

# 络病理论科学求证

吴以岭 主编

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## 内 容 简 介

本书是络病证治体系创建、发展、完善的历史见证。本书详实地记录了在新的历史阶段,络病理论科学内涵及其应用价值科学求证的进程,即将络病理论创新、临床实践、新药研究三者紧密结合、循环往复、螺旋上升的探索过程。全书收录了1996~2006年10月在正式出版物发表的络病理论——通心络胶囊相关论文538篇,按学科内涵和时间顺序分为上、中、下三篇。上篇为总论,由中华中医药学会络病分会主任委员吴以岭教授主笔,重点阐述了络病理论体系的构建及其学科价值,“脉络-血管系统”、“气络-NEI网络”相关性,应用复杂系统、非线性科学的思维方法评价了通络治疗血管病变的效应规律——承制调平与系统效应,以及通心络胶囊的研发历程和畅想,为进一步开展络病理论研究和学科建设启迪思路。中篇为实验研究,汇集了国内关于通心络胶囊对心、脑血管疾病干预作用的实验研究成果论文79篇,从心、脑血管疾病不同的发病阶段、发病机制、作用靶向进行系统总结。下篇为临床研究,汇集了通心络在治疗心脑血管疾病、糖尿病并发症及其他难治性疾病方面的临床疗效论文454篇,为络病理论的科学求证提供了真实、有力的现代科学依据。

本书内容全面、系统、丰富,资料性强,可供基础及临床各科医务工作者参阅,也可作为从事络病理论、基础、临床和教学的科技工作者参考。

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# 前 言

络病是广泛存在于多种内伤疑难杂病和外感重症中的病机状态与过程,其内涵是指疾病发展过程中不同致病因素伤及络脉导致的络脉功能障碍及结构损伤的自身病变,外延包括导致络脉病变的致病因素及络脉病变引起的继发性脏腑组织病理改变。络病理论是研究络病发病特点、病机变化、临床表现、辨证论治、治疗原则及治法方药的应用理论。

络病理论科学求证是学术创新、临床实践、方药研究三者紧密结合、循环往复、螺旋上升、不断探求的实践过程,是求真求实、不断追寻生命奥秘、疾病演变和治疗规律的探索过程,充分反映了中医学科自身的发展规律。春秋战国时期《黄帝内经》奠定络病理论基础;东汉张仲景《伤寒杂病论》首创络病治疗方药,并显示出极高的临床价值;清代名医叶天士继承发展络病治法,并把通络药物广泛应用于内伤杂病,从而形成了络病学说发展史上三个重要的里程碑。可见络病理论在 2000 多年的漫长发展史中,是紧密结合临床实践与方药创新而不断进步的,这对当代创新发展络病理论具有重要的启迪意义。可惜的是,叶天士身后 200 余年络病学说并未引起重视,这不能不说是历史的遗憾,也是留给当代医学工作者的重大历史课题。

自 20 世纪 80 年代初络病理论再次成为中医学术研究的热点,国内一批专家从文献整理、临床研究、创新药物等不同侧面探索络病理论的科学内涵及其应用价值,开始了络病理论科学求证的新历程,在运用络病理论研究血管病变防治方面首先取得突破,络病理论代表方——通心络胶囊研制成功并进入市场。通心络的问世绝不是一般意义上的新药上市,而是代表了络病理论发展新阶段的肇始。通心络胶囊针对“脉络-血管系统病”络气虚滞、络脉瘀阻、络脉绌急的基本病理变化而组方,因首次阐明络脉绌急-冠脉痉挛-血管内皮功能障碍之间的相关性并将搜风通络药应用于冠心病治疗而获得 2000 年国家科技进步二等奖,这是建国以来首次获此殊荣的治疗心脑血管病的中药项目。在此基础上承担的国家中医药管理局中医基础理论研究课题——“络病理论及其应用研究”,首次提出络病研究的理论框架——“三维立体网络系统”,从时空与功能的统一性研究络病理论,系统探讨络病发病、病机、辨证与治疗,被专家鉴定为:“该项目研究按照中医学自身发展规律对络病学说进行了全面系统研究,初步建立‘络病证治’体系,首次形成系统络病理论,为络病学学科建立奠定了理论基础,属国内外创新性科研成果。”2006 年该项目获得国家科技进步二等奖,两次获得国家科技进步奖,反映了络病理论研究的两次重大进展。

通心络作为络病理论的物化以其独特组方及显著疗效引起国内医学界的重视与广泛研究,10 余年来国内外期刊杂志发表的通心络基础与临床研究文章达 800 余篇,其中博、硕士学位论文 86 篇,本书精选收录研究论文 538 篇。大量研究证实,通心络可明显改善血管内皮功能,延缓动脉粥样硬化进程,抑制内膜增殖及再狭窄,稳定易损斑块,缓解血管痉挛,不仅对血管病变共性病理性环节具有确切疗效,而且对急性心肌梗死再灌注晚期微血管完整性、心肌保护及抑制心室重构对急性脑梗死缺血区微血管及脑组织保护显示出独特的优势,标志着复方中药在急危重症抢救中仍有其用武之地。

通心络作为“理论-临床-药物”三位一体发展模式的关键一环,既是络病临床研究产

物,又是络病理论的载体,所显示的药理作用及临床疗效为络病理论科学求证提供了客观依据,并赋予通心络“现代特色中药”的时代内涵。说其现代,不仅是因为在工艺与质量标准上采取了现代高新技术,还因为运用络病理论探讨血管病变的中医病理机制时汲取了现代医学对血管病变的最新研究进展;同时对通心络进行的实验研究所运用的现代实验方法、临床研究进行 Meta 分析(荟萃分析)则是采用了国际公认的科学方法,从而赋予了通心络“现代”的鲜明时代特征。说其特色,是因为理论独特、组方独特、疗效独特,为从络病理论探讨心脑血管病的防治研究开辟了新的有效治疗途径,由此带来的组方不仅吸收了张仲景、叶天士等著名医家的虫类通络用药经验,而且首次把搜风解痉通络药用于冠心病的治疗并取得显效,揭示了络脉绌急与血管痉挛以及内皮功能障碍之间的相关性。通心络针对血管病变多种病理环节而组方,其关键在于面对心脑血管病这类复杂性疾病,究竟是采用对抗与补偿的单靶点干预还是发挥复方中药针对多种病机变化的配伍优势,当西方专家提出 Polypill (多效药丸)研制复方西药、倡导个体化治疗及全身性治疗时,通心络作为复方中药所显示出来的整合调节优势,不仅符合传统中医学“承制调平”效应规律,其有效干预也使“脉络-血管系统病”发生着符合复杂系统特征改变的系统效应——提高自适应、自调节、自修复、自稳态能力。由于复杂性科学的兴起,使我们得以应用复杂系统、非线性科学的思维方法来总结评价复方中药通心络治疗血管病变的整合调节机制。相信随着对通心络更广泛深入的研究和实验数据的数理分析,进一步探讨其效应规律,络络治疗血管病变的科学价值将得到更深刻的揭示。

随着 20 世纪现代科技的迅速发展和以复杂系统非线性科学、系统生物学等新兴学科的兴起,络病理论的发展迎来了前所未有的历史机遇。在保持中医络病理论整体、系统、辨证、恒动理论思维特色的同时,充分借鉴现代科学方法并汲取生命科学的最新进展,将古人用肉眼难以观察到的络脉与络病改变在微观领域逐渐清晰起来,无疑是促进络病理论体系发展、完善的重要途径。在既往的研究中,基于气络与神经内分泌免疫调节网络,脉络与中小血管、微血管及微循环的高度相关性,提出了“气络-NEI 网络”与“脉络-血管系统”概念,围绕“脉络-血管系统病”进行的“络病理论指导血管病变防治的基础研究”列为 2005 年国家“973”计划项目,项目组汇集了国内高层次中医、西医、中西医结合、生物学、复杂系统、数学等多学科专家群体。2006 年通心络被列为国际科技合作计划项目,我们与美国贝勒医学院、德州大学医学院心脏病研究中心、哈佛大学医学院心脏病研究中心、美国东卡大学医学院等有关单位开展的合作研究已经取得良好效果,这标志着络病理论研究由原来的散在研究已经进入到更多专家群体集中研究、规范研究、深入研究、国际合作研究的新阶段。这是在 21 世纪生命科学时代中医自身发展规律的再现,实现了络病理论创新、临床实践总结、创新药物研发在现代科技条件下的高层次结合,它使络病理论科学求证进程进入了一个新的历史阶段。

本书收录的理论探讨、基础研究、临床总结文章多是在以往各类期刊杂志发表的研究论文,以物化的络病理论——通心络为载体,历时 10 余年,区域不分东南西北,专业不分中医西医,均是结合各位专家专业特点与实践,严谨设计、认真研究而完成的。参与研究和文章撰写的专家与青年学子达 1303 人,他们以自己的心血和汗水浇灌着络病理论这棵奇葩,以严谨、务实、细致、坚韧的治学态度科学地求证着络病理论的内涵,围绕着共同的目标——让新兴的络病学进入现代科技之林而奋斗着,前进着……中医络病学的发展历史上将记载下

他们坚实的足迹。

值此本书出版之际,我们向多年来支持络病理论研究的医学界前辈邓铁涛教授、颜德馨教授、路志正教授、焦树德教授、朱良春教授、陈灏珠院士、陈可冀院士,向在百忙之中指导并审阅本书的王永炎院士表示衷心的感谢!向致力于络病研究的国内外专家学者及青年学子们表示衷心的感谢!络病学发展的历史丰碑上将铭刻下你们的名字,愿我们携手并进,在传承创新中再铸辉煌!

A handwritten signature in black ink, appearing to read '王永炎' (Wang Yongyan), written in a cursive style.

2007年1月

# PREFACE

Diseases of the branches of channels (luo diseases) exists widely in the cause and process of many difficult, complicated and obstinate illnesses, whose intension indicates that the causative factors of illness development which cause the functional obstruction and structural damages of branches of the channels (luo mai) and whose denotation includes the causative factors of luo mai pathological changes and the secondary Zang Fu tissue pathological changes. The theory of luo diseases deals with applying theory about the onset characteristics, pathological changes, clinical manifestations, syndrome differentiation and treatments, treatment principles, medication prescriptions.

To prove the theory of luo diseases is a combination of academic innovation, clinical practice, and scientific research on prescriptions, which is to move in endless cycles, develop in spiral movement, explore continuously in the process of practice, seek truth from facts in probing the mystery of life, explore the pathological changes and treatment rules of Traditional Chinese Medicine (TCM). In the periods of Spring and Autumn and the Period of Warring States, *Internal Classics of Huang Di* laid the theory foundation of luo diseases. In East Han dynasty, the book *On exogenous Febrile Miscellaneous Diseases* written by Zhang zhongjing, created the prescription in luo disease treatment and showed the high clinical value. In Ching dynasty, the famous doctor Ye tianshi inherited and developed the treatment of luo diseases and widely applied dredging meridians and activating luos medicine on miscellaneous diseases, which have formed three important milestones in the development history of luo disease theory. From this we can see, the development of the theory of luo diseases in the 2000 years made progressive progress by combination of clinical practice with prescription innovation which has important enlightening significance for the innovative development of today. But it is a pity that in the more than 2000 years after Ye tianshi, luo diseases was not paid any attention which should be regretful in the history, becoming an important historic topic for the medical personnel of today.

Since the 80s of the 20th century, theory of luo diseases has become a hot spot in the academic research for TCM. Some experts have explored its scientific intension and application value from various aspects such as sort out the reference literature, clinical research, innovation of new medicine, starting the new course of research for the theory of luo diseases. We have first made a break through in the prevention and treatment of Cardio-vascular diseases pathological charges—Tongxinluo capsule—representative of the theory of luo diseases have been successful made and entered into market, which has a special significance comparing with other new drugs, representing a new start of the new stage for the development of theory of luo diseases. The prescription of Tongxinluo is for the treatment of stagnation of luo qi, blood stasis in luos, insufficiency of blood circulation in the luos-blood system, which has won the second class award of the national science and technology progress prize in 2000, for the treatment of coronary heart diseases by the explana-

tion of the correlation of the insufficiency of luo blood circulation—coronary spasm, vascular endothelial function obstruction and by expelling wind and dredging luos methods for the first time, which is also the first time to have won such an honor for the treatment of cerebral and cardiovascular diseases by using TCM program. On the basis of this, we undertake the basic theory research subject of TCM given by the national TCM administration bureau. Research on the theory of luo diseases and its clinical application, for the first time the theoretical frame of luo diseases research—three-dimensional solid net system has been put forward, which starts from integrating of space, time and function in the research of the theory of luo diseases and systematically explore the onset, pathological mechanism, differentiation of syndrome, treatment of luo diseases which is also identified by experts as: this research program has carried out a comprehensive and systematic research on luo diseases according as the academic development rules of TCM primarily established syndrome differentiation and treatment system, forming the system of the theory of luo diseases for the first time, laying a theoretical foundation of luo diseases discipline, belonging to innovative scientific research result. In 2006 this program again got the second award of National Science and Technology Progress Prize, which indicated the two major developments in the theoretical research of luo diseases.

Tongxinluo, as materialization of the theory of luo diseases has attracted wide attention and studies from the medical field in our country for its unique prescription and outstanding curative effect. For this more than 10 years, more than 800 papers about Tongxinluo's basic theory and clinical research have been published from the periodicals at home and a broad, among which 86 papers are the thesis for the doctorate and master degree. In this book, 538 articles are included. Large amount of evidence has proved that Tongxinluo can improve endothelial cell function, slow down the process of atherosclerosis, inhibit endotheliosis and the narrowing of vascular, stabilize the vulnerable plaque palliate, vascular spasm, not only have outstanding curative effect for pathological changes common in vascular lesion it also protects the myocardial and the completeness of micro vascular in the reperfusion of acute myocardial infarction. It has unique protective effect on the brain tissue and the micro-vascular of the ischemic area in the acute cerebral infarction, which shows that complex prescriptions of TCM still have its effect in the rescue of emergent, serious and dying cases.

Tongxinluo as a key link in the development pattern of "Theory-clinic-drug", is the clinic research result of luo diseases whose pharmacological effect and its clinical curative effect have provided objective evidence for the scientific research of luo disease theory, which also give epoch intension of "Modern characteristic traditional Chinese drug." Why do we say modern? It is not only because it has adopted modern high new technique in its technological process and quality standard also because it's accepted new research result on vascular pathological changes by modern medical science; At the same time, modern lab techniques have been used in the experimental research on Tongxinluo, such as, the Meta analysis in the clinic research has adopted the international acknowledged science methods, thus Tongxinluo has been given the "contemporary" outstanding, epoch characteristics. Why do we say it has distinguishing feature? It is because it

has distinguished feature in its theory, prescription, curative effect, such as we've opened new effective ways in the prevention and treatment of cardio and cerebral vascular diseases by exploring the theory of luo diseases, thus resulting in new prescription not only include insect dredging luos mediations from some famous doctors of TCM, such as Zhang Zhongjing, Ye Tianshi, etc, but also apply anti-spastic and expelling wind and dredging luos drugs in the treatment of coronary diseases and achieve very effective curative effects, which reveals the correlation between insufficiency blood flow of luos, vascular spasm and endothelial function obstruction. The formation of Tongxinluo prescription is aimed at treating the various pathological changes of vascular diseases, whose key point is whether we should fight against the various pathological changes by using compound prescriptions of TCM. Now when experts from western counties advocate producing poly pill, compound western medicine and individual personal treatment, systematic or whole body treatment, TXL as a complex prescription of TCM has taken the lead in the general regulation in disease treatment, which not only conforms to the effect principles of TCM—Chengzhitiaoping, whose effective interferences of diseases, also make “luo—vascular system diseases”, conform to the systemic effect of complex system characteristic—raising the capability of self-adaptation, self-regulation, and self-repair, homeostasis state. The uprising of the complex science doctrine makes us able to sum up and evaluate the comprehensive regulation system of Tongxinluo a complex prescription of TCM in the treatment of cardio vascular diseases by applying the doctrine of complex science, non-linear science thinking. We believe that, with the deep, profound research on Tongxinluo, the mathematic theory analysis of experimental date and the further exploring the effective rules, the scientific value of Tongxinluo in the treatment of vascular diseases will be revealed more profoundly. With the rapid development of modern science and technology and uprising of complex systematic and non-linear science, the development of the theory of luo diseases has met with favorable historic chances. On the one hand we maintain the thinking characteristics of wholism, systematic, dialectical and constant moving concept, on the other hand, by making use of modern scientific method and absorbing the latest development of life science, capillary and luo diseases charges which could not be seen with raked eyes, now have become gradually clearer in the micro world, which, undoubtedly, will be important ways promoting the development and perfection of the theory of luo diseases. In the past and present research, because of the close interrelationship between Qi luo and neuro-endocrine immunity regulation function, between Mai luo and medium, small, micro vascular, micro-circulation, we put forward the concept of “Qi luo-NEI network” and “Mai luo-vascular system”, so that basic research under the guidance of the theory of luo diseases, which concentrates on Mai luo-vascular became the national 973 plan program of 2005, in which national high level experts of TCM, western medicine, combination medicine, biology, complex system, maths etc, are involved. At the same time, Tongxinluo research became international science and technology co-operation program, whose co-operation research has got good results, such as cooperation researches with Bertler medical college USA, Texas Heart Institute, medical school of Texas university, Heart Institute, medical school of Harvet University, Medical school of Dongka university etc, which indicates Tongxinluo research has entered

into new stage of international co-operate research that involves more experts collective concentration research, which is also the reappearance of its development rules of TCM in the 21<sup>st</sup> century science of life era, realizing a high level combination of innovation in luo disease theory, clinical practice summary, new pharmaceutical research and development, under the condition of modern science and technology, making the research course enter a new historical stage.

The articles published in this book are about the discussion of its theory, basic research clinical summary, most of which have been published in various periodicals, magazines, in the past more than ten years. All articles are with Tongxinluo as the object—the carrier of materialization of luo diseases theory, whose writers are from all over China, either doctors of TCM or western medicine or combination medicine. They finish their research and articles by careful and rigorous scholarship, earnest research and combination with their professional characteristics and practice. 1303 experts and young learners who have taken part in the research and article writing have irrigated and nourished this splendid flower—the theory of luo diseases, by rigorous, practical careful and persistent scholarship, trying hard to prove the intension of the theory of luo diseases and to achieve the same goal—let the newly uprising doctrine of luo diseases enter modern science and technology. They are striving, marching forward, whose footmark and achievement will be recorded in the development history of luo diseases.

At the time of the book publishing, I would like to express our heartfelt thanks to those famous predecessors in our medical field who have supported the theoretical research of luo diseases, such as prof Deng Tietao, prof Yan Dexin, prof Lu Zhizheng, prof Jiao Shude, prof Zhu Liangchun. Academician Chen haozhu, Academician Chen Keji and Academician Wang Yongyan who has guided and checked and proved and the articles in this book, I would also like to express our heart felt thanks to those experts and young learners at home and broad who have devoted themselves to the research of luo diseases. On the monumental work of the research development on luo diseases, your names will indelibly be engraved. Let us march forward hand in hand, try our best to make new brilliant achievement in the inheriting and creation of the theory of luo disease of TCM.

Wu Yiling

Jan, 2007



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