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ORIGINAL ARTICLE

Retrospective Cohort Study

Can PC-9 Zhong chong replace K-1 Yong quan for the acupunctural resuscitation of a bilateral double-amputee? Stating the "random criterion problem" in its statistical analysis

Adrián Ángel Inchauspe

Adrián Ángel Inchauspe, Department of Reseach, HINEA Interzonal Neuropsychiatric Hospital Dr. Alejandro Korn, Melchor Romero, La Plata, Buenos Aires, Aires B1884CUB, Argentina

Author contributions: Inchauspe AÁ solely contributed to this manuscript.

Institutional review board statement: Having consulted on the specific issue with Professor Carlo Guinzburg-Emeritus Professor at Bologna University and promoter of the Index Paradigm - and then submitted this proposal as regards the subjectivity of randomness in scientific research, a protocol for a pilot study was presented to the authorities of the Joint Committee on Health Research and the Central Ethics Committee of the Province of Buenos Aires-the highest authorities in our region-for its approval.

Informed consent statement: Regarding that these victims are unable to give their consent during an "impending death situation", quoted Central Ethics Committee proposed the publication in regional mass media to inform its population about that hospitals will adhere to this protocol.

Conflict-of-interest statement: The author reports no conflict of interest.

Data sharing statement: Consent was not obtained but the potential benefits of sharing these data outweigh the potential harms because, as mentioned before, Central Ethics Committee proposed the publication in regional mass media to inform its population about that hospitals will adhere to this protocol.

Correspondence to: Adrián Ángel Inchauspe, MD, PhD, Department of Reseach, HINEA Interzonal Neuropsychiatric Hospital Dr. Alejandro Korn, Melchor Romero, La Plata, Buenos Aires, 14-4079, Berazategui B1884CUB, Argentina. adrian.inchauspe@yahoo.com.ar
Telephone: +54-11-42561616
Fax: +54-11-42561616

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Abstract

AIM: To present an inclusion criterion for patients who have suffered bilateral amputation in order to be treated with the supplementary resuscitation treatment which is hereby proposed by the author.

METHODS: This work is based on a Retrospective Cohort model so that a certainly lethal risk to the control group is avoided.

RESULTS: This paper presents a hypothesis on acupunctural PC-9 Zhong chong point, further supported by previous statistical work recorded for the K-1 Yong quan resuscitation point.

CONCLUSION: Thanks to the application of the resuscitation maneuver herein proposed on the previously

mentioned point, patients with bilateral amputation would have another alternative treatment available in case basic and advanced CPR should fail.

Key words: PC-9 Zhong chong; Alternative emergency point; Cardiac arrest; Double; Amputee patients

Core tip: The aforementioned inclusion criterion for the impossibility of stimulating K-1 Yong quan introduce PC-9 Zhong chong stimulation, so that the Shao Yin energetic level may be reactivated, restarting this biological pacemaker and the cardiac function. Diabetes increases risk of cardiovascular and cerebrovascular diseases from 50% to 80%; and every three seconds, a diabetic foot is amputated in the world. The proposed study upon a prospective non-intervention group, considering the "patients that may be deceased", states a Retrospective Cohort Study model that will allow us to efface the contingentiality of a possible "fatal damage".

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INTRODUCTION

Research on K-1 was presented back in 2005, during an official account at the Congress Celebrating the Fiftieth Anniversary of the Argentine Acupuncture Association[1], which encouraged us to continue doing research on efficiency criteria derived from its application.

That account was published by *Resuscitation*[2] in April 2010 to an important global repercussion. To date, ever more rescue cases through Yong quan are recorded and several hospitals resort to replacing their protocol due to the increased interest its extraordinary results generate.

This research project was edited first as a cover note in the *World Journal of Critical Care Medicine*[3], whose editorial presented then the validation of its statistical sequence, and now requests the publication of a new, original, paper on this issue of paramount importance.

We shall review the anatomical and functional bases for our hypothesis as well as the parameters which justify its use from the point of view of Traditional Chinese Medicine.

Topographic anatomy of PC-9 Zhong chong

Traditionally, the point is located 0.1 cm from the base of the nail on the radial side of the hand's middle finger. This soft region is innervated by the palmo-digital arteriovenous net which is irrigated by the digital branch of the median nerve[4].

Rather curiously, the finger we refer to is also known as "cordial or heart finger" in Spanish [*dedo cordial* or *corazón*], thus discarding any causal nominative association from its anatomic-functional value. To a certain extent, such names in Spanish connote a close relationship between such finger and the organ it protects[4].

Functions of Zhong chong

PC-9 Zhong chong is the Tsing-well point of the Xin Bao meridian, or "Heart Protector". It is also the Wood-Cheng point of a Fire channel and, as such, it should not surprise its additional function of Stimulating Point of that channel, precisely because it precedes the Fire element in the Five Movement Theory of Traditional Chinese Medicine[4].

Maybe what has been stated before justifies its capacity to reduce the Heart Fire (*Xin*) on that channel: Deriving from either its ignition by excess or the plenitude of its Mother element in the generative cycle, *i.e.,* Wood[5] (Table 1).

This may explain the therapeutic possibility of acting on said channel in order to alleviate every cardiovascular condition resulting from affecting Fire, as well as those effects proper to its state of Well point, which enables restoring the biological pacemaker of the organism. This may either derive from considering gastro-entero-colonic peristalsis to even the very cardiac pacemaker present at the sinoauricular node. This meridian has -under the parameters of Chinese Medicine - the justified property of recovering the Heart from its most severe nosological conditions.

Thus, the Xin Bao channel is provided with points with *Yin/Yang* energy rebalancing properties for the body, consequently harmonizing its biological rhythms. As we previously stated, this enables this point to act as an effective cardiac pacemaker. For this reason, it has been chosen as an Alternative Emergency Point (in case of coma, sudden death or cardiac arrest*)* because of its direct connection with the Shao Yin energetic plane through a short channel branch running between PC-1 to K-27 (Figure 1).

That is the case of another point, namely, PC6-*Nei guan*, *Luo* meridian link and root, able to open up the *Extraordinary Yin Wei Vessel* and, consequently, to regulate the cardiovascular, respiratory and digestive activity of our body. That is why we understand its specific antiemetic property, comparable in strength to that of a well-known medicine ondansetron, widely used as palliative for said collateral effect during anti blastic therapies[6].

MATERIALS AND METHODS

Materials

Materials for the purposes of this paper are a wide range of patients who, for different reasons, have no lower limbs, that situation being the result of a

Table 1 Heat patterns affecting pericardium[5]

Pattern	Heat colapsing pericardium	Murky mucosity obstructing pericardium
Consciousness	Coma; convulsions	Coma; patient sometimes awake
Fever	High fever	Low fever
Fæces	Constipated or no change	Inconsistent
Pulse	Weak or tense and fast	Sunken or unstable and fast
Tongue	Scarlet, with yellow fur	Red, with white or greasy fur

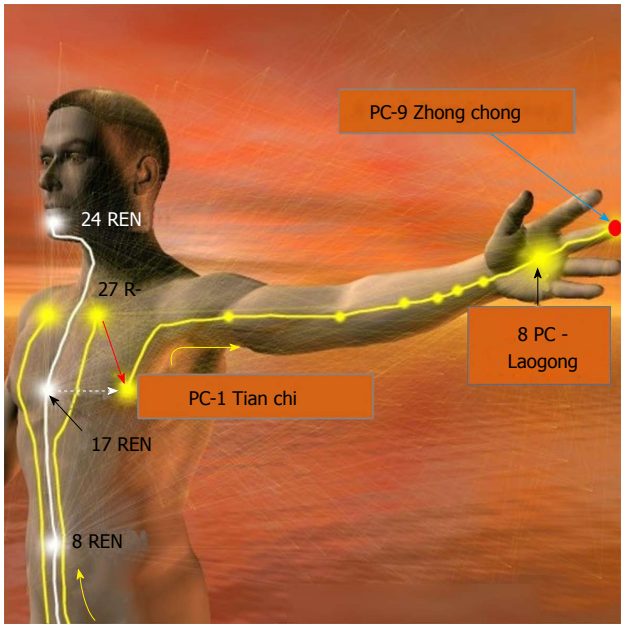

Figure 1 Establishing the connection between Xin Bao and Shao Yin. Source (modif.): http://www.ktthome.com/teorias/mtc/teorias_mtc_1_1_2_8.html.

congenital cause or as a consequence of the evolution of a number of diverse pathologies (*e.g.,* diabetes, traumas, neurologic diseases, toxic causes, *etc.*).

The status of this patient-population - previously set aside from possibility of integration between the supplementary Yong quan resuscitation maneuver and ILCOR's CPR-can now be reconsidered among this new proposal of inclusion criteria. Quoted criteria have been made possible thanks to the development and design of a new, alternative praxis to assist this patient group during imminent death situations[3].

Methods

Those subjects within the Inclusion criterion above mentioned shall be those to whom-because of the impossibility of stimulating K-1 Yong quan-shall undergo stimulation at PC-9 Zhong chong, so that their Shao Yin energetic level may be reactivated as well as their survival axis, thus enabling the resetting and restarting their biological pacemaker and their cardiac function[7].

Stimulation maneuver for PC-9 Zhong chong

In spite of its habitual location described before, whenever in an emergency situation, it may prove convenient to unify topographical criteria and locate the very tip of the middle finger in order to stimulate the point by direct pressure in the distal extremity of its third phalanx, thus a more efficient stimulus is obtained and there is no confusion for the rescuer as to the location of the life-saving point.

It is worth mentioning that Traditional Chinese Medicine also considers valid this location we are proposing[4].

The Chinese indicated bleeding the point to make the maneuver effective; that is why it is better to apply direct pressure on the tip of the middle finger. However, we have been able to verify that the pressure exerted by the nail of the rescuer might be enough to achieve efficient stimulations and positive results on the cardiac pacemaker.

Initially, as in the case of Yong quan, a methodological design was proposed during the investigation in which a certain group would receive the treatment and another would not be benefited (*control group*). Such type of study makes reference to the *random criterion* in order to measure differences and, in that way, establish causal associations which may better determine the intervention mechanism.

Stating the random criterion problem

The randomness principle requires an ever increasing sample - following a *quantitative* interest - in order to get away from uncertainty, thus reducing the variability of fate. Being that generally the case in the validation of any statistical methodology applied in Medicine, it has to make an effort to prove if any association visible through observation is a product of fate or not[3,8].

As inferred by quoted criterion, the control group would not profit from the benefit of providing a second chance by means of the proposed maneuver during rescue. Such determination leaves those included in the control group *deserted to their own ill-fate* should basic and advanced CPR fail.

Application of statistical analysis based on the index paradigm[9]

As was the case while analyzing the Yong quan maneuver statistical tendencies-in spite of what has been so far stated, we have assigned priority to what, in our view, is singular and of qualitative nature. As such, the proposal of a Retrospective Cohort Study model has been able to prove the following suggested affirmation[9].

In statistics, a null hypothesis (Ho) is one made up

with the purpose of supporting another, alternative one (Ha). To develop any medical study necessarily implies determining an association between such two variables under research.

Any statistical treatment contemplates the possibility of a standard error (SE). That is why, the wider the sample, the more precise it becomes; consequently the possibility of results being random is greatly reduced [this analysis was previously published in *WJCCM* August 2013 - ISSN 2220-3141 (online)[3]].

In order to select one of these hypotheses (either Ho or Ha), a security level is required which, in clinical studies, has been standardized at 95%.

Statistical testing functions this way: The scale of difference that exists between the methods to be compared (A and B) needs to be verified. Should such scale be higher than a defined SE multiplied by a security coefficient - which is also given - we can then conclude that the difference between methods A and B is statistically significant. Such statement enables us to reject Ho hypothesis and accept Ha hypothesis[3].

First, we compared classical CPR by manual cardiac massage (method A) with the complementary resuscitation maneuver on Yong quan (method B). By August, 2013, the following values were obtained (out of 58 patients looked after and 9 dead ones):

Method A (Manual CPR) = 6.4% Method B: (Yong quan rescue) = 85%

Thus, if *P* = [PA - PB] = [0.064 - 0.85] = 0.786[3] (where *P* stands for Probability).

To this result, SE is applied, E = $\sqrt{P}$ (1 - P) × (1/n1 + 1/n2). Then, SE × 1.96 = 0.098.

Therefore, 0.786 is higher than 0.098, which demonstrates the difference between PA and PB to be significant, thus concluding that Yong quan rescue is quality sure.

In order to further verify the previous analysis, the sample obtained in May 2015 (with 76 patients looked after and 12 dead ones), rendered the following values:

Method A (Manual CPR) = 6.4% Method B (Yong quan praxis) = 84.21%

Thus, P = [PA - PB] = [0.064 - 0.8421] = 0.778

Again, the result verifies that 0.778 is higher than 0.098, which further debunks Ho hypothesis and once more verifies the alternative hypothesis (Ha).

Furthermore, in August 2013 we also compared the use of defibrillation (Method "A'" - meaning CPR + defibrillation) against the complementary Yong quan resuscitation maneuver (Method "B"). Afterlife indexes on both treatments were as follows:

Method "A'" (CPR + defibrillation): 48% response

Method "B" (Yong quan maneuver: 84.84% response

Thus, [PA' - PB] = 0.48 - 0.84 = 0.36

That, multiplied by SE: SE (0.0076) × 1.96 = 0.0148

Because this result is also higher than SE multiplied by 1.96, it provides a value of 0.00148, a figure which is also statistically significant. This, again, proves the statistical value of the supplementary resuscitation K-1 Yong quan point by means of comparative analysis[3].

Let us compare new values in these two methods provided in May, 2015:

Defibrillator method (Method A') = 30%

Yong quan method (Method B) = 84%

P = [PA - PB]; that is, P = [0.30 - 0.8421] = 0.542

Applying the same process of multiplication by SE: SE × 1.96 = 0.0148

Consequently, as 0.542 is higher than 0.0148, it can be deduced that the difference in P once more becomes significant, rejecting Ho hypothesis and giving support to Ha hypothesis, which implies that this sequence of studies is far from being a random, chance product.

The difference here is also confirmed to be statistically significant; thus, all of the considerations from the previous example are valid, demonstrating once more the comparative value of the Yong quan method[3] (Figure 2).

Even though today there are updated statistics in which manual CPR reached 17% survival rate (see, *e.g.*, www.ymca.org.ar), it is in fact estimated that the actual survival rate would be noticeably lower, this deriving from what results studies indicate.

According to what Dr. Custodio Calvo, member of the Spanish Cardiopulmonary Resuscitation Association, has mentioned, such estimated indices of survival would not for cardiac massage, if truth be told, go further than 5%[10]. Other studies later claim a rise up in survival rate to 10%[11] which, they estimate, may result in an increased value if population had more knowledge on CPR technique and use.

As for the survival percentages due to the application of cardioversion, recent studies presented by Dr. Emilio Marín-Huerta show that premature defibrillation increased this scale from 24% to 30% in cases of cardiac arrest[11]. It is worth noticing that the 2013 statistics made reference to the resuscitation carried out at casinos in Las Vegas, where there is a defibrillator available every 40 m.

As a matter of fact, statistics referring to extra-hospital resuscitations seem to have stuck at a 6.4%, a figure which coincides with the former evaluation of the previous statistical analysis which was presented by this author in this very same publication in August 2013.

It should be mentioned that, if cumulative rates of positive responses to the maneuver be considered (verified by pulse recovery and ECG record), the rate reached a 92.10%; *i.e.,* over 76 cases, 70 patients could manifest objective responses to K-1 stimulation.

Consequently, all the above has made clear that there actually exists a difference if one takes into account as control the group of "deceased patients" instead of considering among them "patients that may be deceased". Stating such consideration into a Retrospective Cohort Study model[9] will allow us to efface the contingentiality of a possible "fatal damage" as proposed by the randomness principle upon a prospective non-intervention group in both K-1 Yong quan

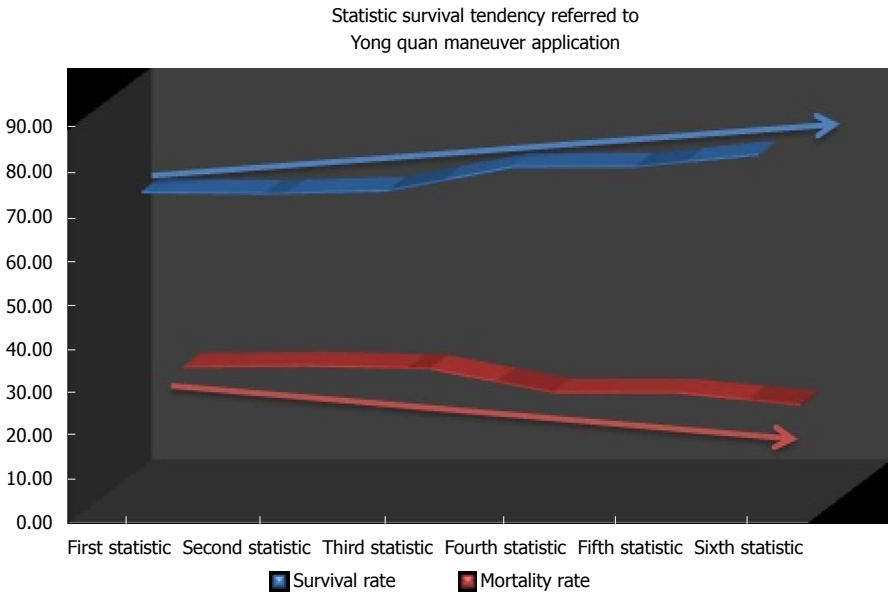

Figure 2 Statistic Survival Trend referred to the Yong quan Maneuver application[3].

and future PC-9 Zhong chong research.

RESULTS

Having had an experience of more than 75 cases treated when basic and advanced CPR had failed, the supplementary K-1 Yong quan maneuver has shown a most promising survival rate (84.84%) once the classic CPR protocols have been proved of no use, thus validating the action of the Shao Yin (heart-kidney) circuit during its support to life maintaining maneuvers[3].

As regards diabetes, the WHO has currently established the following statistics[12]: (1) one in 10 individuals is diabetic (*i.e.,* 10% of world population - about 347 million people worldwide have diabetes); (2) it is estimated that in 2012 diabetes was the direct cause of 1.5 million deaths, mainly due to sugar excess in the blood sample while fasting; and (3) every three seconds, a diabetic foot is amputated in the world these days.

Diabetes has become a major cause for an increased risk of cardiovascular and cerebrovascular diseases - between 50% and 80% of deaths in people with diabetes - making this condition the one which predisposes the most to suffering a stroke (this being, at the same time, cause and effect of cardiac arrest)[7].

From the aforementioned, one can fairly deduce that the group which this hypothesis addresses is one in constant growth, a global trend which apparently shall be only on the rise in the short and long run and make even more frequent the cases under study, quite similar to those already mentioned and studied.

DISCUSSION

The effect on the Shao Yin plane has been irrefutably demonstrated - through the resuscitations published-by stimulation the K-1 Yong quan. We have already made clear that this circuit is part of the so-called "survival axis", which has been confirmed in the Western tradition by the works carried out by Cannon and Seyle on the "fight or flight" or "stress" reaction[7,10] (Figure 3).

Likewise, there also exist relationships that establish their link for the heart governor channel as well. One of them is that Xin Bao has been found to be the "pulse wife" to kidney, located at the same height but on the left wrist or Yang.

Besides, it needs to be remembered that there exists a small collateral branch from K-27 - to the end of the external trajectory of the kidney meridian-through which it receives its daily chrono-biological legacy with the Well and Alarm point of the same *Heart Governor* channel, PC 1 - *Tian chi* (see illustration). According to the descriptions found on Acupuncture norms, the presence of such connection with the Shao Yin energetic plane fully justifies acting on that point when confronted to emergency situations caused by cardiac arrest.

Physiological testing in a bilateral double amputee and healthy volunteers showed significant changes as regards heart rate variation on stimulating PC-9 Zhong chong, very much like what took place when validation for the supplementary resuscitation maneuver on Yong quan was required.

All this justifies our assumption that in those cases in which K-1 stimulus is impossible, we can try successful stimulation when confronted with the unfortunate failure of both basic and advanced CPR. Its categorization as "alternative supplementary pacemaker" when stimulation on K-1 point is rendered impossible shall eventually be more accurately established by a pilot study that shall reliably verify the statistical value of its effects, as was required from the supplementary practice on the Yong quan.

In conclusion, the Heart Governor meridian-through

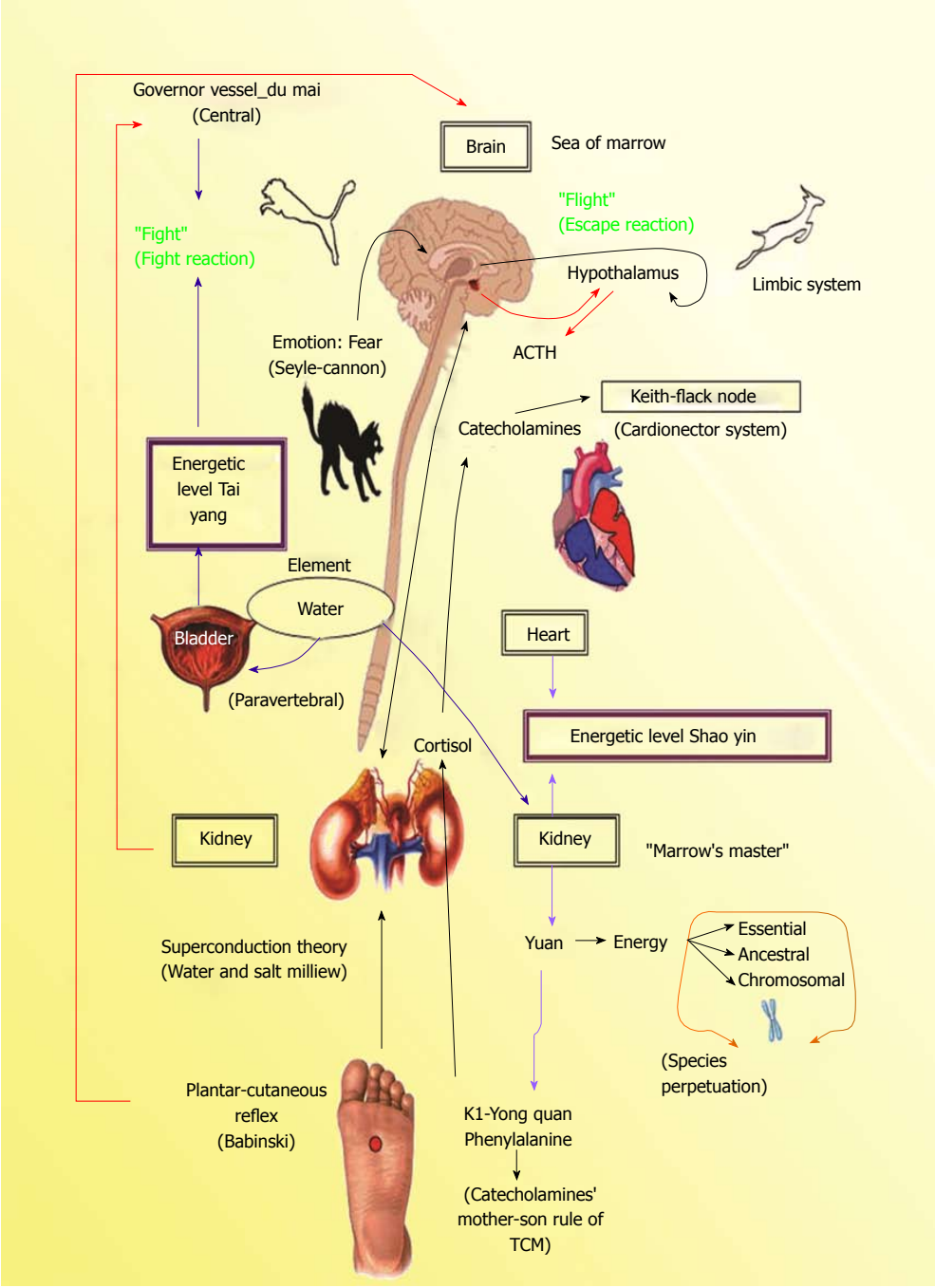

Figure 3 Survival axis as described by Inchauspe Adrián Ángel[13]. TCM: Traditional chinese medicine; ACTH: Adrenocorticotropic hormone.

inner and outer collaterals-ensures blood provision and distribution to the Heart; consequently, it rules the channeling through which both Qi and Heart irrigation flow as regards their function of blood admission and propulsion.

In some way, Xin Bao-according to Dr. Carlos Zaringolami-is a reflection of Xin's drive of Qi; consequently, it shall be directly involved in every circulatory ailment related to pumping disruption: *i.e.,* palpitations, precordalgia, angor pectoris and cardiorespiratory arrest.

As we have previously seen, PC-9 Zhong chong fulfills every prerogative of stimulating the correct paths in order to explain and achieve the expected results so that the unfortunate group of patients, whose condition is already limited, should not be confronted to a most surely fatal situation in case basic and advanced CPR fail.

As in the case of K-1 Yong quan, the proposed new maneuver that is herein contained-on the pertinent section above-offers an extremely simple solution during an emergency situation to a very severe prognostic problem at no cost whatsoever.

COMMENTS

Background

In the authors' 28-year-career resuscitating through the K-1 Yong quan, different situations as to sustaining its supplementary application during life supporting protocol use. However, double-amputee diabetic patients were

considered excluded from Yong quan CPR method in case of basic and advanced CPR failure. This challenge demanded an urgent solution in order to eliminate these patients from the exclusion criteria in the supplementary reanimation maneuver protocols on Yong quan for such unfortunate cases. The proposal of this hypothesis for the use of PC-9 Zhong chong as an alternative resuscitation point will certainly benefit those subjects in whom Yong quan is either anatomically non-existent or impossible to access.

Research frontiers

Statistics from the experimental plan proposed herein shall enable assessment of the real value of PC-9 Zhong chong as an alternative resuscitation point to consider in double amputee patients in whom failure of basic and advanced CPR protocol would leave them hopeless.

Innovations and breakthroughs

This work aims at adding an alternative point to the supplementary resuscitation system designed by the author and endorsed within Traditional Chinese Medicine parameters so that precisely the most unfortunate patients may have another resource in case they need rescue.

Applications

The methodology proposed shall offer yet another therapeutical alternative to add to current life support international protocols available at emergency services.

Peer-review

The author performed a retrospective analysis in order to estimate an inclusion criterion for patients who have suffered bilateral amputation whether they could be treated with the supplementary resuscitation treatment like acupunctural of PC-9 Zhong chong point, further supported by previous statistical work recorded for the K-1 Yong quan resuscitation point. Patients with bilateral amputation independently of the cause were included in the study. The author concludes that thanks to the application of the resuscitation maneuver herein proposed on the previously mentioned point, patients with bilateral amputation would have another alternative treatment available in case basic and advanced CPR should fail.

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