

APPA: an auricular acupuncture protocol for the attenuation of pain and anxiety in humanitarian aid environments



A consensus study to determine a theoretically safe and effective beta protocol

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AIM

To construct a theoretically safe, effective standardised auricular acupuncture (AA) protocol, suitable for use in humanitarian aid environments (HAEs), by consensus.

The protocol is known as APPA (the Auricular Protocol for Pain and Anxiety).

BACKGROUND

The 21st century has seen an increase in armed conflict and natural/man-made disasters, and a rise in the number of global citizens living in conditions of extreme deprivation (collectively identified in this study as HAEs).¹ The general health conditions most prevalent in HAEs are anxiety² and pain,³ including long-term issues arising from physical and psychological distress.⁴ Current medical aid is focused on pharmacological interventions, which have drawbacks including cost, shelf-life, transportation and storage.⁵

AA may offer several advantages in humanitarian aid environments, being cost-effective⁶, comparatively light and space-saving in transportation, having a long shelf-life and little requirement for specialist storage.

When delivered in a standardised form, AA requires relatively little training, no verbal communication and no diagnostic skills to administer safely, effectively and swiftly. This helps to enable wide-scale treatment programmes by local practitioners, increasing local resilience in vulnerable populations and decreasing reliance on outside agencies at a time of acute humanitarian crisis.⁷

AA has been used as an adjunctive therapy in several humanitarian aid situations, mostly in the form of the NADA protocol;⁸ however, there is no methodologically robust evaluation of NADA's effectiveness for pain and anxiety in humanitarian aid environments.

This study set out to determine whether it was possible, by consensus, to construct a standardised AA protocol that is *theoretically* safe; effective in attenuating pain and anxiety; quick to administer; cost-effective; capable of delivery to the greatest number of patients possible, by (local) volunteers without extensive training or any diagnostic skills, using little or no verbal communication; in the challenging treatment conditions typical of humanitarian aid environments.

STUDY DESIGN & METHODS

This study used the Internet-Based Iterative Sequential (Mixed-Methods) structured consensus model in a concurrent monostrand form, with correlational analysis between qualitative and quantitative data.⁹

A literature review was conducted to assemble a list of components (AA points effective in attenuating pain and anxiety; safety procedures; effectiveness procedures) and a list of participants. Two highly experienced acupuncturists (Harriet Lansdown (HL) and Hugh MacPherson (HM)) agreed to act as consultants to the study.

71 AA experts across the world were invited to participate, of which 31 became participants. Questionnaires with quantitative and qualitative elements were designed in Microsoft Word™ and disseminated by email between June and August 2014.

The study sought to refine the longlist of components (including any 'extra' components suggested by participants) over three rounds of consultation, according to the principle of greatest level of agreement. Post-hoc one-

way repeated-measures Analysis of Variance and t-tests were carried out to determine statistically significant levels of agreement.

Four of the original n=31 participants dropped out, and one participant withdrew from the study.

Correlational analysis techniques¹⁰ were applied to interpret qualitative and quantitative data in the light of each other. Successive questionnaires provided a flexible and responsive iterative mechanism for checking and consolidating emergent themes.

An 'active management' approach was adopted, to produce a protocol with maximum theoretical utility in the target environment. This entailed the pragmatic exercise of the clinical, practical and educational judgement of the researcher, validated by the consultant acupuncturists, to moderate outcomes produced by consensus where these were contraindicated by this study's Aims. All decisions taken by 'active management' were submitted to consensus, and were deemed acceptable by inference.

DISCUSSION

Component instability

Between the various traditions of AA (Chinese, European and the 'vagus nerve stimulation' tradition), there are extensive inconsistencies between *name*, *location* and *function* of many AA points.^{11,12,14} This phenomenon was named 'component instability' by this study; it presented multiple difficulties for research, including confusion amongst participants. This phenomenon did not prevent a consensus being reached on a high level of theoretical safety and effectiveness of the draft protocol, but may have affected quality of consensus outcome, i.e., the beta APPA protocol itself.

The standardised protocol: can one size fit all?

There may be safety implications for standardised protocols; some of the functions claimed by AA's most respected sources^{11,12,14} for the points in the APPA protocol (in common with other standardised AA protocols) may not be appropriate to all patients. It remains unclear why trials of standardised AA protocols to date have not reported any patient harms of this kind.

The possibility of personal bias:

The exercise of 'active management' allows the possibility of the researcher's personal bias to potentially affect outcomes. The COREQ¹³ standards for reporting qualitative research require transparency in the form of researcher biography; these were provided by KC, HL and HM. However, it is suggested by this study that study-wide personal bias 'indicators' should be developed as part of reporting standards for qualitative research.

FINDINGS

The final draft APPA protocol was assembled by a combination of consensus and 'active management' processes. It comprises five AA points delivered bilaterally (Figure 1): Shen Men, Sympathetic Autonomic, Point Zero, Thalamus and Tranquilliser.

The points are supported by seven 'effectiveness' procedures covering issues such as dosage levels and retention time; and six 'safety' procedures including practitioner hand hygiene, patient ear cleansing and disposal of waste.

The safety and effectiveness of the draft protocol attracted a high level of agreement between participants at the final round of consultation (Figure 2), which was confirmed by post-hoc ANOVA data analysis (Figure 3).

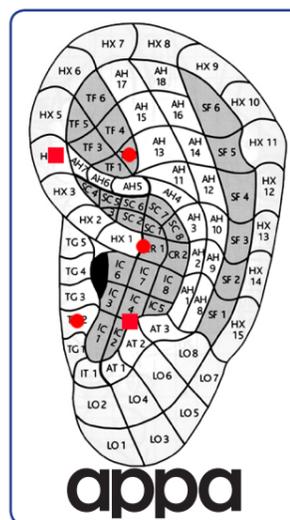


Figure 1: the beta APPA protocol

Points	%/# rating >=8/9
Points	46.2% (n=12)
Effectiveness procedures	69.2% (n=18)
Safety procedures	84.6% (n=22)

Figure 2: Levels of agreement on safety and effectiveness of draft protocol

Effect	Value	F	Hypothesis df	Error df	p-value
TimeAndQuestionnaires Wilks' Lambda	.242	21.907 ^b	2.000	14.000	.000

Figure 3: Results of one-way repeated measures ANOVA analysis showing a significant effect of 'time and questionnaires' on participants' levels of agreement

CONCLUSIONS

This study met its aims of formulating a beta AA protocol that was agreed by experts to be *theoretically* safe and effective in HAEs. However, this result was not achieved by the consensus process alone, as it required some 'active management' by the researcher and consultant acupuncturists. Some methodological limitations may also have affected the quality of the outcome.

It is recommended that the APPA beta protocol should progress to a series of rigorous trials, designed to take account of the limitations encountered in this study, to ascertain whether *theoretical* safety and effectiveness translate into *actual* safety and effectiveness.

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