saúde (OMS) estimam que, em 2030, o número de mortes relacionadas às DCV alcance 24 milhões (OMS, 2004). Estudos têm relatado alta incidência de AVC em indivíduos jovens nos países em desenvolvimento. No Brasil, estima-se que 10,6% dos AVCs isquêmicos afetam indivíduos cada vez mais jovens, com idade entre 15-40 anos (CONFORTO, 2006; OMS, 2009). Apesar dos avanços substanciais no tratamento de suas vítimas, mais de 70% de todos os AVCs que ocorrem a cada ano são de primeira ocorrência, fato que corrobora a imensa importância das estratégias de prevenção e gestão dos fatores de risco gerais e vasculares específicos. Entretanto, uma vez ocorrido o AVC, são necessárias estratégias para minimizar o tempo de recuperação de sequelas parciais e maximizar o ganho das funções perdidas (GOLDSTEIN et al., 2006; RUNDEK e SACCO, 2008).

Os déficits funcionais em pacientes acometidos de sequelas crônicas e graves de AVC tem sido alvo contínuo de estudos e foram ao longo do tempo, tendo suas causas e abordagens de tratamento modificadas e atualizadas. No que tange ao membro superior, acreditava-se que a hiperatividade do bíceps (antagonista para extensão de cotovelo) bloqueava o movimento disponível gerado pelo tríceps (agonista para extensão de cotovelo), gerando a argumentação das terapias cujo foco era a inibição do tônus do bíceps. Mais tarde, verificou-se que esses déficits se deviam ao recrutamento inadequado e ao desequilíbrio de força do agonista, gerado pelo acoplamento anormal entre o neurônio motor com os grupos específicos impedindo a retroalimentação necessária à estabilização do cotovelo. Atualmente, as intervenções de reabilitação dos membros superiores estão voltadas para a ativação do agonista do movimento e no aumento da coordenação dos músculos envolvidos na obtenção da tarefa para qual o paciente está sendo treinado (BARKER et al., 2009).

O conhecimento limitado sobre os efeitos da acupuntura sobre a atividade elétrica do músculo bíceps especificamente, se encontra justificado pela sua influência direta na limitação funcional e na gravidade das sequelas e incapacidades decorrentes do AVC. Ratificando a responsabilidade da comunidade científica de prover e atualizar o conhecimento

envolvido no diagnóstico, prognóstico e tratamento em todas as dimensões da saúde dos sobreviventes.

1.2 Intervenção no Acidente Vascular Cerebral pela Medicina Chinesa

Medicina chinesa é a denominação usualmente dada ao conjunto de práticas de medicina tradicional (técnicas e teorias médicas desenvolvidas antes do que se classifica como medicina moderna), em uso na China desenvolvidas ao longo dos milhares de anos de sua história. Segundo a MC o homem é composto de matéria e energia (substância imaterial constituída de exatas proporções de forças iguais e opostas "Yin e Yang"), sofre influência do meio externo e de fatores inatos e adquiridos. A sua saúde depende da manutenção do equilíbrio entre essas forças e do fluxo suave e seguro do Qi (componente energético) através da rede de canais, que representam e nutrem funções, órgãos e vísceras. Ao longo desses canais situam-se em localizações precisas, pontos onde essa energia pode ser manipulada através de finas agulhas de metal, técnica da MC conhecida como Acupuntura Clássica (AC) (WEN, 2006)

A alta demanda por métodos de tratamento e prevenção de menor complexidade e custo para doenças se somou ao aval, mesmo que parcial, de organismos internacionais de saúde, levando à disseminação a Medicina Chinesa (MC) e à inclusão da acupuntura no arsenal de recursos terapêuticos no Ocidente. No Brasil, o acesso gratuito da população às técnicas da MC foi possível pela implantação de uma Política Nacional de Práticas Integrativas e Complementares, criada em 2006, que através da portaria de nº 971, o Ministério da Saúde recomendou ações e a criação de serviços destinados à prevenção de agravos na saúde, à promoção e à recuperação, além de propor o cuidado continuado, humanizado e integral na saúde, com ênfase na atenção básica. Em 2004, antes da criação da política, o MS mapeou 230 municípios brasileiros e em 2008, pelo menos 1.340 cidades ofereciam alguma prática integrativa e complementar no Sistema Único de Saúde (MINISTÉRIO DA SAÚDE, 2010). Entretanto, a contrapartida da comunidade científica brasileira parece não ter correspondido ao interesse crescente da população e das iniciativas do governo brasileiro em prol das terapias complementares e integrativas propostas pela MC. Dados do Sistema Nacional de Ética em Pesquisa mostram que o número total de projetos de pesquisa em acupuntura aprovados pelo Conselho Nacional de Ética em Pesquisa tiveram

representatividade de 0.16% em 2008 nos estados de maior concentração de programas de pós-graduação *stricto sensu* em saúde (SP, RJ, RS, MG, PN) (GEOCAPES; SISNEP, 2010).

O AVC é considerado como uma entidade clínica na MC há pelo menos 2.000 anos e suas sequelas motoras, cognitivas e sensoriais são relatadas desde então. Através de sua própria teoria, os casos são diagnosticados com métodos tradicionais de exame e tratados por meio de recursos tais como acupuntura e fitoterapia (MACIOCIA, 1996). A possibilidade de investigação científica do diagnóstico e intervenção terapêutica da MC com instrumentos de medida fidedigna das funções humanas vem motivando pesquisadores a investigarem sua eficácia no tratamento dos déficits funcionais do AVC. Porém, a maioria dos ensaios clínicos de acupuntura controlados em indivíduos pós-AVC, realizados nesta década e na anterior, não conseguiu obter resultados significantes no aspecto funcional, levantando a questão sobre se a acupuntura tem de fato ação sobre a fisiologia neuromuscular (PARK, 2001; SZE et al., 2002; SZE et al., 2002b).

1.3 Avaliação dos efeitos da acupuntura sobre a atividade motora por meio da eletromiografia de superfície

A eletromiografia de superfície (EMGs) permite avaliar o grau e a duração da atividade muscular, a ocorrência de fadiga, a alteração da composição das Unidades Motoras (UM) resultante de programas de treinamento muscular, assim como as estratégias neurais de recrutamento. Dentre os parâmetros de quantificação da EMGs no domínio do tempo, a Raiz Quadrática Média (*Root Mean Square*, RMS) tem sido o mais utilizado nas pesquisas referentes à função neuromuscular por melhor refletir a relação entre a tensão muscular e o eletromiograma correspondente (FERREIRA et al., 2010). Entretanto, os poucos estudos conduzidos pra observar o efeito da acupuntura por meio da EMGs tem mostrado resultados contraditórios.

A atividade mioelétrica da estimulação de agulhas de acupuntura foi estudada em 17 homens saudáveis submetidos a testes de força e resistência de músculos da mão e perna não dominante, através do sinal de EMGs gravado simultaneamente a exercícios isométricos e isocinéticos no Cybex II. Os resultados não indicaram diferença significativa no desempenho do exercício. No entanto, havia uma diferença significativa nas respostas de EMG durante a flexão máxima do joelho em que o músculo foi estimulado e na resistência de flexão do joelho no músculo não estimulado ($p = 0,04$ e $0,05$) respectivamente, em repetidas medidas

ANOVA). Nenhuma diferença significativa foi observada no eletromiograma durante o máximo aperto de mão após a estimulação acupuntural. (TOMA et al., 1998).

Touch (2006) conduziu um estudo com 30 voluntários saudáveis com idades variando entre 18 a 70 anos, aleatoriamente divididos em 3 grupos: G1: estimulação com 20 minutos de DeQi nos pontos DC-4 (Hegu) e DC-10 (Shousanli), G2 de DeQi falsos ou inadequadas no PC-3 (Quze) e PC6 (Neiguan) e G3 sem estimulação (controle); com o objetivo de analisar os efeitos imediatos da acupuntura em atividade EMG dos músculos dos extensores de pulso comum. Os resultados mostraram que o procedimento de EMG foi altamente confiável, com coeficiente de correlação intraclasse de 0.9996 e um erro-padrão de medição de 0,014 mV. Quarenta e cinco pacientes com AVC e 40 indivíduos saudáveis participaram do estudo de Lukács et al. (2008), que avaliou a ocorrência de perda seletiva de recrutamento das unidades motoras (UM) de alto e baixo limiar no pós-AVC. Os sinais do músculo abdutor digiti minimi foram registrados em dois níveis de força de saída (alto e baixo) no macro-EMG e apontaram uma perda seletiva funcional das grandes UM de alto limiar, fornecendo uma visão mais aprofundada da fisiopatologia do déficit motor após um AVC.

Os efeitos mioelétricos de 20 minutos de estimulação manual de dois acupontos selecionados segundo a localização (sobre o tibial anterior) e a sua ação de acordo com a MC foram avaliados em dois grupos de 15 indivíduos sadios cada. O primeiro, *Zusanli* (E36) encontra-se sobre a porção proximal do músculo tibial anterior e o *Yinlingquan* (BP9), reconhecido pela sua ação terapêutica sobre o membro inferior, situado sobre a face medial do joelho (COSTA e ARAÚJO, 2008). Os efeitos da estimulação manual de ambos os acupontos foram avaliados por meio da EMGs e um transdutor de força (conectado ao pé dominante, em ligeira planti-flexão) durante o repouso e a dorsiflexão isométrica, antes e depois da estimulação. Uma redução significativa nos valores de RMS foi observada em ambos E36 (t=-3,80, P=0,001) e BP9 (t=6,24, P=0,001) nos grupos após a acupuntura. Apesar da diferença significativa de atividade elétrica nos dois grupos, houve diminuição na força apenas após estimulação do E36 (t=-2,98, p=0,006). Os valores de RMS não tiveram uma diferença significativa no pós-tratamento entre o E36 e o BP9 (t=0,36; p=0,71), mas houve uma diminuição significativa da força após acupuntura no grupo E36 (t=2,51; p=0,01). Os autores explicaram os efeitos observados como decorrentes de uma alça reflexa local para relaxamento muscular pós-estimulação.

Moncayo & Moncayo (2009) verificaram as alterações mioelétricas com EMGs, antes e após a utilização de testes de cinesiologia aplicada manual, cujos músculos se relacionavam com meridianos de acupuntura. As técnicas de tonificação e inibição do tônus muscular e a

eleição de acupontos foram definidas de acordo com teoria da AK (Applied Kinesiology**)** e da MC. Os dados sEMG mostraram uma diminuição da intensidade de sinal quando o procedimento de sedação foi usado. No entanto essas alterações, não foram corrigidas por técnicas de tonificação dos acupontos.

1.4 Hipóteses

1. O eixo ético-metodológico atual das pesquisas em MC não acompanha as diretrizes internacionais para realização de ensaios clínicos com intervenção por acupuntura em indivíduos com sequela sensoriomotora de AVC;
2. A frequência de indicação dos acupontos para tratamento de sequelas sensoriomotoras é diferente quando comparados os autores pré-modernos (livros clássicos) e os autores modernos (literatura científica);
3. Acupuntura manual não promove estímulos neuromusculares para alterar imediatamente o recrutamento das unidades motoras e consequentemente a força muscular tanto em indivíduos sadios quanto em pacientes hemiparéticos crônicos, quando avaliados por meio da EMGs
4. A distribuição dos padrões identificados de acordo com a teoria da MC é diferente entre indivíduos sadios e pacientes hemiparéticos crônicos.

1.5 Objetivo geral

Avaliar os efeitos imediatos da estimulação manual de acupontos sobre a função muscular (atividade elétrica e força) do bíceps braquial de indivíduos saudáveis e pacientes hemiparéticos espásticos crônicos.

1.6 Objetivos específicos

1. Revisar as diretrizes e os ensaios clínicos com intervenção por acupuntura em indivíduos com sequela sensoriomotora de AVC para determinar o eixo ético-metodológico adequado para um estudo clínico;
2. Revisar a fisiopatologia do AVC segundo a MC;

3. Descrever a frequência de indicação dos acupontos para sequelas sensório-motoras a partir da literatura de MC moderna e pré-modernae comparar as prescrições entre os autores dessas épocas
4. Propor um desenho de estudo para avaliar os efeitos imediatos da estimulação de acupontos em indivíduos sadios e pacientes hemiparéticos crônico, por meio da EMGs;
5. Verificar os efeitos imediatos da estimulação de acupontos em indivíduos sadios e pacientes hemiparéticos crônicos, por meio da EMGs e avaliar a distribuição dos padrões identificados.

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ENSAIOS CLÍNICOS COM ACUPUNTURA: QUESTÕES BIOÉTICAS E METODOLÓGICAS

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RESUMO

A alta demanda por evidências científicas sobre a efetividade e os mecanismos de ação da acupuntura tem motivado pesquisadores de todo o mundo a realizar ensaios clínicos controlados, aplicando protocolos de técnicas da Medicina Tradicional Chinesa e suas variantes, em grupos de portadores de disfunções e patologias de diversos sistemas corporais. Os resultados dos principais estudos da última década, revelam inconsistências que não são compatíveis com a prática terapêutica segura. Um olhar mais atento, como o proposto por este estudo, aponta para questões muito mais abrangentes, detecta e descreve as falhas metodológicas que permeiam os ensaios clínicos em suas diferentes etapas, revela os equívocos na concepção que ferem a ética das pesquisas com seres humanos, e por fim recomenda medidas para minimizar a ocorrência de tais erros.

Palavras chave: Ensaios Clínicos, Acupuntura, Bioética, Metodologia Científica

ABSTRACT

The high demand for scientific evidence on the effectiveness and mechanisms of action of acupuncture has motivated researchers around the world to conduct clinical trials, protocols applying techniques of traditional Chinese medicine and its variants in groups of patients with disorders and diseases of various body systems. The results of studies examining the last decade, reveals inconsistencies that are not compatible with the therapeutic practice safely. A closer look, as proposed by this study points to much broader issues, detects and describes the methodological flaws that permeate clinical trials at various stages in the design reveals the mistakes that hurt the ethics of human research, and finally recommend steps to minimize the occurrence of such errors.

Keywords: Clinical Trials, Acupuncture, Bioethics, Scientific Methodology

1. Introdução

A MTC (Medicina Tradicional chinesa) e suas práticas estão inseridas em contextos filosóficos e teorias naturalistas (Yin e Yang, cinco elementos etc.), que ressaltam a confiabilidade do comum e consciência sensorial humana, noções pré-científicas que costumam ser rejeitadas por muitos acupunturistas. Tal rejeição, somada aos desafios metodológicos intrínsecos à investigação clínica científica da acupuntura, tem repercutido na comprovação de seus efeitos e conseqüentemente na confiabilidade de sua indicação. (Kaptchuk, 2002)

Muitos ensaios clínicos se destinaram a elucidar os mecanismos de ação ou a levantar hipóteses plausíveis para as ações terapêuticas da acupuntura nos últimos 30 anos. Análises sistemáticas subseqüentes buscaram evidências, compilando os achados de intervenções testadas no tratamento de um amplo espectro de condições médicas.

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Mayer (2000) relatou os resultados positivos obtidos pela acupuntura no alívio de náuseas e vômitos pós-operatórios ou induzidos pela quimioterapia e revelou as bases fracas que apoiavam o seu uso na remissão da dor de cabeça, dor lombar, dependência de álcool e paralisia resultante de acidente vascular cerebral. O autor encorajou os pesquisadores a conceber ensaios controlados duplo-cegos, com protocolos de tratamento adequados à hipótese que está sendo testada e amostras de tamanho suficiente para embasá-la. Pois, segundo ele, a ausência de evidência da ação da acupuntura na maioria destas condições, não é evidência de sua ausência.

Nahin e Straus (2001), diretores do Centro Nacional para Medicina Complementar e Alternativa (NCCAM), principal agência de investigação científica do Governo Federal Americano para produtos médicos e práticas terapêuticas não convencionais, como a acupuntura, divulgaram os principais problemas da pesquisa nesta área. Dentre os listados, destacam-se: As graves falhas metodológicas dos primeiros ensaios clínicos, as dificuldades impostas pela utilização de um conjunto de terapias e a individualização do tratamento, os problemas encontrados para acumular, randomizar e reter os pacientes no ensaio, e ainda, a falta de identificação de intervenções placebo adequadas.

No mesmo ano, um grupo internacional de pesquisadores em acupuntura se encontrou para discutir a concepção dos ensaios clínicos e elaborou um conjunto de recomendações para melhorar a qualidade dos relatórios das intervenções em paralelo, com o objetivo de facilitar e melhorar as condições de avaliação crítica, análise e replicação. Estas recomendações (Tabela 1) foram designadas *Standards for Reporting Interventions in Controlled Trials of Acupuncture* (STRICTA) e foram concebidas para serem usadas como extensão do *checklist* do item de intervenção da declaração CONSORT *(Consolidated Standards for Reporting of Trials).* (MacPherson, 2002)

Tabela 1: Recomendações STRICTA

Item de intervenção	**Explanação**
Lógica da Acupuntura	Declaração sobre o estilo e abordagem de acupuntura utilizada (Ocidental ou Oriental). Razões explícitas para o tratamento de escolha, incluindo o diagnóstico, seleção de ponto, e os procedimentos de tratamento e suas variáveis, caso existam.
Detalhes do agulhamento	Localização específica dos pontos, número, duração e profundidade das inserções, respostas pretendidas do agulhamento, técnicas de estimulação e descrição completa da agulha utilizada.
Regime de Tratamento	Número de sessões, freqüência de tratamento e variações.
Co-intervenções	Técnicas auxiliares e de auto tratamento prescritos, consultorias de qualidade de vida, orientais ou ocidentais etc.
Pano de fundo do acupunturista	Duração da formação, tempo de experiência clínica e os detalhes da perícia em tratar a condição específica a ser avaliada, assim como qualquer outra experiência que pode ser relevante para o julgamento.
Controle da intervenção	A escolha do controle e seu efeito pretendido deverão ser apresentados e justificados em relação à questão da investigação e da metodologia. E incluir uma descrição precisa da intervenção do próprio controle, incluindo detalhes do agulhamento e seu regime caso sejam diferentes dos utilizados no grupo da acupuntura.

A confiabilidade dos ensaios clínicos foi levada em consideração, quando em 2003, a OMS (Organização Mundial da Saúde) publicou um relatório classificando as doenças ou afecções para as quais a acupuntura foi testada de forma controlada, ordenando-as em quatro grupos, segundo o rigor científico e a credibilidade dos resultados:

- Grupo1: Doenças ou sintomas para as quais o tratamento com acupuntura é considerado eficaz por sido provado através de ensaios controlados.
- Grupo 2: Doenças, sintomas ou condições para que o efeito terapêutico da acupuntura tem sido demonstrado, mas que precisam de mais provas e evidências.

- Grupo 3: Doenças ou sintomas para as quais há somente estudos controlados individuais relatando alguns efeitos terapêuticos, mas para as quais a acupuntura é a uma alternativa porque o tratamento convencional é difícil.
- Grupo 4: Doenças ou sintomas para as quais a acupuntura pode ser usada desde que o praticante esteja sob supervisão médica e o paciente seja monitorado por equipamento moderno e adequado.

A alta demanda por métodos de tratamento e prevenção de doenças de menor complexidade e custo se somou ao aval (mesmo que parcial) de organismos internacionais de saúde, levando à disseminação da MTC (Medicina Tradicional Chinesa) e a inclusão da acupuntura no arsenal de recursos terapêuticos no ocidente.

No Brasil o acesso gratuito da população a técnicas não convencionais de medicina pelo SUS (Sistema Único de Saúde) cresce de forma surpreendente. Tal incremento foi possível pela implantação de uma Política Nacional de Práticas Integrativas e Complementares (PNPIC), criada em 2006. Através da portaria de nº. 971, o Ministério da Saúde (MS) recomendou ações e a criação de serviços destinados à prevenção de agravos na saúde, a promoção e a recuperação, além de propor o cuidado continuado, humanizado e integral na saúde, com ênfase na atenção básica.

Com a política, os brasileiros têm acolhimento gratuito nas áreas de Medicina Tradicional Chinesa/Acupuntura, Homeopatia, Plantas Medicinais e Fitoterapia. Eles são atendidos, principalmente, nas Unidades Básicas de Saúde e nos Núcleos de Apoio à Família (NASFs), além de hospitais. Em 2004, antes da criação da política, o MS mapeou 230 municípios brasileiros que realizavam alguma prática. Em 2008, pelo menos 1.340 cidades oferecem alguma prática integrativa e complementar no SUS.

Em 2007, foram realizados 97.240 procedimentos de acupuntura com a utilização de agulhas e, em 2008, foi 216.616 um crescimento de 122%. O investimento em acupuntura teve incremento de 1.420%, em 2000, foram gastos R$ 278.794,00 enquanto em 2008, o montante aplicado foi de R$ 3.960.120,00. (Fonte: Ministério da Saúde do Brasil)

A contrapartida da comunidade científica brasileira parece não ter correspondido ao interesse crescente da população, e das iniciativas do governo brasileiro em prol das terapias complementares e integrativas propostas pela MTC. Dados do SISNEP (Sistema Nacional de Ética em Pesquisa) mostram que o número total de projetos de pesquisa em acupuntura aprovados pelo CONEP (Conselho Nacional de Ética em Pesquisa) tiveram baixa representatividade em relação ao total dos aprovados em 2008, nos estados de maior concentração de programas de pós graduação PPG (mestrado e doutorado) em saúde segundo o GEOCAPES (Figuras 1, 2 e 3).

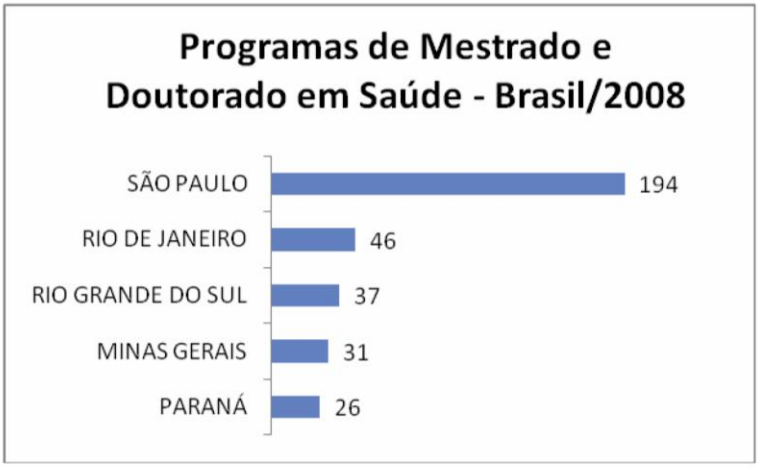

Figura 1: Unidades da federação sedes de 104 a 686 programas de pós-graduação em saúde. Fonte: GEOCAPES - Sistema de dados georreferencial da Coordenação de Aperfeiçoamento de Pessoal de Nível Superior.

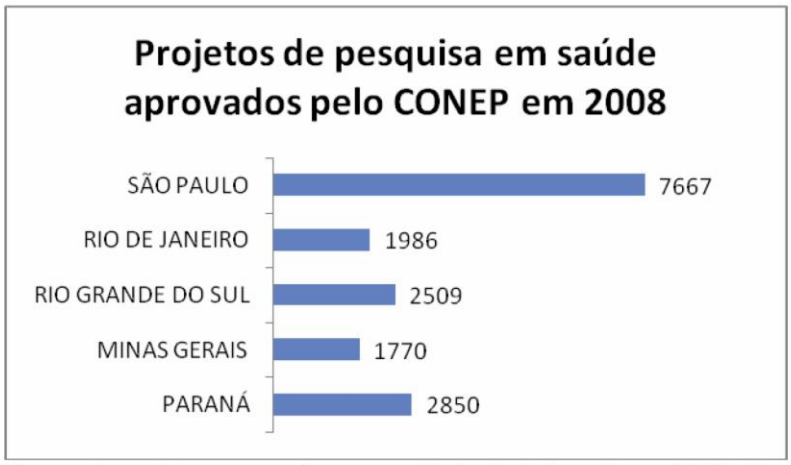

Figura 2: Número de projetos aprovados por unidade da federação em 2008. Fonte SISNEP

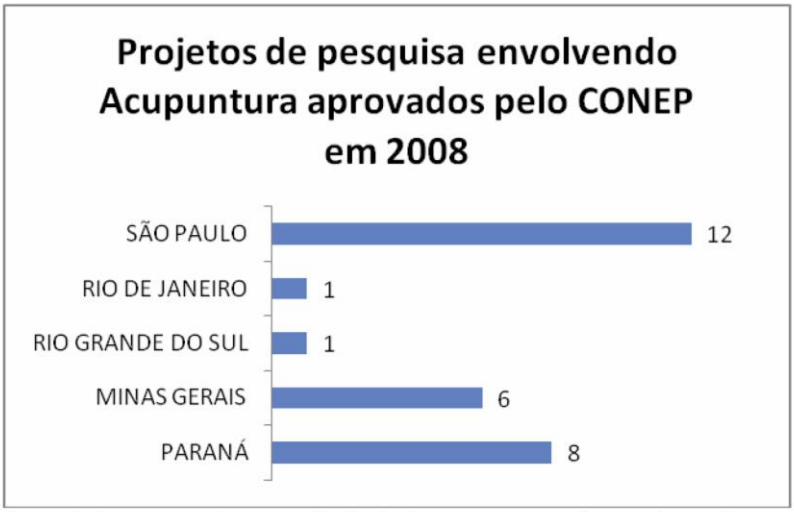

Figura 3: Número de projetos aprovados, resultado de busca com a palavra chave Acupuntura, por unidade federativa em 2008. Fonte SISNEP

Se a procura e a oferta por métodos de tratamento orientais estão aumentando, por que tão poucos estudos estão disponíveis? Uma razão provável é a falta de financiamento para esses estudos por parte do governo, já que o interesse das indústrias pela acupuntura é pequeno. A segunda razão, em parte relacionada à primeira, se deve ao lento desenvolvimento de uma estrutura de investigação competente. E a terceira razão pode estar ancorada na dificuldade da própria concepção dos estudos clínicos, devido ao alto nível de complexidade e heterogeneidade do grupo de intervenções que abrangem a Medicina Tradicional Chinesa. (Linde, 2001)

Considerando o exposto, este estudo objetiva detalhar e discutir as principais questões metodológicas e éticas que envolvem os ensaios clínicos com acupuntura.

2. Metodologia

Em 2008, o grupo de cientistas responsável pela declaração CONSORT, reviu e estendeu as suas recomendações para melhorar a comunicação dos ensaios pragmáticos, devido ao reconhecimento do seu caráter de informativo para a tomada de decisões sobre as práticas terapêuticas. O grupo considerou que multiplicidade e a independência dos elementos constitutivos da concepção dos ensaios pragmáticos existem para garantir que o pragmatismo não é um atributo de todos ou nenhum, e sim que esses elementos devem ser concebidos para contribuir de forma contínua ao longo de várias dimensões. E por tal razão, devem ter seus procedimentos de intervenção descritos com precisão, para que os leitores sejam capazes de avaliar a sua viabilidade. (Zwarenstein *et al*, 2008).

Moffe (2008 e 2009) realizou duas revisões sistemáticas usando como critério de inclusão, os ensaios clínicos controlados de acupuntura publicados em Inglês e indexados no PUBMED nos anos de 2005 e 2006. O primeiro estudo teve o objetivo de avaliar os trabalhos que forneceram explicações científicas para suas intervenções, se seus autores claramente diferenciaram os procedimentos de intervenção dos de controle, e se foram observadas diferenças estatisticamente significantes nos resultados.

Dos 78 ensaios clínicos selecionados, 36 tiveram alguma razão de ser. Vinte e dois estudos comparavam a acupuntura com os cuidados habituais ou outros controles de acupuntura; 82% destes mostraram diferença estatística significante nos resultados, mas não conseguiram controlar os efeitos do placebo. Dezesseis estudos utilizaram controles placebo e 69% desses, apresentaram diferenças significativas nos resultados. Dos 40 estudos que compararam intervenções da acupuntura diferenciadas de acordo com a MTC, 48% apresentaram resultados significativos.

O segundo procurou determinar se a acupuntura *sham* (falsa, farsa) é tão eficaz como a acupuntura verdadeira, considerando no primeiro grupo, as intervenções onde houve a inserção de agulha em não acupontos e ou em acupontos não indicados para o tratamento da condição patológica em questão. A maioria dos estudos (22/38 - 58%) não encontrou nenhuma diferença estatisticamente significativa nos resultados, dentre eles, 13 consideraram que a acupuntura *sham* pode ser tão eficaz quanto à verdadeira, principalmente quando agulhamento superficial foi aplicado em não acupontos. Tais achados colocam em dúvida a validade da MTC no que tange a localização e a indicação dos acupontos.

Em resposta a esses e outros achados conflitantes, em 2009, estudiosos de várias instituições de ensino e pesquisa discutiram em uma mesa redonda da Conferência Norte Americana de Investigação em Medicina Integrativa e Complementar (NARCCIM), os pontos de incoerência encontrados na concepção e nos resultados nos ensaios clínicos dos últimos anos, levantados na Conferência Internacional da Sociedade de Pesquisa em Acupuntura (SAR) que ocorreu em 2007. As principais questões giravam em torno de dois paradoxos: A eficácia da acupuntura sham e a inserção de variáveis capazes de influenciar os resultados dos ensaios clínicos. (Wayne *et al*, 2009).

As causas dos paradoxos supracitados parecem ter origens mais profundas, sérios danos metodológicos na concepção e na lógica dos ensaios, onde a condição patológica a ser submetida ao ensaio é eleita, o tamanho da amostra é calculado e os procedimentos de intervenção, controle e avaliação são estabelecidos. No entanto, o grande problema, que muitos pesquisadores consideram estar ainda por resolver, é a definição de um adequado controle placebo. O uso inadequado de controles placebo tem prejudicado a investigação da acupuntura e levado a má interpretação dos resultados dos ensaios clínicos. (Vincent & Lewith, 1995)

Hammerschlag (1998) afirmou que o maior desafio para os ensaios futuros era a criação de meios capazes de imitar a acupuntura na prática clínica, e de determinar intervenções teste, fundamentadas nas tradições médicas orientais de diagnóstico. O autor contribuiu com a detecção e classificação dos tipos de controle mais comumente usados nos ensaios clínicos de acupuntura:

1) Tipo I - Lista de espera ou nenhum tratamento: A eficácia da acupuntura é avaliada em relação à história natural da doença, mas não para controlar os efeitos do tratamento não-específico.
2) Tipo II - Controles Placebo: Definidos como procedimentos não-invasivos, tais como a estimulação elétrica nervosa transcutânea (TENS) inativa e Laseracupuntura inativa usados para avaliar se a acupuntura tem um efeito além da do meio terapêutico (a inserção da agulha na pele).
3) Tipo III - Controles Sham: Definidos como procedimentos invasivos, mas inadequados, como a inserção de agulhas superficiais, em não acupontos, ou em acupontos não indicados para a condição em questão. Avalia se a eficácia da acupuntura depende do estilo e do local da inserção.
4) Tipo IV – Tratamento ocidental padrão: Compara os efeitos da acupuntura com medicamentos e outros procedimentos médicos ou fisioterapia.
5) Tipo V - Compara tratamento padrão associado à acupuntura e sozinho.

Se a acupuntura tem pelo menos algum efeito placebo atribuível aos efeitos psicológicos da administração de uma nova terapia, era de se esperar um número menor de ensaios controlados com placebo para mostrar as diferenças entre os grupos, do que os ensaios sem controle com placebo. Ensaios de acupuntura sem controle com placebo não podem ser cegos e, portanto, alcançam menor pontuação em escalas de qualidade. Dado que as ligações entre a qualidade do estudo e os resultados são confundidas com as questões dos efeitos não-específicos, e tendo em conta que os ensaios com grupos de controle diferentes,

respondem a questões diferentes, as análises para verificar a influência de aspectos de qualidade sobre os resultados só deverão ser realizadas dentro de grupos de estudos controle comparáveis. (Linde, 2001)

Do ponto de vista metodológico, também deve ser considerado que a maioria dos ensaios clínicos de acupuntura tem avaliado a sua eficácia através da administração de um protocolo de tratamento fixado com base no diagnóstico biomédico ocidental. Prática induzida pela globalização da medicina chinesa, que produz múltiplas visões localizadas de um sistema de cura, cuja marca registrada é a heterodoxia, fato que torna impossível distinguir pontos verdadeiros de falsos já que as bases anatômicas, fisiológicas e fisiopatológicas da acupuntura em si são uma construção histórica. (Tao, 2008 e Hammerschlag, 1998).

Devemos ainda considerar que ao projetar um estudo controlado randomizado para a acupuntura, o investigador é confrontado com escolhas relativas à seleção de pontos, a profundidade de inserção da agulha, o tipo de estimulação, a freqüência e programação do tratamento. A menos que essas escolhas sejam feitas com base em um teste de moda, o julgamento estará comprometido. (Nahin & Straus, 2001)

3. Bioética

Miller e Kaptchuk (2007) denunciaram irregularidades no processo de obtenção do consentimento dos participantes de ensaios clínicos randomizados de acupuntura. Nos estudos controlados por placebo ou acupuntura *sham*, ao invés de serem avisados da possibilidade de serem submetidos a uma simulação, são informados de que uma ou mais formas de acupuntura estão sendo comparadas no estudo. Esta prática de divulgação enganosa, além de não possuir uma razão metodológica convincente, viola a exigência ética de obtenção do consentimento informado.

O processo de mascaramento do tratamento é geralmente considerado eticamente aceitável, desde que a ignorância partilhada seja explícita no processo de consentimento. Trabalhos recentes sobre a ética de ensaios com cegagem simples têm enfocado a relação risco-benefício das intervenções invasivas sham. Pois apesar de estarem eticamente fundamentados por uma lógica metodológica, apesar de terem sido revisados e aprovados por um comitê de ética em pesquisa, e ainda, de possuírem o consentimento dos sujeitos da pesquisa, as intervenções falsas costumam causar desconforto moral no clínico-investigador. O mal estar dos pesquisadores pode ser devido ao fato de serem treinados para realizar intervenções invasivas apenas para o benefício dos pacientes, estarem administrando procedimentos falsos e levando ao paciente a criar uma falsa crença de que o procedimento. (Miller & Kaptchuk, 2004)

Em contrapartida, o procedimento sham é uma experiência científica em que o ativo é um engano metodologicamente necessário para produzir resultados válidos. A autorização prévia por sujeitos de pesquisa é que faz a diferença entre a fraude, o legítimo e o ético. A ética da pesquisa clínica segundo Miller e Kaptchuk (2004), exige uma ponderação complexa de compromissos para a ciência rigorosa, a melhoria dos cuidados médicos e proteção dos sujeitos da pesquisa de riscos desnecessários, de danos e exploração. Um falso procedimento médico, que seria fraudulento e deplorável na prática clínica, pode ser legítimo em atividades de investigação. Aqueles que argumentam contra os procedimentos sham, consideram impróprio o controle sem nenhum tratamento, e apóiam o uso da lista de espera ou de dois grupos de tratamento padrão em que todos os pacientes recebem tratamento. (Hammerschlag, 1998)

4. Considerações finais

Embora estudos clínicos aleatórios controlados seja o padrão aceito de pesquisa clínica, outros tipos de investigação de alta qualidade como os estudos observacionais e os experimentos com animais, possa se tornar uma opção viável de pesquisa quando randomização dos pacientes possa ser considerada antiética ou inaceitável. (Moffe, 2009 e Wayne *et al,* 2009)

Mas, se a questão a ser respondida pela pesquisa com acupuntura, exigir a intervenção em seres humanos portadores de condições patológicas, este estudo sugere os seguintes passos:

1) Efetuar um vasto levantamento fisiopatológico ocidental e oriental da doença ou disfunção alvo do estudo.
2) Selecionar biomarcadores validados, capazes de detectar os efeitos fisiológicos e terapêuticos decorrentes das intervenções na condição patológica em questão.

3) Garantir que o grupo controle, caso exista, esteja recebendo comprovadamente o melhor tratamento disponível, seja ele ocidental ou oriental.
4) Determinar a partir de fundamentação teórica, se a intervenção testada envolverá uma abordagem completa (Acupuntura, moxabustão, fitoterapia, dietoterapia e exercícios físicos orientais) ou parcial (Só acupuntura) da MTC.
5) No caso de intervenções com acupuntura, descrever a metodologia de localização dos acupontos, deixar clara a razão da prescrição e dos procedimentos de inserção, de manipulação e o tipo de agulhas.
6) Utilizar um grupo sham (Agulhamento de acupontos não indicados para a patologia, agulhamento de não acupontos, estimulação mecânica ou elétrica ou térmica ou eletromagnética de acupontos) apenas quando a hipótese nula for a eleita. Tendo o cuidado de conhecer os ruídos sinérgicos, aditivos ou subtrativos destes na biomarcação.
7) Nas condições onde o efeito psicossomático da intervenção não puder ser excluída da biomarcação, eleger procedimento placebo (Intervenção inerte, inativa que faz com que o paciente acredite que está recebendo o tratamento real) validado.

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Manuscrito 2 – Aceito para publicação pela "Revista Augustus" em Maio/2011

A fisiopatologia do acidente vascular cerebral segundo a medicina Chinesa

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Resumo

Diante da gravidade do contexto epidemiológico, do reconhecido potencial letal, do prognóstico incapacitante que cerca o acidente vascular cerebral (AVC) e das questões que envolvem o tratamento primário (fatores comportamentais e intermediários) e secundário (seqüelas da lesão cerebral), se faz necessária a identificação de abordagens mais personalizadas para a prevenção do AVC e tratamento de suas seqüelas. A Organização Mundial da Saúde publicou em 2003 um relatório onde classifica as doenças ou afecções para as quais a acupuntura tem sido testada em ensaios clínicos controlados e tiveram sua eficácia terapêutica comprovada, dentre as quais figuram o AVC, a depressão e estados de neurose depressiva pós-AVC. Este estudo objetiva ampliar a compreensão etiopatogênica e fisiopatológica do AVC e suas seqüelas, à luz da milenar teoria da Medicina Chinesa (MC) e a evolução do estado da arte ao longo dos séculos.

Palavras-chave: Acidente vascular encefálico; medicina Chinesa; diferenciação de padrões.

1. Introdução

A medicina Chinesa (MC) é historicamente referenciada como pioneira na valorização da prevenção de doenças e nas intervenções terapêuticas baseadas em dietas, exercícios, uso de plantas como remédio e o conhecimento da influência dos fatores ambientais sobre a saúde. Sua visão holística vem se tornando mais relevante a cada dia, quando se considera os três principais males da vida moderna: a globalização de estilos e hábitos de vida pouco saudáveis; a urbanização não planejada; e o envelhecimento demográfico. Tais tendências globais apresentam consequências globais para a saúde, principalmente no que se refere ao aumento da incidência e prevalência das doenças crônicas não-transmissíveis, como as disfunções e incapacidades decorrentes do acidente vascular cerebral (AVC) (CHAN, 2008).

O objetivo deste estudo é descrever a etiologia e a fisiopatologia do AVC e suas sequelas sensoriomotoras à luz da MC e a evolução do estado da arte ao longo da história.

2. Desenvolvimento teórico

2.1 Literatura clássica em medicina Chinesa sobre o acidente vascular cerebral

Os padrões patológicos que envolvem a hemiplegia foram descritos por diversos médicos chineses desde a antiguidade. Pode-se observar que as teorias estabelecidas por cada um divergem principalmente quanto à etiopatogenia (WANG, 2007). Em seguida, são apresentados em ordem cronológica os autores clássicos e contemporâneos de MC e suas respectivas representações do AVC e hemiplegia.

O *Su Wen* e o *Ling Shu* compõem o *Huang Di Nei Jing*, o livro mais antigo de MC existente até hoje. Estima-se ter sido compilado pela primeira vez no Período dos Estados Guerreiros (475-221 a.C.), com trechos adicionados na dinastia Qin (221-206 a.C.) e Han (206 a.C. - 220 A.D.) e compilado publicamente no início da dinastia Han Ocidental (206 a.C. - 24 A.D.). O *Su Wen* descreve o golpe de vento (*zhongfeng*) como o causador da atrofia hemilateral, o qual invade os pontos dos órgãos e vísceras. No *Ling Shu*, atribuiu-se o estado de vazio perverso de *qi* dos canais defensivos e construtivos como causa da atrofia hemilateral (MING, 2001).

Em seus livros dois livros *Shang Han Lun* (MITCHEL et al. 1999) e *Jinkui Yaolue* (LUO, 1985), *Zhang Zhong-jing* (150-219) também considerou o vento como alvo de seus estudos e atribuiu a este fenômeno diversas doenças e distúrbios, incluindo a hemiplegia.

Liu He-jian (1120-1200) afirmou que o golpe de vento não é um movimento interno

do vento do fígado (*gan*) e que este também não é causado por um ataque de vento externo, e sim de uma recuperação insuficiente de um estado de fogo interno (WANG, 2007).

Li Dong-yuan (1180-1251) teorizou a existência de uma divisão etiológica para o golpe de vento, classificando-o como: visceral; orgânico; dos vasos sanguíneos; e da rede de canais baseado no vazio de *qi* e ataque de vento externo (YANG & LI, 1993).

Zhu Dan-xi (1281-1358) escreveu que quando o *qi*, tanto do oeste quanto do norte é frio, ocorre o verdadeiro golpe de vento, e quando tanto o *qi* do leste quanto o do sul é úmido ocorre o falso golpe de vento. Isso porque nos estados de vazio de *qi* e sangue, a umidade se transforma em fleuma e esta em calor e este último em vento (YANG, 1993).

Li Shi-zhen (1518-1593) associou o golpe de vento à pré-existência de deficiência de *qi* e de sangue (*xue*). Afirmou ainda que os casos graves de colapsos e coma são gerados por golpes de fleuma (*tanyin*) e que os colapsos súbitos e frios são causados por distúrbios emocionais que bloqueiam a circulação de *qi* nos órgãos e vísceras (LI, 1985; LI, 1998).

Yang Ji-zhou (1522-1620) atribuiu ao golpe de vento mais de uma centena de doenças, já que o vento pode atacar cada sistema corporal e gerar inúmeras combinações de sinais e sintomas. Outros elementos, com fleuma ou *qi*, raiva ou alegria apenas contribuem para variações do quadro clínico (WANG, 2007).

Wang Qing-ren (1768-1831) afirmou que o "falso" golpe de vento pode ser atribuído ao vento interno e a uma variedade de doenças diferenciadas pelo canal e rede de vasos afetados, que na medicina ocidental pode corresponder ao AVC e à paralisia de Bell. O "verdadeiro" golpe de vento caracteriza-se por um ataque súbito com perda de consciência e em alguns casos desvio de boca e olhos, hemiplegia, afasia e incontinência vesical (WANG, 2007).

2.2 Literatura contemporânea em medicina Chinesa sobre o acidente vascular cerebral

Ross (1994) afirmou que os sintomas mais importantes do *yang* hiperativo são aqueles ocasionados pela turbulência causada pelo movimento rápido para cima do *yang*. A hemiplegia resulta da ascensão se combina com o fogo e invade os canais da parte superior do corpo, interrompendo o fluxo de *qi* e sangue (*xue*). O mesmo pode ocorrer quando a turbulência e obstrução são geradas pelo vento e a mucosidade.

Maciocia (1996) atribuiu à etiologia do golpe de vento há quatro grupos de condições fundamentais:

- Excesso de trabalho, estresse emocional e atividade sexual excessiva, causadoras de

deficiência de yin do rim (*shen*) e fígado (*gan*) e ascensão do yang do fígado (*gan*) que especialmente nos idosos, pode gerar vento no fígado (*gan*);

- Alimentação irregular e esforço físico excessivo: grandes quantidades de alimentos doces, laticínios e frituras enfraquecem o baço (*pi*) e geram mucosidade (fator predisponente de obesidade), que pode se combinar ao fogo;
- Atividade sexual excessiva e repouso inadequado enfraquecem a essência do rim (*shen*) e gera deficiência da medula (*sui*), que falha em nutrir o sangue (*xue*) e eventualmente a quadros de estase (estagnação) do mesmo;
- Esforço físico excessivo e repouso inadequado enfraquecem o baço (*pi*), os músculos e os canais, permitindo a manifestação do vento interno pela deficiência de *qi* e sangue nos mesmos e a maior suscetibilidade aos ataques de vento exterior.

Em 2006, Maciocia descreveu o conjunto de sinais e sintomas que caracterizam os padrões que descrevem a apoplexia:

- ✓ Colapso do *yang*: hemiplegia, inconsciência súbita, confusão mental, olhos fechados, boca e mãos abertas, incontinência urinaria, respiração fraca, membros frios, cútis branco-brilhante, transpiração da fronte, língua pálida e curta, pulso escondido e disperso;
- ✓ Colapso do *yin*: Hemiplegia, inconsciência súbita, desvio do olho e da boca, olhos fechados, boca e mãos abertas, respiração fraca, membros frios, face vermelha, língua vermelha sem saburra, pulso mínimo.

Pode-se observar que, apesar de os dois padrões acima serem referidos ao momento de ocorrência do AVC (apoplexia), o autor inclui a hemiplegia como uma possível manifestação. Este fato sugere uma indissociação entre o AVC e suas seqüelas na interpretação da MC.

Segundo a Administração Estatal de Medicina e Farmácia Tradicionais Chinesas (AEMFTC, 2007), a apoplexia pode estar relacionada a:

- ❖ Quadros de deficiência de *yin* do fígado (*gan*) e rins (*shen*), resultante de estresse, atividade sexual excessiva e idade avançada, e ainda por deficiência de *qi* e sangue (*xue*), complicada por estagnações nos meridianos, caracterizada por desvios musculares faciais e hemiplegia;
- ❖ O ataque de vento externo invade os canais quando a resistência está enfraquecida, impede a circulação de *qi* e sangue (*xue*), podem ser acompanhados de fleuma súbita

provocando perda de sensibilidade;

- ❖ O vento interno derivado da hiperatividade do *yang* do fígado (*gan*) e da deficiência de *yin* e induzida por descontroles emocionais, excesso de álcool, estresse ou clima anormal para a época do ano;
- ❖ A umidade-fleuma produzida por alimentação inadequada (gordura, doces e álcool), comum em pacientes obesos e estressados, desequilibra o transporte e transformação do *qi* do baço (*pi*) e estômago (*wei*), pode cronicamente se transformar em calor e obstruir os meridianos, se combinar com a invasão de fogo no baço (*pi*) e vento do fígado (*gan*) e ascender;
- ❖ A hiperatividade do fogo do coração e do fígado (*gan*) causada principalmente por excesso de raiva e deficiência de *yin* dos rins (*shen*) e fígado (*gan*).

Em resumo, o vento, a mucosidade, o fogo e a estase são os quatro fatores patogênicos do AVC na MC, que podem aparecer em combinação e se apresentar com diversos graus de intensidade. A hemiplegia é conseqüência da obstrução dos canais por ação do vento e da mucosidade, a rigidez das articulações e a contração dos músculos indicam estase de sangue (*xue*), sobre um fundo de deficiência de *qi*, sangue (*xue*) ou *yin*. Após um golpe de vento é importante observar os desequilíbrios que causaram o primeiro episódio, podem estar ainda latentes, predispondo o paciente a futuras crises (MACIOCIA, 1996; MACIOCIA, 2006).

2.3 Padrões associados à Hemiplegia

Em MC, as manifestações (sinais e sintomas) possíveis de serem encontradas nos indivíduos encontram-se agrupadas, e recebem a denominação de padrões de disfunção anatomofuncional, que podem ou não representar a totalidade de achados dos quadros patológicos diagnosticados como doenças na medicina ocidental. A Tabela I apresenta os padrões encontrados na literatura contemporânea (MACIOCIA, 1996; MACIOCIA, 2006; AEMFTC, 2007). Reitera-se que não é necessário que o paciente apresente todas as manifestações descritas no perfil do padrão, mas somente um subconjunto já é suficiente para o estabelecimento do diagnóstico - chamado de diferenciação de padrões. Baseado nesta revisão observa-se uma diversidade e sobreposição nas definições dos padrões associados ao pós-AVC.

2.4 Modelos automáticos para identificação dos padrões de AVC

Kim *et al.* (2011) em um estudo multicêntrico de base comunitária, que envolveu 806 pacientes com até 30 dias pós acometimento por AVC, propôs um modelo para identificação dos padrões da MC em indivíduos pós-AVC. Foram avaliadas as características gerais dos pacientes e sintomas relacionados à identificação de padrões, que era considerada válida quando dois médicos especialistas em MC concordavam sobre os achados. Para determinar quais variáveis afetam o padrão de identificação, análise de regressão logística binária foi utilizada. Entre os 480 pacientes que foram identificados como pertencentes a um padrão, 210 apresentaram o padrão de "fleuma umidade", 110 foram identificados com "deficiência de *qi*", 100 com o padrão "calor do fogo", 51 pacientes foram identificados com "deficiência de *yin"* e 9 deles identificados com padrão de "estase de sangue". Após a análise de regressão, e a aplicação de equações de predição logística sugeriram os quatro padrões (calor do fogo, umidade fleuma, deficiência de *qi* e deficiência de Yin) como os mais incidentes, e que os critérios utilizados pelo estudo podem ser úteis para determinar padrão etiopatogênico dos pacientes vitimados de AVC. Os autores apontaram ainda para a necessidade da sua replicação para que o método e seus critérios possam ser validados.

Considerações finais

Pode-se observar que as causas atribuídas ao AVC e suas sequelas não diferem significativamente desde os relatos clássicos chineses até os dias de hoje. Deve-se sim enfatizar o detalhamento das associações entre os fatores predisponentes (hábitos contemporâneos) e o refinamento dos padrões chineses possibilitado pela evolução dos estudos modernos sobre a fisiologia da MC. Cabe ainda mencionar a importância da caracterização da história natural do AVC e a diferenciação da fisiopatologia pré-AVC, do colapso em si (apoplexia) e do padrão que o paciente pode apresentar no pós-AVC. Finalmente, a possibilidade de desenvolvimento de métodos reprodutíveis para identificação de padrões pode permitir um grande avanço para os estudos clínicos baseados em acupuntura como intervenção.

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Tabela I: Padrões associados ao pós-AVC na medicina chinesa.

Padrões pós-AVC comumente encontrados (Maciocia, 1996; Maciocia, 2006)

1 Mucosidade-Vento: contração dos membros, rigidez, tontura severa, vertigem, língua rígida, língua desviada, pulso em corda

2 Umidade-Mucosidade: sensação de peso no corpo, sensação de opressão no tórax, expectoração profusa, ruído na garganta, visão borrada, tontura, língua inchada, língua com revestimento pegajoso, pulso escorregadio

3 Estagnação de Qi e Sangue: hemiplegia, dores no ombro, dores no quadril, língua púrpura, pulso firme

4 Deficiência de Yin com Calor Vazio: sensação de calor à tarde e no início da noite, tontura, zumbido, calor na palma das mãos, sensação de peso na parte superior do corpo, fraqueza na parte inferior ao andar, língua vermelha, língua sem revestimento, pulso flutuante, pulso vazio, pulso rápido

Padrões em que o achado principal é a hemiplegia (Maciocia, 2006)

1 Vento nos canais: hemiplegia, desvio do olho, desvio da boca, afasia

2 Vento do Fígado: hemiplegia, tremores, entorpecimento dos membros, tontura intensa, tinidos, dor de cabeça, língua rígida, língua desviada, língua móvel, pulso em corda

3 Vento-Fleuma: hemiplegia, entorpecimento dos membros, formigamento dos membros, tontura intensa, visão turva, tinidos, náusea, muco na garganta, sensação de opressão no tórax, língua rígida, língua desviada, língua aumentada, pulso em corda, pulso deslizante

4 Fleuma-Fogo: hemiplegia, entorpecimento dos membros, inconsciência súbita, confusão mental, desvio do olho, desvio da boca, contração das mãos, dentes cerrados, face vermelha, olhos vermelhos, som crepitante na garganta, sensação de opressão no tórax, expectoração de muco amarelo, expectoração de muco pegajoso, língua vermelha, língua aumentada, língua com saburra amarela, língua com saburra pegajosa, pulso deslizante, pulso rápido

5 Umidade-Fleuma: hemiplegia, entorpecimento dos membros, inconsciência súbita, confusão mental, dentes cerrados, muco na garganta, sensação de opressão no tórax, expectoração profusa de muco pegajoso, cútis branca, cútis pastosa, membros frios, língua aumentada, língua com saburra branca, língua com saburra pegajosa, pulso deslizante

6 Deficiência de qi e estase se sangue: hemiplegia, cor da pele embotada, edema, rigidez dos tendões, contrações dos membros superiores, membros inferiores relaxados e estirados, cansaço, falta de apetite, fezes amolecidas, voz fraca, respiração ligeiramente curta, cútis pálida, língua azul-arroxeada, pulso fraco, pulso áspero

7 Deficiência do fígado e do rim: hemiplegia, dor lombar, membros moles, tontura, tinidos, memória fraca, visão turva, confusão mental, língua pálida, língua vermelha

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Statistical distribution of acupoint prescriptions for sensory-motor impairments in post-stroke subjects

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Abstract

Variability in acupoints prescription for stroke-related patterns may help explain contradictory results in clinical trials of either improvement or maintenance of sensory-motor functions in post-stroke patients. Few research studies analyzed acupoints prescriptions for stroke or post-stroke patients. This study performed a literature search to statistically describe the characteristics of acupoint selection for therapeutic intervention in post-stroke subjects based on pre-modern and modern literatures. Twelve classic textbooks in Chinese medicine and fourteen research articles had their acupoints listed and organized under each author in a chronological manner. A total of 84 different acupoints were collected from pre-modern and modern authors. No significant difference was observed between pre-modern and modern authors regarding the frequency of acupoints grouped by channel (P=0.482) or grouped by channel nature (pre-modern: yang=76.9%; yin= 23.1%; modern: yang=77.3%; yin=22.7%; P=0.966). Considering all authors, only 1 (1.2%) acupoint (LI-4) presented the highest frequency with 12 (44.4%) authors reporting its use for sensory-motor impairments, and 49 (58.3%) acupoints were prescribed only once. It was demonstrated that pre-modern and modern authors selected channels for intervention in a similar fashion.

Keywords: Stroke; acupuncture; Chinese medicine.

1 Introduction

Personalized medicine and rehabilitation have gained interest of the scientific community in recent years for disease treatment and Chinese medicine is appropriate to such an approach. Acupoint selection is a complex task performed to each subject under treatment in every session. The amount of prescribed acupoints may vary from one to several acupoints[1] depending on whether symptomatic or pattern differentiation strategy is adopted, being the latter preferred since it leads to better therapeutic outcomes in many medical fields[2]. In case several acupoints are selected, some acupoints may be eliminated by simultaneous consideration of redundant therapeutic principles and balancing among local, distant and specific acupoints into opposite body parts (*i.e. yin-yang* channels)[3,4]. Nevertheless, an acupoint prescription may be intentionally left unbalanced to achieve specific therapeutic principles. Other aspects such as individual constitution, anatomical variations, needle manipulation, application of other techniques (*e.g.* moxibustion, cupping, blood-letting, etc.)[3,4] and practitioner experience also influence the variability of acupoint prescription. Although variability of acupoint prescription is clinically accepted in Chinese medicine, it limits comparison among clinical studies such that the Standards for Reporting Clinical Trials of Acupuncture recommended that detailed needling information should be reported[5].

Stroke-like manifestations were recognized by Chinese Medicine practitioners for at least 2000 years[6] and it is still a major public health problem[7]. For instance, it was traditionally described as wind-stroke (*zhongfeng*), with sequelae such as one-sided (or hemilateral) withering, hemilateral impediment, or hypertonicity of the sinews. Currently, patterns may be used to describe the manifestation profile of post-stroke patients[8]. The inherent diversity of stroke-related sensory-motor impairments is potentially the major factor that increases variability of acupoint prescription since patients with different patterns – as well as patients

with the same pattern – may present different manifestations profiles[9-11]. Such a variability, if present, might help explain contradictory results in clinical trials of either improvement[12] or maintenance[13] of sensory-motor functions in post-stroke patients, to the point that there is no clear evidence on the rehabilitation effects of acupuncture on acute[14], subacute or chronic stroke[15]. Hence, knowledge about characteristics of acupoints prescribed for post-stroke subjects is necessary.

Few research studies analyzed acupoints prescriptions for stroke or post-stroke patients. Xu and Bi[16] reviewed twenty-eight Chinese medicine books with complete prescriptions prior to the Qing Dynasty. These authors observed that in ancient times, treatment of stroke was based on its symptoms: 77 different acupoints were prescribed for hemiplegia (mainly located in the Large Intestine channel); 34 acupoints for unconsciousness; 41 for aphasia; 9 for wry mouth; and 20 for convulsion. In another study, Zhao et al.[17] analyzed ancient and current medical literature to summarize the characteristics of acupoint selection in the treatment of apoplexy. They found that: a) acupoints of the head are mostly used (including both channel acupoints and scalp acupuncture); b) peripheral acupoints are mainly selected according to the course of nerves; c) acupoints of the *yang* channels are usually used to balance *yin* and *yang*; and d) "special" (selected by pattern differentiation) and empirical (neither channel nor extra-channel) acupoints are often combined. However, none of the above-cited works compared pre-modern and modern acupoint prescriptions.

The aim of this study was two-fold: 1) to describe the characteristics of acupoint prescription for therapeutic intervention in post-stroke subjects based on pre-modern and modern literatures; and 2) to test for difference and association between pre-modern and modern acupoint prescriptions for post-stroke patients.

2 Methods

2.1 Pre-modern literature review

Twelve classic textbooks in Chinese medicine with English versions available were reviewed[18-30]. The index of each textbook was searched for the following traditional terms related to post-stroke sensory-motor impairment: “wind-stroke”, “wind-strike”, “apoplexy”, “hemiplegia”, “hemilateral withering”, and “hemilateral impediment”. All textbooks that presented any of those terms in their index had its content analyzed and the acupoints prescribed regarding the stroke-related terms were annotated into a spreadsheet. Textbook that did not prescribe any acupoint were still retained for descriptive analysis but removed from further statistical tests. Each acupoint was described by the following variables: a) channel nature; b) channel name; c) numbered sequence on channel; d) abbreviation; and e) author. The resulting table of acupoints was organized under each author in a chronological manner and is available in English language upon request to the authors.

2.2 Modern scientific literature review

A web-based search was performed in Pubmed database to find clinical studies on acupuncture treatment of stroke-related sensory-motor impairments that reported the acupuncture prescription. The following keywords were used: “acupuncture”, “stroke”, “rehabilitation”, “cerebrovascular disorders”, “hemiplegia”, and “hemiparesis”. Only studies reporting manual acupuncture for post-stroke motor impairments were used and those not clearly reporting the acupoints were excluded. Fourteen articles were used in this review[12,13,31-42]. The content of each article was analyzed and the acupoints prescribed were annotated. Acupoint from modern works were described by the same variables as the pre-

modern ones. The resulting table of acupoints was organized under each author in a chronological manner and is available in English language upon request to the authors.

2.3 Statistical analysis

A first, descriptive analysis of the frequency counts of acupoints was performed for both groups of pre-modern and modern authors. The frequency of acupoints including all reviewed authors was also determined. In a second analysis, pre-modern and modern acupoint prescriptions were grouped by channel and further grouped by channel nature (*yin* or *yang*). The χ^2 test was used to test the null hypothesis of no difference on frequency distributions among pre-modern and modern works grouped by channels, as well as grouped by channels' nature. Pearson product moment correlation was used to calculate the association among prescribed acupoints (prescribed = "1"; not prescribed = "0") in comparisons between: a) dual pre-modern authors; b) dual modern authors; and c) pre-modern versus modern authors. Correlation values were categorized as a nominal variable corresponding to no association (r=0.00) to perfect association (r=±1.00) for further analysis[43]. All analyzes were performed in Excel® for Windows®. Significant values were considered at $P<0.05$.

3 Results

The acupoints prescribed by Chinese medicine authors grouped by authors' epoch is presented in Table 1. Sixty-five acupoints were identified from pre-modern authors, while only 45 were identified from modern ones. Overall, a total of 84 different acupoints were collected. Three channels (Gall-bladder, Bladder, and Stomach) were the most frequently used ones (13.1% each). Conversely, no acupoint on the Kidney channel was reported. No significant difference (P=0.482) was observed between pre-modern and modern authors regarding the frequency of acupoints grouped by channel.

PLEASE INSERT TABLE 1 HERE

The frequency of acupoints grouped by channels' nature is exhibited in Table 2. A preference for acupoints on *yang* channels over *yin* channels in both pre-modern (76.9% versus 23.1%, respectively) and modern (77.3% versus 22.7%, respectively) authors was observed. No significant difference (P=0.966) was found between pre-modern and modern authors concerning the frequency of acupoints grouped by channel nature.

PLEASE INSERT TABLE 2 HERE

The frequency of acupoints prescribed by all reviewed authors is presented in Table 3, exhibited by high-to-low overall observed frequency. Among pre-modern authors, 6 (9.2%) acupoints (LI-4, LU-5, SI-4, BL-13, BL-18, and PC-7) were prescribed 2 times and 59 (90.8%) acupoints were uniquely prescribed by an author. Among modern authors, 4 (9.1%) acupoints (LI-4, LI-11, GB-34, and ST-36) were prescribed 9 times, while 24 (54.5%) acupoints were cited by a single author. Considering all authors, only 1 (1.2%) acupoint (LI-4) presented the highest frequency with 12 (44.4%) authors reporting its use for sensory-motor impairments, and 49 (58.3%) acupoints were prescribed only once.

PLEASE INSERT TABLE 3 HERE

Association analysis on acupoint prescriptions among pre-modern, modern, and pre-modern versus modern authors is presented in Figure 1. Weak to negligible grades of negative association (range=[-0.40; -0.01]) were observed among pre-modern authors. Weak, negative

to positive, negligible grades of association (range=[-0.20; 0.40]) were observed between pre-modern and modern authors. Modern authors exhibited grades of association from negative, negligible to positive, strong ones (range=[-0.20; 0.99]).

PLEASE INSERT FIGURE 1 HERE

4 Discussion

This study described the characteristics of acupoint prescription for therapeutic intervention in post-stroke subjects based on pre-modern and modern literature. This is the first study to collect and report acupoints prescribed to post-stroke patients in a manner that allowed statistical comparisons. The main findings of this study are: 1) pre-modern and modern authors selected channels for intervention in a similar fashion regarding the selection of channels as well as the preference of acupoints in *yang* channels; 2) variability among acupoint prescriptions is higher among pre-modern authors as compared to modern works; and 3) *hegu* (LI-4) was the most prescribed acupoint for sensory-motor impairments due to stroke.

The results of the present literature research are in agreement with other studies that qualitatively described characteristics of acupoint for stroke-related impairments[16,17]. Most importantly, this study demonstrated that pre-modern and modern authors selected channels for intervention in a similar fashion, *i.e.* regarding the selection of channels as well as the preference of acupoints in *yang* channels. While *yang* channels are preferred by pre-modern authors due to symptomatic manifestation, modern authors seem to prefer *yang* channels since they reflect both traditional and contemporary, anatomical reasoning. Motor impairments on post-stroke subjects usually affect the flexor muscle groups on upper extremities and extensor

muscle groups on lower extremities[7], both regions reflect the *yang* anatomical aspect of the human body[1,3,4]. Less frequent selection of acupoints on *yin* channels reflects the need to reduce the unbalance in prescriptions and to treat the etiologic pattern underlying stroke. Collectively, these results suggest that differences between pre-modern and modern authors are probably not the major factor affecting the outcome of clinical studies.

Hsu Ta-chun[28] discussed the large amount of acupoints in a prescription as a loss of tradition. According to him, "when the two classics [Ling-shu and Su-wen] refer to the treatment of an illness, they do, of course, quite often state: 'in case of such-and-such an illness, select such-and-such an insertion point.' In all other cases, though, they refer to the conduits and not to the insertion point… Today, for each illness, a number of holes are specified". The impression of Hsu Ta-chun was observed in this study as most modern authors selected their acupoints based on pattern differentiation and personalized needs. The use of several acupoints is attributed to the pattern differentiation process, which conduct to the treatment of the primary and secondary patterns presented by patients[1,3,4]. Standardization is a necessary step for research on the clinical effects of acupuncture in rehabilitation and pattern differentiation may be an appropriate method to balance standardization and personalized intervention[2]. This should provide a contextual framework for scientific testing of acupuncture principles inside its own Chinese medicine theory.

The physiologic effects of the most frequent acupoint (LI-4) on the nervous system have been extensively investigated. For instance, studies reported an increase in both sympathetic and parasympathetic activity during the stimulation period[44], an increase in the parasympathetic activity after intervention[44], increase on the cerebral blood flow[45], initial pressor response and long-term decrease of blood pressure[45], modulation of limbic cingulum activity that may

decrease nociceptive processing[46], and decrease in regional cerebral blood flow in the putamen[47]. From this bundle of evidence, it is suggested that needle stimulation of LI-4 may stimulate the central nervous system. However, no evidence was provided regarding motor functions to support the isolated use of this acupoint. Further studies are needed to understand the physiologic effects on the muscle contraction related to the acupuncture insertion on LI-4 and to support the isolated prescription of this acupoint for stroke-related impairments.

This study was limited to the pre-modern classics available in English. Nevertheless, all revised pre-modern works are attributed to eminent Chinese medicine scholars and thus they are representative for analysis of traditional content. This reinforces the need for internationally available and accurate translations of ancient books to promote Chinese medicine traditional knowledge to a higher scientific level and to integrate it with conventional medicine.

5 Conclusions

Pre-modern and modern authors selected channels for intervention in a similar fashion regarding the selection of different channels, and a preference for acupoints in *yang* channels was observed. Variability among acupoint prescriptions is higher among pre-modern authors as compared to modern works for stroke-related sensory-motor impairments.

List of abbreviations

Legend: LU=Lung; LI=Large Intestine; KI=Kidney; BL=Bladder; LR=Liver; GB=Gall-bladder; HT=Heart; SI=Small Intestine; SP=Spleen; ST=Stomach; GV=Governor Vessel; CV=Conception Vessel; PC = Pericardium; TE = Triple Energizer.

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Figure Legend

Figure 1: Frequency distribution of correlation coefficients according to the compared groups of authors

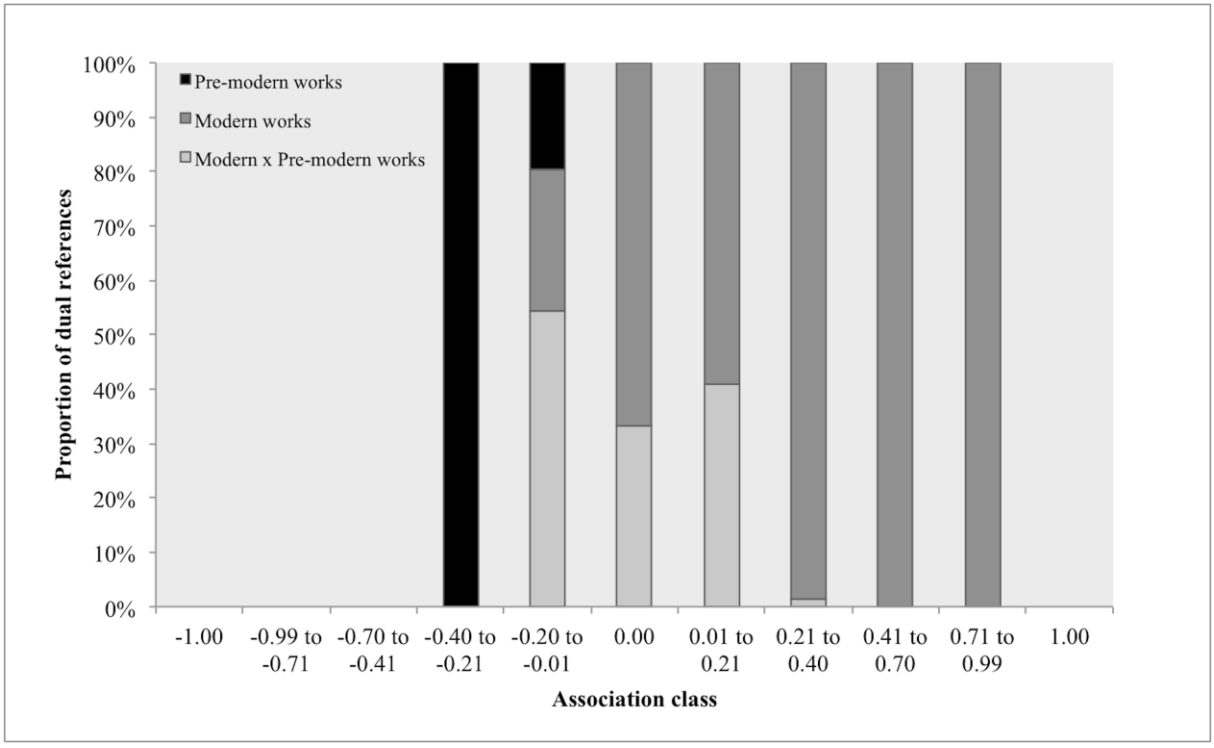

Table 1: Acupoints prescribed by Chinese medicine authors grouped by individual channels.

	Pre-modern		Modern		Total	
Channel	**n**	**%**	**n**	**%**	**n**	**%**
Xin	4	6.2%	1	2.2%	5	5.9%
Fei	5	7.7%	2	4.4%	5	5.9%
Gan	1	1.5%	1	2.2%	2	2.4%
Pi	0	0.0%	1	2.2%	1	1.2%
Shen	0	0.0%	0	0.0%	0	0.0%
Xinbao	4	6.2%	1	2.2%	4	4.7%
Dachang	6	9.2%	7	15.6%	9	10.6%
Xiaochang	7	10.8%	4	8.9%	9	10.6%
Dan	8	12.3%	7	15.6%	11	12.9%
Wei	8	12.3%	8	17.8%	11	12.9%
Pangguang	10	15.4%	2	4.4%	11	12.9%
Sanjiao	6	9.2%	5	11.1%	8	9.4%
Du Mai	5	7.7%	2	4.4%	5	5.9%
Ren Mai	1	1.5%	4	8.9%	4	4.7%
Total	**65**	**100%**	**45**	**100%**	**85**	**100%**

P=0.518

Table 2: Acupoints prescribed by Chinese medicine authors grouped by channel classification.

	Pre-modern		Modern		Total	
Channel nature	**n**	**%**	**n**	**%**	**n**	**%**
Yin	15	23.1%	10	22.2%	21	24.7%
Yang	50	76.9%	35	77.8%	64	75.3%
Total	**65**	**100%**	**45**	**100%**	**85**	**100%**

P=0.916

Table 3: Frequency of prescription of acupoints considering both classic and contemporary Chinese medicine authors.

Frequency		Pre-modern		Modern		Total		
n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**Acupoints**
11	42%	0	0.0%	0	0.0%	1	1.2%	LI-4
10	38%	0	0.0%	0	0.0%	3	3.6%	LI-11, GB-34, ST36
9	35%	0	0.0%	4	9.1%	0	0.0%	-
8	31%	0	0.0%	0	0.0%	1	1.2%	TE-5
7	27%	0	0.0%	2	4.5%	1	1.2%	LR-3
6	23%	0	0.0%	0	0.0%	2	2.4%	LI15, GV-20
5	19%	0	0.0%	2	4.5%	2	2.4%	LI-10, GB-30
4	15%	0	0.0%	2	4.5%	1	1.2%	GB-39
3	12%	0	0.0%	4	9.1%	8	9.5%	*
2	8%	6	9.2%	4	9.1%	14	16.7%	*
1	4%	59	90.8%	26	59.1%	51	60.7%	*
26	**100%**	**65**	**100%**	**45**	**100%**	**85**	**100%**	

* Acupoints not described due to the large quantity.

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1 mensagem

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11-Nov-2011

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Immediate effects of manual acupuncture on brachial biceps muscle function in healthy individuals and chronic hypertonic stroke patients: A randomized trial study protocol

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Background: Stroke is a morbid entity in Chinese Medicine recognized for at least 2,000 years with sensory-motor impairments reported by several classic authors. However, the majority of controlled clinical trials of acupuncture on post-stroke patients failed to obtain significant long-term results on functional recovery. Moreover, contradictory results were obtained about the immediate effects of acupuncture stimulation on the electrical activity of human skeletal muscles as observed with surface electromyography. Those results raise the question on whether acupuncture has any effect on the neuromuscular level. This study aims to evaluate the immediate effects of manual acupoints stimulation on the biceps brachii electrical activity and strength of healthy individuals and patients with chronic hypertonic hemiparesis. Methods and Design: It is proposed a randomized clinical trial, with four parallel groups, single-blinded. Healthy subjects and post-stroke patients with chronic spastic hemiparesis will be submitted to a single acupuncture intervention on either Quchi (LI11) or Tianquan (PC2). Immediate effects on muscle function will be assessed by surface electromyography and isometric force of the biceps brachii muscle as the primary outcome. Secondary outcomes comprise the frequency of patterns in each group, as well as the frequency distribution of manifestations. Discussion: The proposed study design includes some improvements on common methodological issues on clinical trials with an integrative design. It is expected this study design to provide new insights on the neuromuscular effects of acupuncture stimulation in healthy and post-stroke subjects.

Trial registration: Brazilian Clinical Trials Registry (www.ensaiosclinicos.gov.br) in English and Portuguese in October 2011. Registration number: RBR-5g7xqh.

Funding resources: None declared.

Keywords: Manual acupuncture; Stroke; Motor impairment; Surface electromyography; Clinical protocol.

1. Introduction

1.1 Background

The World Health Organization estimate that deaths related to cardiovascular disease will increase to 24 million in 2030. It is estimated that 10.6% of all ischemic strokes affect the Brazilian population aged between 15 and 40 years[1-3]. Although advances were achieved in primary and secondary preventive medicine, annually more than 70% of all strokes are first-ever events. Altogether, these data reinforce the importance of management of risk factors for stroke as well as the research on new interventions for rehabilitation for minimization of both recovery time and neurologic impairments and maximization of functional independence of stroke survivors[4-5].

Stroke is a morbid entity in Chinese Medicine (CM) recognized for at least 2,000 years[6] with sensory-motor impairments reported by several classic authors[7-10]. In CM, acupuncture and herbal compounds are commonly reported interventions that depend on underlying patterns[11]. The advances of scientific methods and the worldwide effort for development of an integrative, personalized medicine motivate researchers to investigate the efficacy of acupuncture for stroke-related functional deficits. However, the majority of controlled clinical trials of acupuncture on post-stroke patients failed to obtain significant long-term results on functional recovery[12-13]. Those results raise the question of whether acupuncture has any effect at the neuromuscular level.

Functional deficits in chronic, post-stroke patients have been described as the expression of abnormal synergies and co-contraction of agonist and antagonist muscles, especially in the upper or lower extremities. It was found that those deficits were due to improper Motor Unit (MU) recruitment and imbalance of strength between agonist and antagonist muscles. Such an argument suggests that assessment of MU recruitment may add

information on the effects of interventions aiming to improve agonist motor function in post-stroke patients[14].

Surface electromyography (sEMG) has been used to evaluate muscle activity in health and morbid conditions. It is a noninvasive technique that assesses the amount and duration of muscle activity, as well as strategies of neural recruitment. Among several parameters of sEMG quantification, the root mean squared (RMS) value has been the most used time-domain parameter since it better reflects the relationship between muscle tension and the corresponding gross MU recruitment[15-16]. Hence, it can be used to monitor changes in myoelectric activity due to rehabilitation interventions.

1.2 Preliminary studies

Contradictory results were obtained on the immediate effects of acupuncture stimulation on electrical activity of human skeletal muscles as observed with sEMG. Toma et al.[17] studied 17 healthy men (aged 20-38 years) to analyze the immediate effects of acupuncture stimulation on sEMG of the following muscles: flexor digitorum superficialis, flexor digitorum profundus, and semitendinous. Interventions comprised of perpendicular needle insertion into muscles during 15 minutes (no acupoint was specified). Results showed a significant difference in sEMG responses during maximal knee flexion but no significant difference was observed for the handgrip sEMG values. The authors concluded that single acupuncture stimulation affected the neuromuscular function.

Tough[18] conducted a study with 35 healthy volunteers (aged 18-70 years) to analyze the immediate effects of acupuncture on sEMG activity of the common wrist extensor muscles. All subjects received 20-minutes stimulation in a random sequence: true *deqi* at LI4 (Hegu) and LI10 (Shousanli) points, false or inappropriate *deqi* in the PC3 (Quze) and PC6 (Neiguan), and no stimulation considered as control. Results showed that sEMG was reliable

(intra-class correlation coefficient= 0.9996). Friedman analysis revealed no significant difference among the three protocols. Also, paired *t*-tests for the purpose of the first two interventions showed no detectable carry-over effect. Although no significant immediate changes were detected in sEMG activity following those acupuncture interventions, this study provides a sound protocol to plan future researches.

Costa & Araújo[19] investigated the myoelectric effects of a 20-minute manual stimulation of two acupoints in healthy subjects (2 groups, n=15 per group). The effects of manual stimulation on individual acupoint (ST36 and SP9) were evaluated by the RMS value and maximal isometric force estimated from the sEMG and the force signal, respectively. A significant reduction in RMS values was observed in both ST36 and SP9 immediately after acupuncture. Muscle strength was significantly reduced only after stimulation of ST36 despite the significant decrease in RMS values, in both groups. RMS values were not significantly different in post-treatment between ST36 and the SP9, but there was a significant decrease of strength after acupuncture in ST36. These authors suggested that manual acupuncture stimulation in healthy subjects triggered a neuromuscular reflex that lead to reduced muscle strength, which agree with the findings from a previous study[17] but contradict another[18].

Moncayo & Moncayo[20] suggested in their study that traditional acupuncture concepts of tonification lead to an improved function of any meridian while sedation reduces the excess. Therefore, as related to sEMG signals derived from those muscles, the signal should increase in tonification and decrease in sedation. Additionally, they claim that previous results[19] are better explained by Chinese medicine theory than by the stimulation-reflex loop.

Currently, no study investigated the immediate effects of manual acupuncture stimulation on sEMG in post-stroke patients and results with healthy subjects[17-19] cannot be extrapolated to post-stroke patients. CM theory states that healthy subjects may present different frequency distributions of patterns compared to post-stroke patients with different

responses to acupuncture stimulation. From the biopsychosocial model, the structural lesion observed in post-stroke patients will impose a limited control of muscle activation leading to different strategies for MU recruitment. Thus, this study is justified by the seriousness of motor impairments and functional disability arising from stroke, and especially in the scientific community's responsibility to provide and update methods for early diagnosis and treatment of these survivors. Therefore, this work proposes a study protocol for assessment of the muscle function in the upper extremity to be applied post-stroke patients with chronic spastic hemiparesis.

1.3 Study aims and hypothesis

The aim of this study protocol is to evaluate the immediate effects of manual acupoints stimulation on both electrical activity and strength of the biceps brachii in two samples (healthy individuals and post-stroke patients with chronic hypertonic hemiparesis). It was hypothesized that manual acupuncture does not provide neuromuscular stimuli to promote immediate changes in MU recruitment in healthy subjects or post-stroke patients.

2. Methods

This study protocol comprises a randomized clinical trial, with parallel groups, single-blinded. This study protocol follows the recommendations of both the Consolidated Standards of Reporting Trials[21] and Standards for Reporting Interventions in Clinical Trials of Acupuncture[22]. Also, this study protocol follows the Declaration of Helsinki and is currently approved by the Institutional Committee of Ethics in research for execution (CAAE-0006.0.307.000-10). The flowchart of this study design is depicted in Figure 1.

2.1 Eligibility: Inclusion and exclusion criteria

Inclusion criteria for healthy volunteers (HG) are age equal or greater than 20 years (both sexes), and absence of pain, acute inflammation or trauma in the upper limbs, pregnancy, aversion to needles, undiagnosed or apparent medical conditions (*e.g.* peripheral circulatory disease, coagulation disorders, malnutrition, systemic hypertension). Inclusion criteria for post-stroke patients (Case Group; CG) comprise all those valid to HG plus diagnosis of ischemic or hemorrhagic stroke confirmed by image exams, chronic (*i.e.* >6 months) upper limb partial motor impairment, ability to pose the affected elbow in range 80º to 100º, and absence of mental disorders that compromise understanding, communication and implementation of the experimental protocol. Exclusion criteria comprise incomplete responses on the assessment questionnaire, incomplete acquisition of the pre or post-intervention sEMG signal (characterized by the absence of 2-out-of-3 periods of muscle activation) and low signal-to-noise ratio (characterized as the absence of visual detection of sEMG periods of muscle contraction).

Healthy volunteers will be selected among the academic graduation community and data will be collected at the Laboratory of Human Movement Analysis. Post-stroke patients will be referred from Fluminense Association of Rehabilitation (AFR) and data will be collected at the rehabilitation gymnasium. All subjects will read and sign a written informed consent form after explanation of research aims and methods.

2.2 Procedures and interventions

2.2.1 Phase One: Sample screening

All volunteers will be asked to answer questions regarding their clinical status in a questionnaire form[23] that describes CM patterns related to stroke patients (Figure 2). Items in the questionnaire for pattern differentiation are considered as dichotomous variables that will be used as input variables for the regression equations provided by the authors[23]. Also,

pattern differentiation will be performed by the pattern differentiation algorithm validated to Zangfu patterns[24-26]. All volunteers will be characterized by age, sex, and the following clinic and anthropometric variables. Weight and height will be measured by analog scale and stadiometer, respectively. Heart rate will be measured by pulse palpation and digital chronometer. Systolic and diastolic blood pressure will be measured by aneroid sphygmomanometer. CG will be additionally characterized by stroke etiology (annotated from the patient's medical chart), lucidity, orientation, and communicability (observed during clinical examination).

2.2.2 Phase Two: Acupuncture intervention and electromyographic evaluation

Volunteers will sit on a chair with support for the upper limb to pose the elbow at 90º (flexion) throughout this study. Acupuncture and signal acquisition will be conducted by a physical therapist (APFS), specialized in acupuncture and with 16 years of clinical practice. The experimental protocol will consist of:

1) Locating acupoints according to modern standards[11,27] (Table 1). Skin locations will be cleaned with sterile cotton soaped with alcohol (70%) and moistened with saline solution (a 0.90%) for safety of the patient and improvement of sEMG signal conductivity;

2) Positioning of adhesive electrodes (double-disk, Ag/AgCl, diameter=10 mm; inter-electrode distance: 20 mm; Hal Industria, SP, Brazil) for sEMG signal acquisition at the biceps brachii (short head)[28]. sEMG signals will be collected by an analog device EMG400C (EMG System, SP, Brazil) connected to a data acquisition card NI-6009 (14 bits, National Instruments, Texas, USA) and a computer. All electrodes will be fixed with adhesive tape to minimize artifacts produced by movements of the skin. Maximum isometric force will be measured by a load cell (0-200 kg; EMG System, SP, Brazil) connected to the same amplifier, fixed on the ground at 90º.

3) Synchronous acquisition of sEMG and isometric force signals at a sampling rate of 1.0 kHz per channel. To record and process the signals, algorithms written in LabVIEW (National Instruments) Windows® will be used. Volunteers will execute 3 repetitions of a maximal isometric voluntary contraction (MIVC) of the biceps brachii muscle during 5 seconds, followed by 2 minutes to allow resting and metabolic recovery;

4) Unilateral, slanted puncture (45º) of acupoint towards the direction of *qi* circulation with a sterile, disposable stainless steel needle (Lizhou, China; 0.20x13 mm) at approximately 1.5 cm depth. Following insertion, the needle will be rotate clockwise until volunteers report the *deqi*. Manual stimulation consisting of rotating the needle clockwise for 10 seconds will be performed after needle insertion, 5, 10, 15, and 20 minutes, and should be accompanied by the report of *deqi*;

5) The needle will be removed 20 minutes after insertion and then step 3 will be repeated.

2.3 Rationale for acupoint selection

Two acupoints were selected for this research on the basis on previous studies[29] on acupoint prescription for stroke-related disorders (Table 1). Acupoints LI11 (Quchi) was among the most cited acupoints among pre-modern authors and modern research. Also, LI11 present traditional functions and location related to motor impairments in post-stroke patterns. PC2 (Tianquan) were selected as a control acupoint mainly because of tis location.

2.4 Outcomes

The primary outcome of this study is the RMS value estimated from sEMG signals and MIVC values. All signals will be stored for off-line processing by another author (ASF). sEMG signals will be bandpass filtered (cut-off frequencies: 5-450 Hz, Butterworth 2nd order, bidirectional) and an automatic, double-threshold method[30] will be used to detect periods of

myoelectric activity before estimation of RMS on each detected epoch. The average value of all detected epochs will be used as a representative value of RMS. Force signals will be lowpass filtered (cut-off frequency: 5 Hz, Butterworth 2nd order, bidirectional) and synchronously segmented with sEMG. The maximum value among all detected epochs will be used as a representative value of MIVC. No normalization will be performed on the sEMG signal amplitude.

Secondary outcomes of this study comprise the frequency of patterns in each group, as well as the frequency distribution of manifestations. Additionally, by comparison of the estimated probabilities of the linear regression model[23] between HG and CG, a cut-of value will be determined and its accuracy evaluated in the studied sample.

2.5 Sample Size

Sample size estimation was based on equations for binary outcomes between two proportions (RMS decrease or not), considering α=5% (Z_α=1.96; significance level) and β=80% (Z_β=0.84; power of test)[31]. A sample size of 36 subjects is necessary to observe reduced RMS values on at least 80% of the sample after acupuncture at LI11 (intervention acupoint) as compared to a 50% (random) probability in the group after stimulation at PC2 (control acupoint). The calculated sample size was inflated by 10% to account for potential losses, yielding 39 healthy and post-stroke individuals.

2.6 Randomization and blinding

Four parallel groups will be randomly generated using a web-based random numbers generator[32]. Two sets of numbers (one per group) with 39 numbers each will be sorted, annotated and inserted into envelopes that will be sealed before distribution to volunteers by the author (APFS). Envelopes contain one of the following guidance for intervention: PC2 in

non-dominant arm of healthy individual, LI11 in non-dominant arm of healthy individuals, PC2 in the paretic upper limb, and LI11 in the paretic upper limb. Volunteers will receive their envelope in order of arrival. The researcher will open the envelope to determine the guidance for acupuncture but will not report to the patient the actual acupoint name. Signals will be stored without referring to the selected acupoint to allow a blinded signal processing of sEMG data by another author (ASF).

3. Discussion

This work proposes a study design protocol for evaluation of the immediate effects of acupoints manual stimulation on the biceps brachii electrical activity and isometric strength in healthy individuals and post-stroke patients. Several difficulties rise when planning a study design with an integrative approach and are discussed in here.

Although pattern differentiation has been used to increase the efficacy of CM intervention[33], it was decided to not base acupuncture prescription on the identified pattern until clear evidence of neurophysiologic effect is observed. Moreover, single acupoints and not complex prescriptions are proposed to avoid confusion bias on the expected physiologic effect. LI-11 is among the top-three acupoints most cited by both pre-modern and modern CM authors[29] and therefore it is considered as a representative site for stimulation of muscles in the upper extremity. From another aspect, sEMG signals present limitations that may influence the interpretation of physiologic responses to acupuncture such as crosstalk, dependency on voluntary activation of muscles, and high inter-subjects variability[34]. Additionally, normalization of sEMG is often a necessary step for reducing inter-subject variability but it will not be performed because both pre and post test conditions comprise MIVC. It is considered that analyzing the dichotomous status (decrease or increase of RMS values) is an adequate substitute to account for the inherent inter-subject variability on sEMG

values.

Planning clinical trials with an integrative design is challenging but is a necessary task to investigate CM therapeutic effects. It is expected that new insights will be provided by this study design regarding the neuromuscular effects of manual acupuncture in healthy and post-stroke subjects.

Competing interests

None declared.

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Author's contribution

APSF designed the study, performed questionnaire interview, evaluated the subjects for enrollment in the study, and drafted the manuscript. ASF designed the study, developed the computational methods for pattern differentiation, performed the statistical analysis, and drafted the manuscript. All authors revised and approved the final version of the manuscript.

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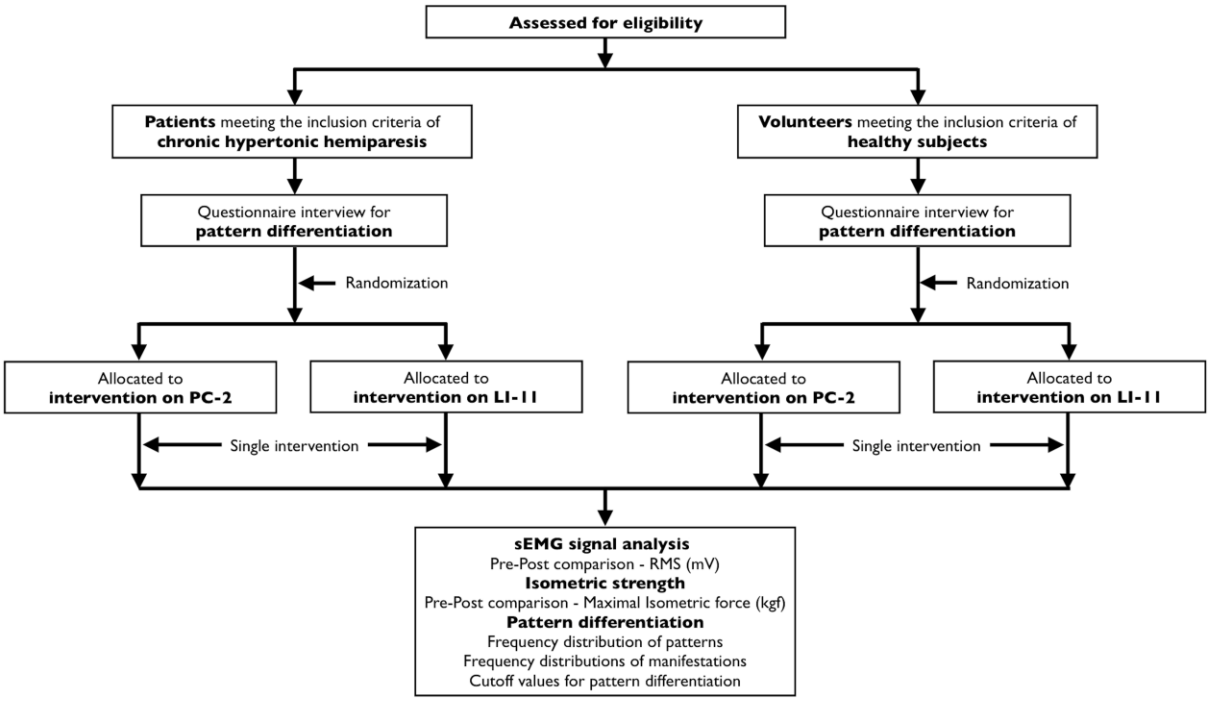
Figure legends

Figure 1: Flowchart of the study design.

Figure 2: Questionnaire for assessment of elegibility and pattern differentiation.


Assessed for eligibility
Patients meeting the inclusion criteria of chronic hypertonic hemiparesis
Volunteers meeting the inclusion criteria of healthy subjects
Questionnaire interview for pattern differentiation
Questionnaire interview for pattern differentiation
Randomization
Randomization
Allocated to intervention on PC-2
Allocated to intervention on LI-11
Allocated to intervention on PC-2
Allocated to intervention on LI-11
Single intervention
Single intervention
sEMG signal analysis
Pre-Post comparison - RMS (mV)
Isometric strength
Pre-Post comparison - Maximal Isometric force (kgf)
Pattern differentiation
Frequency distribution of patterns
Frequency distributions of manifestations
Cutoff values for pattern differentiation

1. Identification

1.1 Number: _____ 1.2 Name (initials):_____ 1.3 Age:_____ years 1.4 Gender: ❑ M ❑ F

1.5 Dominant side: ❑ Right ❑ Left 1.6 Weight:_____ kg

1.7 Height:_____ m 1.8 Heart rate:_____ BPM 1.9 Blood pressure:_____/_____ mmHg

2. Clinical characterization

2.1 Etiology: ❑ Ischemic ❑ Hemorrhagic 2.2 Location:_____

2.3 Affected side: ❑ Right ❑ Left 2.4 Time after first stroke _____ months

2.5 Tone of the affected upper limb: ❑ Hypertonia ❑ Hypotonia ❑ Eutonia

2.6 Degree of active flexion of elbow: ❑ Total-0º ❑ Total-90º ❑ 90º-0º

2.7 Space-time orientation: ❑ Yes ❑ No 2.8 Lucidity: ❑ Yes ❑ No 2.9 Communication: ❑ Yes ❑ No

3. Inspection

3.1 Overweight [1]: ❑ Yes ❑ No 3.2 Flushed cheek ❑ Yes ❑ No 3.3 Eye congestion: ❑ Yes ❑ No

Complexion: ❑ 3.4 Pale ❑ 3.5 Yellow ❑ 3.6 Reddened ❑ 3.7 Darkish ❑ N/A

Color of the tongue: ❑ 3.8 Pale ❑ 3.9 Pale red ❑ 3.10 Red ❑ 3.11 Bluish-purple

Body of the tongue: ❑ 3.12 Ulcerated ❑ 3.13 Teeth-marked ❑ 3.14 Enlarged ❑ 3.15 Spotted ❑ 3.16 Mirror ❑ N/A

Tongue Fur: ❑ 3.17 White ❑ 3.18 Yellow ❑ 3.19 Dry ❑ 3.20 Thick ❑ N/A

4. Auscultation - Olfaction

4.1 Phlegm rale ❑ Yes ❑ No 4.2 Faint low voice ❑ Yes ❑ No

5. Questionnaire

5.1 Eyeball dryness	❑ Yes ❑ No	5.2 Insomnia	❑ Yes ❑ No
5.3 Constipation	❑ Yes ❑ No	5.4 Fatigue	❑ Yes ❑ No
5.5 Chest discomfort	❑ Yes ❑ No	5.6 Borborigmus	❑ Yes ❑ No
5.7 Heat in the palms and soles	❑ Yes ❑ No	5.8 Nausea	❑ Yes ❑ No
5.9 Afternoon tidal fever	❑ Yes ❑ No	5.10 Halitosis	❑ Yes ❑ No
5.11 Reversal cold of the extremities	❑ Yes ❑ No	5.12 Night sweating	❑ Yes ❑ No
5.13 Frequent urination	❑ Yes ❑ No	5.14 Profuse sweating	❑ Yes ❑ No
5.15 Aversion to heat	❑ Yes ❑ No	5.16 Headache	❑ Yes ❑ No
5.17 Vexing heat in the extremities	❑ Yes ❑ No	5.18 Bitter taste in the mouth	❑ Yes ❑ No
5.19 Reddish yellow urine	❑ Yes ❑ No	5.20 Thirsty	❑ Yes ❑ No

6. Palpation

Depth: ❑ 6.1 Floating ❑ 6.2 Deep Width: ❑ 6.3 Thin ❑ 6.4 Flooding

Strength: ❑ 6.5 Strong ❑ 6.6 Vacuous Speed [2]: ❑ 6.7 Rapid ❑ 6.8 Slow

Characteristic: ❑ 6.9 Slippery ❑ 6.10 Rough ❑ N/A

7. Exclusion criteria

7.1 Myopathies	❑ Yes ❑ No	7.2 Serious peripheral nerve injury	❑ Yes ❑ No
7.3 Poor Nutrition	❑ Yes ❑ No	7.4 Serious peripheral circulatory injury	❑ Yes ❑ No
7.5 Uncontrolled hypertension	❑ Yes ❑ No	7.6 Severe cardiopulmonary disease	❑ Yes ❑ No
7.7 Coagulation disorders	❑ Yes ❑ No	7.8 Acute inflammation in affected arm	❑ Yes ❑ No

8. Group and intervention

Group: ❑ 8.1 Case (post-CVA) ❑ 8.2 Control	Intervention: ❑ 8.3 XB-2 ❑ 8.4 DC-11

[1] BMI>23 kg/m^2

[2] Fast>5 pulses/ breathing; Slow<4 pulses/breathing

Table I: Location of acupoints selected for the study.

	Acupoint	
Description	***Quchi* (LI-11)**	***Tianquan* (PC-2)**
Status	Intervention acupoint	Control acupoint
Location	With the elbow flexed, the radial end of the elbow, at the midpoint of the line connecting *Chize* (LU5) to the lateral epicondyle of the humerus	On the medial side of the arm, 2 *cun* below the anterior end of the axillary fold, between long and short heads of biceps brachii
Therapeutic actions	Expels exterior wind, clears heat, cools the blood, resolves dampness, regulates the qi and blood and nutritional benefits tendons and joints	Local
Reasons for prescription	It is the second most frequent prescription of the treatment of stroke in the literature. In addition to his actions, it is the point of the channel *yang* situated more proximal to the evaluated muscle	Regarding the points of *yin* meridians that run along the front of the arm, is the point which is located on the biceps

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Immediate effects of acupuncture on biceps brachii muscle function in healthy and post-stroke subjects: Results of a parallel-group, randomized, controlled trial

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Abstract

Background

Results obtained on the effects of acupuncture on muscle function in healthy subjects are contradictory and cannot be extrapolated to post-stroke patients. This study evaluated the immediate effects of manual acupuncture on myoelectric activity and isometric force in two parallel groups.

Methods

A randomized clinical trial, with parallel groups, single-blinded study design was conducted with 32 healthy volunteers and 15 post-stroke patients with chronic hemiparesis. Surface electromyography from biceps brachii during maximal isometric voluntary tests was performed before and after 20-minute intermittent, manual stimulation of acupoints LI11 or PC2. Pattern differentiation was performed by an automated method based on logistic regression equations.

Results

Healthy volunteers showed a decrease in RMS values after stimulation of LI11 (pre: 1.392±0.826 V; post: 0.612±0.0.320 V; P=0.002) and PC2 (pre: 1.494±0.826 V; post: 0.623±0.320 V; P=0.001). Elbow flexion MIVC was not different after acupuncture stimulation of LI11 (pre: 22.2±10.7 kg; post: 21.7±9.5 kg; P=0.288) or PC2 (pre: 18.8±4.6 kg; post: 18.7±6.0 kg; P=0.468). Post-stroke patients exhibited no significant decrease in RMS values after stimulation of LI11 (pre: 0.627±0.335 V; post: 0.530±0.272 V; P=0.187) and PC2 (pre: 0.601±0.258 V; post: 0.591±0.326 V; P=0.398). Also, no significant decrease on MIVC was observed after acupuncture stimulation of LI11 (pre: 9.6±3.9 kg; post: 9.6±4.7 kg; P=0.499) or PC2 (pre: 10.7±5.6 kg; post: 10.2±5.3 kg; P=0.251). Different frequency of patterns was observed among healthy volunteers and post-stroke patients groups (χ^2=9.759; P=0.021).

Conclusions

Manual acupuncture provides sufficient neuromuscular stimuli to promote immediate changes in motor unit gross recruitment without repercussion in maximal force output in healthy subjects. Post-stroke patients exhibited no-significant reduction on myoelectric activity and

maximal force output after manual acupuncture and needs further evaluation with a larger sample.

Keyword

Manual acupuncture; Stroke; Motor impairment; Surface electromyography.

Trial registration

Brazilian Clinical Trials Registry RBR-5g7xqh

Background

Deaths related to cardiovascular disease are expected to increase up to 24 million in 2030 [1,2]. Although advances were achieved in primary and secondary preventive medicine, annually more than 70% of all strokes are first-ever events. These data reinforce the importance of management of risk factors for stroke. Also, they stimulate research on rehabilitation techniques that minimize both recovery time and neurologic impairments while maximize functional independence of post-stroke patients [3,4].

The possibility of scientific investigation of Chinese Medicine (CM) therapies with reliable instruments has motivated researchers to assess efficacy of CM intervention in stroke-related functional impairments. However, most controlled trials on acupuncture in post-stroke patients conducted in the last two decades failed to obtain significant, long-term improvement of the functional aspect [5], suggesting that new methodological approaches are needed such as observation of neuromuscular activity [6-9]. Surface electromyography (sEMG) has been used to evaluate muscle activity in health and morbid conditions in a noninvasive manner. sEMG signals allow the assessment of the proportion and duration of muscular activity as well as the neural recruitment strategies. Among several parameters for quantification of sEMG signals, the root mean-squared (RMS) value has been the most used time-domain parameter since it better reflects the relationship between muscle force and corresponding gross motor unit (MU) recruitment [10]. Hence, it can be used to monitor changes in myoelectric activity in rehabilitation interventions.

Results obtained from healthy subjects about the immediate effects of acupuncture on the sEMG parameters are contradictory and not clearly understood. Toma et al. [11] analyzed the sEMG signals of the flexor digitorum superficialis, flexor digitorum profundus, and semitendinous (n=17; 20-38 years). Interventions comprised of perpendicular needle insertion into these muscles during 15 minutes but no acupoint was specified. A significant increase in sEMG responses was observed during maximal knee flexion but no significant differences were observed for the handgrip sEMG values. Tough [12] analyzed sEMG activity of the common wrist extensor muscles (n=35; 18-70 years). All subjects randomly received: a) 20-minutes stimulation of *deqi* true at LI4 (Hegu) and LI10 (Shousanli) points; b) *deqi* false or inappropriate in the PC3 (Quze) and PC6 (Neiguan); and c) no stimulation considered as control. Results showed that sEMG was reliable (intra-class correlation coefficient= 0.9996), but no significant difference was observed among protocols. Costa & Araújo [13] investigated sEMG signals from the tibialis anterior muscle (n=15 per group, 18-25 years). The effects of

manual stimulation on acupoints ST36 (Zusanli) and SP9 (Yinlingquan) were evaluated by RMS value and maximal isometric voluntary contraction (MIVC) force estimated from sEMG and force signal, respectively. A significant reduction in RMS values was observed in both ST36 and SP9 immediately after acupuncture, but MIVC was significantly reduced only after stimulation of ST36. Therefore, as related to sEMG signals derived from those muscles, the signal should increase in tonification and decrease in sedation. However, no convincing data was provided to support this statement and no model was proposed to explain the observed results.

To the best of our knowledge, no study investigated the immediate effects of acupuncture on sEMG amplitude and MIVC in post-stroke patients. Also, results obtained from healthy subjects cannot be extrapolated to post-stroke patients due to several reasons. For instance, CM theory states that healthy subjects may present different frequency distributions of patterns compared to post-stroke patients with different responses to acupuncture. From the biopsychosocial model, the structural lesion observed in post-stroke patients imposes a limited control of muscle activation leading to different strategies for MU recruitment. Thus, this study is justified by the severity of motor impairments and functional disability arising from stroke and especially in the scientific community's responsibility to provide up-to-date methods for early diagnosis and treatment of these survivors.

The aims of this study were two-fold: 1) to evaluate the immediate effects of manual stimulation of acupoints on both electrical activity and strength of the biceps brachii muscle in two parallel groups (healthy individuals and post-stroke patients with chronic hypertonic hemiparesis); and 2) to propose a model to explain the relationship between acupoint stimulation and variables of muscle function (RMS and MIVC). It was hypothesized that manual acupuncture provide neuromuscular stimuli to promote immediate changes in gross MU recruitment and consequently muscle force in either healthy subjects and post-stroke patients.

Results

Clinical study 1: Muscle function of healthy volunteers

Results from sEMG and load cell signals are presented in Table 1. A significant decrease in RMS values was observed after stimulation of both LI11 (pre: 1.392±0.826 V; post: 0.612±0.0.320 V; P=0.002) and PC2 (pre: 1.494±0.826 V; post: 0.623±0.320 V; P=0.001). This result was not accompanied by a significant decrease on elbow flexion MIVC after

acupuncture stimulation of LI11 (pre: 22.2±10.7 kg; post: 21.7±9.5 kg; P=0.288) or PC2 (pre: 18.8±4.6 kg; post: 18.7±6.0 kg; P=0.468). No significant differences were observed between LI11 and PC2 acupoints in post-pre (Δ) values of MIVC and RMS (P=0.340 and P=0.391, respectively).

Repeatability analysis showed no significant difference on RMS values obtained from three repetitions of maximal voluntary effort before interventions on LI11 (P=0.885) or PC2 (P=0.892), as well as after stimulation of those acupoints (P=0.736; P=0.906; respectively). Similarly, MIVC force was also not significantly different among the three repetitions before interventions on LI11 (P=0.864) or PC2 (P=0.977), as well as after stimulation of those acupoints (P=0.763; P=0.986; respectively).

Clinical study 2: Muscle function of post-stroke patients

Post-stroke patients exhibited a behavior that differed from the one observed in healthy subjects (Table 1). Pre-intervention, MIVC values of all post-stroke patients were significantly reduced (50%; P<0.001) in comparison to healthy volunteers. No significant decrease in RMS values was observed after stimulation of both LI11 (pre: 0.627±0.335 V; post: 0.530±0.272 V; P=0.187) and PC2 (pre: 0.601±0.258 V; post: 0.591±0.326 V; P=0.398). This result was also accompanied by a no significant decrease on MIVC after acupuncture stimulation of LI11 (pre: 9.6±3.9 kg; post: 9.6±4.7 kg; P=0.499) or PC2 (pre: 10.7±5.6 kg; post: 10.2±5.3 kg; P=0.251). No significant differences were observed between LI11 and PC2 acupoints in ΔMIVC and ΔRMS (P=0.303 and P=0.220, respectively).

Repeatability analysis showed no significant difference on RMS values obtained from three repetitions of maximal voluntary effort before interventions on LI11 (P=0.933) or PC2 (P=0.750), as well as after acupuncture of those acupoints (P=0.998; P=0.731; respectively). Similarly, MIVC force was also not significantly different among the three repetitions before interventions on LI11 (P=0.480) or PC2 (P=0.970), as well as after stimulation of those acupoints (P=0.861; P=0.881; respectively).

Pattern differentiation

Significant different frequency distributions of patterns were observed among healthy volunteers and post-stroke patients (χ^2=9.759; P=0.021; Table 1). Two patterns – "Phlegm dampness" and "Qi deficiency" – were the most commonly identified among healthy subjects (47% and 35%, respectively, on each acupoint group LI11 and PC2). Among post-stroke

patients, pattern “Fire heat” was the most frequent one (LI11 group: 43%; PC2 group: 50%), followed by “Phlegm dampness”, “Qi deficiency” and “Yin deficiency” patterns.

Discussion

This study evaluated the immediate effects of manual stimulation of acupoints on both myoelectric activity and strength of the biceps brachii in two parallel samples. The main findings of this study comprise: 1) manual acupuncture immediately decreased RMS but not MIVC values in healthy subjects; 2) manual acupuncture did not immediately decreased RMS or MIVC values in post-stroke patients; 3) LI11 and PC2 elicited similar effects in both healthy and post-stroke groups; and 4) the frequency of identified patterns differ between the healthy and post-stroke groups.

Clinical study 1

The absence of significant difference among the three-repetition test suggests that the average values of RMS and MIVC are representative for further analysis in both parallel groups. Additionally, the MIVC value of healthy volunteers was similar to those previously reported (189N ≈ 19.3 kg) [14].

On the sample of healthy volunteers, RMS values were decreased immediately after acupuncture but without a respective significant change in MIVC. These results are similar to those reported by [13] in which the rationale for acupoint selection (specific indication versus location), methods for acupuncture stimulation (rotation every 5 minutes) and signal-processing details (epoch duration = 5 seconds; RMS estimation) are similar. Other studies that reported no significant difference on post-intervention RMS values [11,12] reported also samples similar to the present one and thus differences in sEMG signal analysis and maybe acupoint selection may explain the contradictory results. Toma et al. [11] reported the use of an inter-electrode distance of 32 mm and integration of sEMG signal during the entire range of motion divided by contraction time. Although the inter-electrode distance may be adequate to record relative contributions of deep and superficial MU [15], it is larger than currently recommended (<20 mm) [16]. Tough [12] used methods quite similar to those reported on the present study (sample size, intervention duration, etc.), acupoint selection (LI10 instead of LI11) and sEMG analysis (average of three trials, signal sampling frequency, statistical analysis, absolute amplitude values, etc.) except for epoch duration (10 seconds each for RMS estimation) but did not assessed MIVC. Finally, the recommendations from the Surface Electromyography for the Non-Invasive Assessment of Muscles (SENIAM) project [16] for

electrode positioning and signal processing were not reported [11-13] and may compromise external validity.

Clinical study 2

On the sample of post-stroke patients, neither RMS nor MIVC values were decreased after acupuncture stimulation. Clinical trials on acupuncture for post-stroke motor impairments often used functional outcomes to test the efficacy of such an intervention [5-7], while few researches used electromyography to evaluate the physiologic effects of acupuncture intervention in post-stroke patients. For instance, Zhao et al. [17] evaluated functional and electromyographic parameters (F-wave) and reported significant reduction in spasticity in chronic post-stroke patients submitted to 30 days of acupuncture due to reduced excitability of α-motoneurons. Yan & Hui-Chan [18] used functional scales, MIVC and electromyography (co-contraction ratio) in post-stroke patients with acute motor impairments and showed that 3 weeks of electroacupuncture significantly increased MIVC while decreased co-contraction of medial gastrocnemius and tibialis anterior. The latter authors attributed these results to enhancement of presynaptic inhibition o the hyperactive stretch reflex and disinhibition of voluntary commands to the α-motoneurons of the paretic muscles. To the best o our knowledge, this is the first study to present results on immediate effects of acupuncture stimulation on muscle function in this population.

The lack of significant difference in this sample was attributed to a combination of at least four factors. First, RMS pre-intervention values were lower (42.4%) in post-stroke patients than healthy subjects probably as a consequence of a lower MIVC (50.0%) – confirming the negative features of upper limb paresis in this sample. This implies in a different "operational point" of the force-MU recruitment relationship and may have influenced the sEMG signal composite pattern. Second, as pre-intervention values were reduced and baseline noise was not different during the 20-minute experiment, the possible range for reduction after intervention was compressed and then a larger sample might be necessary to detect a significant difference, if existent. Third, motor impairments are distributed among MU in such a manner that knowledge on the known neurophysiology of MU recruitment do not hold true for this population [19]. Fourth, chronic hemiparetic patients present reduced neuromuscular activation and muscle unloading but retained neuromuscular connectivity, which lead to changes in fiber type composition (mainly type-II fibers) in the affected limb [20]. Therefore, the results of this study should be considered as preliminary until a large-sample study confirm the results showed in this research. Also, it is suggested to perform pre

and post-intervention comparisons on smaller percentages of MIVC (*eg* 50%) to evaluate the effect of the above-cited issues.

An alternative model: From needle insertion to sEMG and MIVC interpretation

Currently, physiologic explanation for the observed neuromuscular behavior is limited to a "reflex loop" hypothesis but without clear explanations on physiologic mechanisms and enrolled structures [11-13]. Based on the current results and along with consideration on the sEMG signal characteristics and neurophysiology, a theoretical model was proposed for explanation of the results observed in healthy subjects that is compatible to the adaptive changes observed in post-stroke subjects and considers acupuncture technique.

Initially, insertion of the acupuncture needle 15 mm deep into the tissue penetrates the dermis and subcutaneous muscles and creates a small wound (needle radius = 0.2 mm) with probably fluid exudation [21]. Rotation of the needle following insertion promotes the mechanical coupling between the needle and connective tissue and causes winding of tissue surrounding the needle [22,23]. This mechanical signal (passive deformation) is transmitted to connective tissue cells and is amplified due to increased tissue displacement during needle rotation [19]. The superficial area of tissue deformation may reach 25 mm^2 or more around a single needle hole [23] and stimulates several afferent nerve types, evidenced by the variety of subjective report of the *deqi* sensation [24] most frequently described as "aching" or "soreness" [25]. Traditional theory states that *deqi* must be achieved and sustained throughout the session to maximize therapeutic effects and thus needle is intermittently manipulated at short-time intervals (3 to 5 minutes). Finally, a significant higher pullout force is necessary for needle extraction from real acupoints [26] with additional tissue injury due to connective tissue adherence to the needle tip. Altogether, CM acupuncture intervention (= needle insertion + intermittent manipulation with *deqi* + needle extraction) evokes an uncomfortable albeit supportable sensation during the entire session and sometimes is prolonged after intervention.

Regarding sEMG signal interpretation, it was reported that decreased MU discharge rate with pain is accompanied by changes in the population of MU used to maintain force [27]. Moreover, pain decrease MU synchronization with a consequent decrease in sEMG amplitude estimators mainly due to amplitude cancellation between positive and negative phase of the MU action potential [28]. Hence, decreased RMS (healthy group: -56% to -58%; post-stroke patients: -2% to -16%) and sustained MIVC (healthy group: 0% to -2%; post-stroke patients: 0% to -5%) values observed after acupuncture intervention in both LI11 and PC2 acupoints

are fully consistent with the sustained painful sensation causing decreased MU discharge but not MIVC. The lack of acupoint specific effects was also reported by other studies with sEMG [11,12] and other clinical outcomes [29] and is consistent with the results of the present study and the proposed model. Further studies are necessary to validate the proposed model, especially if the long-term effects are to be attributed to multiple short-term acupuncture stimulation on sEMG variables.

On the methods

The biceps brachii is well suited for sEMG analysis because of its long, parallel fibers with a main innervation zone often located at the muscle belly. Moreover, it is an important muscle commonly affected in upper neuron lesions. Although our parallel groups present different characteristics on gender and age at baseline, a recent study found no significant effects of gender and age (range: <10 to 70 years) subjects regarding electromyographic parameters obtained from the biceps brachii [30] and thus we believe that this factor had no major influence on the obtained results. As acupoints are distributed all over the body and are generally perforated with needles, other muscles also affected by stroke need evaluation. RMS is considered as the best parameter to represent levels of muscle activity due to the relationship between MU recruitment strategies and sEMG signal power but still fails to yield a general relationship with muscle strength [31]. Hence, changes in the RMS values of sEMG after an intervention may not rigorously reflect altered levels of neural drive to the muscle [31]. Additionally, recent studies have demonstrated that the high frequency band (>440 Hz) of sEMG signals allow an accurate estimation of the force-RMS relationship and needs further attention [32] to assess the robustness of the proposed model to changes in sEMG processing techniques.

On pattern differentiation

In the present study, CM pattern differentiation was performed by an automated model designed for post-stroke patients from a large sample study [33]. The interesting result is that despite the small sample size of post-stroke patients, this study support the CM theory that different frequency distributions of patterns may occurs between them and healthy subjects. However, a larger sample study and a proper study design may be necessary to provide more definitive conclusions on this issue. Nevertheless, the obtained results may be used to design studies on pattern differentiation, *eg* determining sample sizes based on prevalence of patterns. As a limitation, the binary logistic regression method was not yet validated and its

diagnostic accuracy is unknown. Moreover, it was not yet applied to a sample of healthy subjects until now. Ongoing research on this topic includes determination of diagnostic accuracy of the method in post-stroke patients, the establishment of cutoff points for probabilities estimates from each regression equation, and comparison with other automated methods for pattern differentiation [34-36]. As it was argued that pattern differentiation may lead to best therapeutic results [37], the automated model with highest diagnostic performance should be used in future clinical trials to determine the therapeutic intervention in a reproducible manner.

Conclusions

Manual acupuncture provides sufficient neuromuscular stimuli to promote immediate changes in MU gross recruitment without repercussion in maximal force output in healthy subjects. Post-stroke patients exhibited no-significant reduction on myoelectric activity and maximal force output after manual acupuncture and needs further evaluation with a larger sample.

Methods

A detailed description of this randomized clinical trial, with two parallel groups (described as ‘clinical study 1’ and ‘clinical study 2’, respectively), single-blinded study design has been published [38]. The flowchart of this study design is depicted in Figure 1. This study protocol followed recommendations of both the Consolidated Standards of Reporting Trials [39], Standards for Reporting Interventions in Clinical Trials of Acupuncture [40], and Declaration of Helsinki. Also, this study protocol was approved by the Institutional Committee of Ethics in research before execution (CAAE-0006.0.307.000-10). All subjects read and signed the written consent form after explanation on the research aims and methods.

Casuistic

Demographic characteristics are presented in Table 2. Healthy volunteers (clinical study 1; n=40) were selected among the academic institutional community and were included if presenting no pain, trauma or musculoskeletal injuries in the upper limbs, pregnancy, or any other contra-indication to acupuncture on clinical screening. Post-stroke patients (clinical study 2; n=22) were recruited from the Fluminense Rehabilitation Association (AFR) and were included if presenting clinical diagnosis of upper neurons lesion – confirmed by image exam – and a chronic (> 6 months), partial motor impairment on the upper limb plus the above-cited characteristics of healthy volunteers. The research was completed with 32 healthy

subjects and 15 post-stroke patients, all cases being excluded due to incomplete sEMG signal acquisition or sEMG low-quality signals.

Setup for signal acquisition

Location of acupoints was performed according to standard, modern Chinese [41,42]. LI11 was located with the elbow flexed, the radial end of the elbow, at the midpoint of the line connecting Chize (LU5) to the lateral epicondyle of the humerus. PC2 was located on the medial side of the arm, 2 *cun* below the anterior end of the axillary fold, between long and short heads of biceps brachii muscle. These sites were cleaned with sterile cotton soaped with 70% alcohol and moistened with a 0.90% saline solution for safety of the patient and improvement of sEMG signal conductivity. sEMG signals were collected using an analog device EMG400C (EMG System, SP, Brazil) connected to a computer by a data acquisition card (NI-6009, 14 bits; National Instruments, Texas, USA). Disposable, auto-adhesive double-disk electrodes (Ag/AgCl; diameter=10 mm; inter-electrode=10 mm; Hal Industria, SP, Brazil) were placed according to the SENIAM [22] recommendations for the biceps brachii (short head). Active differential electrodes (gain: 20x) were used to collect sEMG signals from surface electrodes to the analog device. Isometric force signals were acquired by a load cell (range: 0-200 kg; EMG System, SP, Brazil) connected to the same analog device synchronously to sEMG signals at a sampling rate of 1.0 kHz per channel. Algorithms written in LabVIEW (National Instruments, Texas, USA) were developed to record and process the signals in the time domain.

Procedures and intervention

On admission, all volunteers answered questions on their clinical status in a questionnaire form to perform pattern differentiation developed for post-stroke patients [32] (Additional file 1). In sequence, each volunteer was positioned in a chair with support for the upper limb to remain with the elbow at 90º (flexion) throughout the intervention in a room with controlled temperature (21-23ºC). Both acupuncture and signal acquisition were conducted by the same author (APSF) who is a physical therapist with specialized training obtained from a nationwide recognized institution and presenting 16 years of clinical experience.

Volunteers executed three repetitions of isometric elbow flexion at MIVC during 5 seconds interleaved by 2 minutes interval to allow resting and metabolic recovery. In sequence, unilateral slanted puncture (45º) of the selected acupoint was performed towards the direction of *qi* circulation with a sterile, disposable stainless-steel needle (Lizhou, China;

0.20x13 mm) at a depth of approximately 1.5 cm (the needle length was chosen to minimize the depth of needle insertion among all volunteers). Following insertion, needle was rotated clockwise until the volunteer reported the first *deqi*. Manual stimulation consisted of clockwise needle rotation lasting 10 seconds and it was performed immediately after needle insertion, 5, 10, 15, and 20 minutes, and should all be accompanied by the report of *deqi*. According to this needle manipulation, the stimulated traditional functions [40] generate an expectation of decreased RMS and MIVC values. After 20 minutes the needle was removed and signal acquisition was repeated. Surface electrodes were not removed during acupuncture intervention to avoid changes due to electrode position relative to the innervation zone and improve inter-subject reliability.

Rationale for acupoint selection

Two acupoints were selected for this research on the basis on previous studies [43] on acupoint prescription for stroke-related disorders. Acupoints LI11 (Quchi) was selected as the 'intervention acupoint' among the most cited acupoints among pre-modern authors and modern research. Also, LI11 presented traditional functions and its location is related to motor impairments in post-stroke patterns. PC2 (Tianquan) was selected as the active 'control acupoint' mainly because of its location.

Signal processing and study outcomes

The primary outcome of this study is the RMS value and MIVC estimated from sEMG and load cell signals, respectively. Signals were amplified by the analog device (gain: 2,000x) and digitally stored for off-line processing, which was performed by another author (ASF). Load cell signals were lowpass filtered (cut-off frequency: 5 Hz, Butterworth 2^{nd} order, bidirectional) and processed by an automatic, double-threshold method [44] that detected epochs of increased muscular force production for estimation of MIVC value on each detected epoch. The maximum value among detected epochs was used as the representative value of MIVC at the respective test condition (pre or post intervention). sEMG signals were bandpass filtered (cut-off frequencies: 5-450 Hz, Butterworth 2^{nd} order, bidirectional) and synchronously segmented with the load cell signal. All detected epochs were averaged to represent the RMS value at the respective test condition (pre or post intervention). In addition, the amplitude of a 5-seconds epoch of baseline signal was estimated with RMS for assessment of the lower boundary. Secondary outcomes of this study comprise the frequency distribution of patterns in each group.

Randomization and blinding

Four parallel groups were randomly generated using a web-based generator. Two sets of numbers (one per group) with 39 numbers per set in range 1-39 were sorted, annotated and inserted into sequentially numbered, opaque sealed envelopes before distribution to the volunteers by one of the authors (APSF). Each envelope contained the guidance of the acupuncture intervention: PC2 in non-dominant arm of healthy individual; LI11 in non-dominant arm of healthy individuals; PC2 in the paretic upper limb; and LI11 in the paretic upper limb. Volunteers received their envelope in order of admission to the study. The researcher opened the envelope to determine the guidance for acupuncture but did not report to the patient the actual acupoint name and function. Additionally, signals were stored without referring to the selected acupoint to allow a blinded signal processing of sEMG data.

Statistical analysis

Sample sizes were estimated from equations suggested to stroke-related outcomes [45]. A sample size of 36 subjects was calculated to observe reduced RMS values on at least 80% of healthy volunteers after acupuncture at LI11 (intervention acupoint) as compared to a 50% (random) probability in the same group after stimulation at PC2 (control acupoint) considering α=5% (Z_α=1.96; significance level) and β=80% (Z_β=0.84; power of test) [43]. Results from the healthy group were used to calculate the sample size for the post-stroke patients, yielding an estimated sample of 14 patients under the same α and β values.

Kolmogorov-Smirnov analysis showed that RMS (average of the three repetitions) and MIVC (average of the maximal value of each repetition) followed a Gaussian distribution. Intragroup (acupoint) analysis was conducted with unicaudal, paired student's t-test to test the null hypothesis that there was no difference on either RMS or MIVC between pre and post-intervention. Repeatability was tested with one-way ANOVA for differences among the three repetitions of isometric contraction separately for acupoint group and test condition (pre and post-intervention). Items in the questionnaire for pattern differentiation are considered as dichotomous variables (present=1; absence=0) used as input variables for the regression equations for pattern differentiation and descriptive statistics of patterns was provided. Chi-square (χ^2) test was used to test the null hypothesis of no difference in frequency distributions of patterns between healthy and post-stroke subjects. Statistical analysis was performed with SPSS® software and the significance level was considered at $P<0.05$.

Competing interests

None declared.

Acknowledgements

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Authors' contributions

APSF designed the study, performed questionnaire interview, evaluated the subjects for enrollment in the study, and drafted the manuscript. ASF designed the study, developed the computational methods for pattern differentiation, performed the statistical analysis, and drafted the manuscript. All authors revised and approved the final version of the manuscript.

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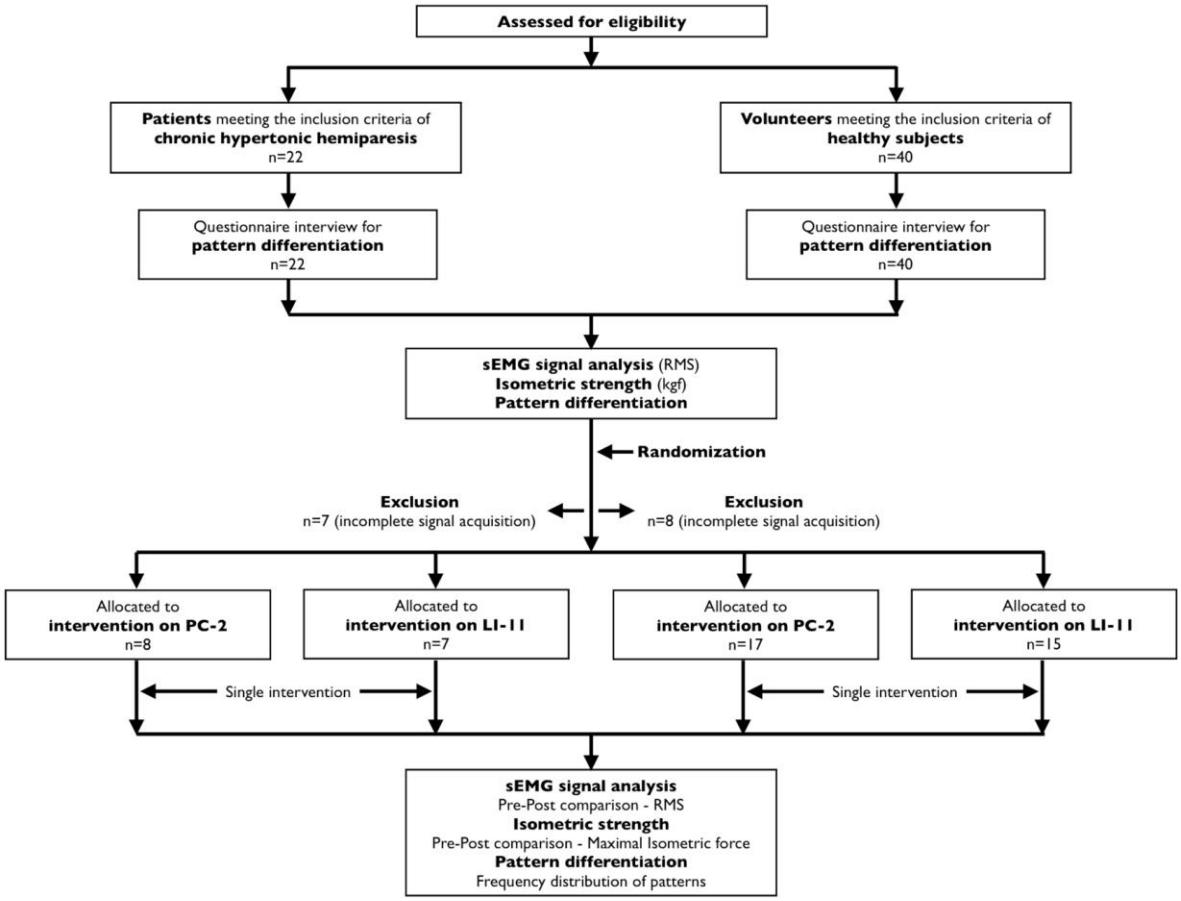
Figures

Figure 1 - Flowchart of the study.



Tables

Table 1 - Results from surface electromyography, maximal isometric voluntary contraction and pattern differentiation

	Healthy subjects		Post-stroke patients	
	LI11	**PC2**	**LI11**	**PC2**
Maximal isometric voluntary force, kg				
Pre-intervention	22.2±10.7	18.8±4.6	9.6±3.9	10.7±5.6
Post-intervention	21.7±9.5	18.7±6.0	9.6±4.7	10.2±5.3
P (post x pre)	0.288	0.468	0.499	0.251
P (∆MIVC LI11 x PC2)	0.340		0.303	
Root mean square value, V				
Baseline noise	0.105 ±0.010	0.115 ±0.026	0.202 ±0.085	0.179 ±0.052
Pre-intervention	1.392±0.826	1.494±0.826	0.627±0.335	0.601±0.258
Post-intervention	0.612±0.320	0.623±0.320	0.530±0.272	0.591±0.326
P (post x pre)	0.002	0.001	0.187	0.398
P (∆RMS LI11 x PC2)	0.391		0.220	
Identified pattern				
Fire heat	0 (0%)	3 (18%)	3 (43%)	4 (50%)
Phlegm dampness	7 (47%)	6 (35%)	2 (29%)	2 (25%)
Qi deficiency	7 (47%)	6 (35%)	1 (14%)	1 (13%)
Yin deficiency	1 (7%)	2 (12%)	1 (14%)	1 (13%)
P (healthy x patients)	χ^2=9.759; P=0.021			

Table 2 - Clinical data from studied sample

	Healthy subjects			Post-stroke patients		
	LI11	**PC2**	**P**	**LI11**	**PC2**	**P**
Sample size	15	17		7	8	
Female	11 (73%)	15 (88%)		2 (29%)	5 (63%)	
Male	4 (27%)	2 (12%)		5 (71%)	3 (38%)	
Age, y	24.1±6.0	26.1±6.6	0.381	50.9±19.2	50.9±0.3	0.126
Weight, kg	66.5±10.9	63.6±11.9	0.480	74.6±23.3	70.9±25.1	0.666
Height, m	1.64±0.07	1.65±0.06	0.940	1.70±0.33	1.67±0.32	0.388
Heart rate, b/min	74.3±11.1	75.8±11.0	0.717	76.9±25.5	81.8±0.4	0.578
Systolic pressure, mmHg	112.0±16.1	114.7±15.9	0.637	121.4±37.1	132.5±0.5	0.286
Diastolic pressure, mmHg	65.3±13.0	67.6±10.3	0.586	80.0±25.1	80.0±0.0	1.000

Additional files

Additional file 1 – Questionnaire for assessment of eligibility and pattern differentiation. This illustration presents the complete form grouped by: subject's identification; clinical characterization; inclusion criteria; manifestations regarding patterns distributed among the Examination methods; exclusion criteria; and acupoint assignment.

Considerações Finais

As diretrizes e os ensaios clínicos com intervenção por acupuntura em indivíduos com sequela sensoriomotora de AVC foram revisados para determinar o eixo ético-metodológico que as questões metodológicas e éticas levantadas por estudos clínicos com acupuntura apontam incongruências que vão desde a eleição da intervenção, aos métodos de avaliação e suas variáveis, bem como a ausência de critérios de randomização e controle e o uso de procedimentos placebo questionáveis. No levantamento bibliográfico sobre a etiopatogenia e fisiopatologia da hemiparesia, observou-se que as causas atribuídas ao AVC e suas sequelas não diferem significativamente desde os relatos clássicos chineses até os dias de hoje, e que os padrões sindrômicos achados com maior frequencia na população de hemiplégicos foram o de Fogo e Fleuma. Descrevendo a frequência de indicação dos acupontos para tratamento de sequelas sensoriomotoras a partir da literatura de MC clássica e contemporânea dectou-se que os canais Yang dos membros são os estimulados com maior frequencia e o IG4 o ponto mais citado entre os autores pesquisados. Por fim, ao verificar os efeitos imediatos da estimulação de acupontos em indivíduos sadios e pacientes hemiparéticos crônicos, por meio da EMGs, observamos que a acupuntura manual (IG11 e CS2) promove uma estimulação neuromuscular suficiente para gerar significativa redução do sinal recrutamento eletromiográfico de unidades motoras do bíceps em indivíduos sadios, mas o mesmo não aconteceu nos voluntários portadores de hemiparesia espástica crônica.

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Apêndice 1 – Carta de aprovação do comitê de ética

UNISUAM
COMPROMISSO PARA A VIDA TODA

Sociedade Unificada de Ensino Augusto Motta
Centro Universitário Augusto Motta

A (o) Sr. (a) Ana Paula de Sousa Fragoso
Pesquisador Principal

Registro CEP no. 018/2010
Título do Projeto: Efeitos imediatos da acupuntura manual sobre a função muscular do bíceps braquial de indivíduos saudáveis e hemiparéticos espásticos crônicos.

Sr (a) Pesquisador (a)

Informamos que o Comitê de Ética em Pesquisa da UNISUAM, em reunião realizada em 09/12/2010, avaliou o projeto "Efeitos imediatos da acupuntura manual sobre a função muscular do bíceps braquial de indivíduos saudáveis e hemiparéticos espásticos crônicos", o qual foi considerado "**APROVADO**", conforme parecer cuja cópia encaminho em anexo.

Estamos encaminhando a documentação pertinente para o CONEP, com vistas a registro e arquivamento.

Atenciosamente,

Dr. Júlio Guilherme Silva
Coordenador do Comitê de Ética em pesquisa
CEP - UNISUAM

Prof. Júlio Guilherme Silva
Coordenador do CEP / UNISUAM

Apêndice 2 – Termo de Consentimento Livre e Esclarecido

Título do Projeto: **Efeitos imediatos da acupuntura manual sobre a função muscular do bíceps braquial de pacientes hemiparéticos espásticos crônicos**

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

As informações contidas neste termo foram elaboradas para sua participação voluntária neste estudo, que tem como objetivo avaliar os efeitos da acupuntura manual sobre o músculo bíceps braquial, (situado no braço). Os resultados deste estudo serão úteis para conhecer o efeito dos pontos de acupuntura sobre a função muscular em pessoas sadias e em indivíduos com sequela de AVC (Acidente Vascular Cerebral). No grupo de pacientes acometidos de AVC, o procedimento é constituído de: Avaliação do grau de rigidez (espasticidade) do braço comprometido, avaliação geral, segundo a medicina chinesa, avaliação eletromiográfica, onde eletrodos adesivos gravarão os sinais elétricos imperceptíveis gerados pelo músculo durante a contração muscular. Após as avaliações que são realizadas de forma não-invasiva, uma única agulha de acupuntura será colocada em um ponto do braço, que permanecerá durante 20 minutos. Todo o procedimento levará aproximadamente 60 minutos. Os procedimentos serão executados da mesma forma no grupo de voluntários sadios, com exceção das avaliações neurológicas e da medicina chinesa. Durante a colocação da agulha, os voluntários podem experimentar a sensação de peso, formigamento ou irradiação (como um choque leve) no local, que pode ficar um pouco vermelho após a aplicação. Os benefícios que você poderá ter decorrente da participação neste trabalho incluem uma sensação de relaxamento ou de aumento de atividade e força do movimento de dobrar o cotovelo. Em qualquer etapa do estudo, você terá acesso ao profissional responsável (Dra. Ana Paula de Sousa Fragoso) que pode ser encontrada no telefone (22-81261646). Se tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o Comitê de Ética em Pesquisa (CEP): Av. Paris, nº 72 – Bonsucesso, Rio de Janeiro - RJ. Se desejar desistir do estudo em qualquer momento, você tem toda liberdade de fazê-lo, garantindo que a recusa de participação não acarretará penalização no seu cuidado. As informações a serem recebidas durante o estudo serão analisadas em conjunto com as informações obtidas de outros voluntários, não sendo divulgada a identificação de nenhum participante. Tais informações serão utilizadas pelos pesquisadores envolvidos no projeto para fins estatísticos e científicos e não será permitido o acesso a terceiros, garantindo assim proteção contra qualquer tipo de discriminação. Se desejar, você pode ser informado sobre os resultados parciais da pesquisa. Não haverá despesas pessoais para o participante em qualquer fase do estudo, nem haverá compensação financeira relacionada à sua participação. Em caso de dano pessoal diretamente causado pelos procedimentos propostos neste estudo, você terá direito a tratamento médico, bem como às indenizações legalmente estabelecidas. Acredito ter sido suficientemente informado a respeito das informações sobre o estudo acima citado que li ou que foram lidas para mim. Eu discuti com a Dra. Ana Paula de Sousa Fragoso (CREFITO-2 n°13111), sobre a minha decisão em participar nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que minha participação é isenta de despesas, que tenho garantia de acesso a tratamento hospitalar quando necessário e que não implica em tratamento regular no ambulatório de acupuntura da Associação Fluminense de Reabilitação. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido.

_____ Nome/Assinatura do participante	Data: ____/____/____
_____ Dra. Ana Paula de Sousa Fragoso	Data: ____/____/____