

Vorbemerkung der Redaktion

Für Marco Romoli galt die Ohrkarte, d. h. die Verteilung von Organen und Funktionen nicht als gesichertes Wissen. Romoli ärgerte die Tatsache, dass die Ohrakupunktur i. G. zur Körperakupunktur trotz der unterschiedlichen Lehrmeinungen verschiedener Schulen sehr schlecht untersucht ist. Im letzten Jahr wandte er sich an die DZA. Sein erster Artikel sollte den Beginn einer Forschungsinitiative markieren. Am 1. Januar schickte er den ersten Teil und bat um etwas Aufschub. Doch der Artikel sollte nicht mehr fertig werden. Am 19. Januar verstarb er, hinterließ den zweiten Teil in Form handschriftlicher Notizen, die wir glücklicherweise von seinem Sohn erhielten, und denen man ansieht, dass ihm das Schreiben schon schwerfiel. So wird dieser Artikel zum Vermächtnis dieses großartigen Mannes an die Ohrakupunkteure, ihre bisherigen Behauptungen kritisch-wissenschaftlich zu hinterfragen. Auch als Fragment wird sein Anliegen doch deutlich.

Editors' preliminary note

Marco Romoli did not consider the ear chart, meaning the somatotopic distribution of organs and functions, as established knowledge. Romoli resented the fact that ear acupuncture, contrary to body acupuncture and in spite of the diverse doctrines of various schools, has been poorly studied. Last year he contacted DZA. His first paper was meant to mark the onset of a scientific initiative. He provided the first part of the article on January 1st and asked for some delay. However, the paper was not to be finished. The author died January 19th, leaving the second part in form of handwritten notes which his son fortunately passed on to us. They display the difficulty he had hand writing during his last days. Thus, this paper becomes this great man's legacy to ear acupuncturists, urging them to scientifically scrutinize their past and current assertions. Even this fragment clearly expresses his concerns.

✉ M. Romoli

Why do we fail throughout the world to perform good clinical research in auriculotherapy/auricular acupuncture?

Wieso gelingt uns weltweit keine gute Erforschung der Aurikulotherapie/Ohrakupunktur?

Abstract

The first systematic review on the efficacy of Auriculotherapy concerning insomnia and sleep disorders was published in 2007. In recent years (2007–2015) further reviews have been issued on pain management, smoking and preoperative anxiety. The “delayed” number of systematic reviews (SR) and meta-analyses (MA) reported in literature seems to be indicative of the insufficient quantity and quality of RCTs published in the last 40 years on the potentials of our innovative discipline. Almost all SR and MA are written in English, but there is one in French language which should be carefully consulted and understood by our readers entitled “Évaluation de l’efficacité de la pratique de l’Auriculothérapie”, published 25-07-2013 by the “Institute National de la Santé et de la Recherche Médicale” (INSERM). In this review several inadequacies and biases were found in the reported RCTs which may represent an obstacle in the develop-

ment of research and the achievement of a solid scientific basis. The insufficient quality of the studies is mainly of methodological order and appears to be associated with an incomplete application of EBM guidelines.

Further specific factors are discussed in this article, which slow down a qualitative research in this field, such as the insufficiently validated auricular diagnostic methods, the bi-dimensional representation of auricular zones and the proliferation of new auricular charts without any proof of clinical value.

Keywords

Auriculotherapy, auricular acupuncture, ear acupuncture, evidence-based medicine, auricular diagnostic methods, bi-dimensional representation of auricular zones, systematic review

Zusammenfassung

Die erste systematische Übersichtsarbeit zur Wirksamkeit der Aurikulotherapie wurde 2007 veröffentlicht und betraf Schlaflosigkeit und Schlafstörungen. In den letzten Jahren (2007–2016) erschienen weitere Arbeiten zu Schmerzmanagement, Rauchen und präoperativen Angstzuständen. Der „Verzug“ an systematischen Übersichtsarbeiten (systematic reviews SR) und Metaanalysen (MA), wie der Literatur zu entnehmen, könnte ein Hinweis sein auf die ungenügende Quantität und Qualität der RCTs, die in den vergangenen 40 Jahren zum Potenzial unseres innovativen Faches erschienen sind. Fast alle SR und MA wurden in englischer Sprache verfasst, mit Ausnahme einer französischen Arbeit, die es

verdient, herangezogen und gründlich studiert zu werden. Sie trägt den Titel „Évaluation de l’efficacité de la pratique de l’Auriculothérapie“ und wurde am 25. Juli 2013 vom „Institute National de la Santé et de la Recherche Médicale“ (INSERM) herausgegeben. In der vorliegenden Arbeit wird auf eine Reihe von Unzulänglichkeiten und Vorurteilen in den veröffentlichten RCTs hingewiesen, die der Entwicklung der Forschung und der Begründung einer tragfähigen wissenschaftlichen Basis hinderlich sein könnten. Die ungenügende Qualität der Studien hat im Wesentlichen methodologische Gründe und hängt offenbar damit zusammen, dass die EBM-Leitlinien nicht umfassend befolgt wurden.

Es werden weitere spezifische Faktoren diskutiert, die sich hemmend auf eine qualitative Forschung in diesem Gebiet auswirken, etwa die unzureichend validierten Methoden der

Schlüsselwörter

Aurikulotherapie, Aurikuloakupunktur, Ohrakupunktur, evidenzbasierte Medizin, Methoden der Aurikulodiagnostik,

Ohrdiagnostik, die bi-dimensionale Repräsentation von Aurikulärzonen und die Verbreitung neuer Aurikulärkarten ohne nachgewiesenen klinischen Wert.

bi-dimensionale Repräsentation von Aurikulärzonen, systematische Übersicht

Introduction

Auriculotherapy was historically introduced by French Doctor Paul Nogier in 1957 and is based on the somatotopic representation of anatomical structures and functions in both the lateral and medial surfaces of the auricle [1–3]. This diagnostic-therapeutic paradigm differs from Traditional Chinese Medicine with its “energy (*qi*) flowing system” and its in part metaphorical reading of the body.

One important phase in the history of Auriculotherapy/Ear acupuncture (AT, EA) has been, in the early ‘70s of the last century, the collaboration of Chinese researchers who introduced in their auricular maps some terms and concepts derived from TCM. This integration has been considered an intrusion by some European schools of AT/EA. We should notice, however, that the Chinese auricular maps (even the contemporary ones published in 1993 and confirmed in 2008) correspond almost totally with the original maps as reported by Paul Nogier in his first historical publications [4–5].

Despite the great enthusiasm all over the world about this innovative method, the first systematic review on clinical applications of AT/EA appeared in literature as late as 2007. It was followed by at least further 6 reviews on the same topic, insomnia and sleep disorders. Five of them were performed by different Chinese groups, who also consulted databases in Chinese. The last one was proposed in 2015 by a Brazilian group, dealing with sleep disorders in postmenopausal women, including some RCTs applying also AT and EA. [6–12].

What is surprising in these first systematic reviews of AT/EA is the main involvement of Asian researchers and their interest into an easy, cost-effective and non-invasive therapeutic approach performed with Vaccaria seeds and magnetic pellets rather than applying acupuncture needles. Another topic, which was considered important for all practitioners in our field, was the efficacy of AT/EA in Pain Management [13–15]. In particular the control of postoperative pain, reviewed in 2 systematic reviews, confirmed that the increasing number of qualitative RCTs may change significantly the conclusions drawn by a meta-analysis. The first article written on this topic in 2008, covering 9 RCTs, which did not allow any meta-analysis, was followed by a second paper in 2015 reviewing 59 RCTs. Nine of these publications were in Chinese and the remaining 50 ones were in English. The studies included had been conducted in mainland China, Hong Kong, Taiwan, the United States, Germany, Austria, South Korea, Japan, Iran, the United Kingdom, Brazil, Sweden, Singapore, Italy and Turkey. This second article allowed a meta-analysis and in conclusions offered implications for practice and research as well: “This study indicates that, thus far, there is still insufficient evidence to conclude that Acupuncture Point Stimulation (APS) is an effective method for controlling postoperative pain in surgery patients, although the

evidence does suggest that APS can reduce patients’ analgesic requirements with no significant adverse effects” [15].

An interesting review on adverse effects of AT/EA [16] was added in 2014 indicating that all events reported by 43 RCTs using EA, 40 RCTs using Auricular Acupressure (AP) and 2 RCTs applying Auricular Electroacupuncture (AEA) were considered short-term, mild and tolerable reactions such as local discomfort, transient tenderness and pain, local skin irritation, minor bleeding and dizziness. Some of them were potentially avoidable, and no serious adverse effects were detected. The conclusions of this review then were that “based on our findings, the safety of AT seems superior to other traditional therapies such as body acupuncture, moxibustion and cupping.” [16]

In the same year of 2014 two further meta-analyses faced two different topics which have been considered important both by patients and practitioners: the first one reviewed the efficacy of AT/EA for cessation of cigarette smoking at end-of-treatment, three, six and 12 months follow-up in 25 RCTs (for a total of 3735 smokers). The adopted Ear acupuncture/Acupressure programs vs. non-specific/inactive control were superior at three and six months follow-up, but data were insufficient at 12 months. A second comparison was made between Ear acupuncture/Acupressure programs vs. specific behavioral interventions vs. specific body acupuncture for smoking cessation. This second study showed no superiority of Ear acupuncture/Acupressure programs over the behavioral ones at 3 and 6 months follow-ups [17].

The other meta-analysis reviewed the efficacy of APS in reducing preoperative anxiety, identifying 14 RCTs, 5 of them applying auricular points and 4 applying both auricular and body points to patients carried to the hospital for traumatic reasons, surgery, lithotripsy etc. [18]. This review opened the approach, already well known, to an important aspect of auricular stimulation, which is nowadays classified or considered as a Neuromodulation technique of the Vagal System, especially since the vagal innervation of the auricle has been brought into light thanks to the anatomical studies of Peuker who demonstrated the relevant anatomical supply of fibers of the X° nerve both on the lateral and medial surface of the ear [19, 20].

In my opinion, this group of “delayed” systematic reviews and meta-analyses on the potential clinical applications of AT/EA, includes an important and remarkable review in French entitled “Évaluation de l’efficacité de la pratique de l’Auriculothérapie”, published 25-07-2013 by the “Institute National de la Santé et de la Recherche Médicale” (INSERM). The total and rigorous document counting 224 pages (!) also provides ample space for educational programs and for the various applied techniques, including furthermore the personal communications of leading French authors like Yves Rouxville, Raphael Nogier, David Alimi etc. Beyond this kindness motivated by the wish

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