卫生部“十二五”规划教材

全国高等医药教材建设研究会“十二五”规划教材

全国高等学校药学专业第七轮规划教材

供药学类专业用

药学英语（下册）

第4版

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卫生部“十二五”规划教材
全国高等学校药学类专业第七轮规划教材

出 版 说 明

全国高等学校药学类专业本科卫生部规划教材是我国最权威的药学类专业教材，于1979年出版第一版，1987年、1993年、1998年、2003年、2007年进行了5次修订，并于2007年出版了第六轮规划教材。第六轮规划教材主干教材29种，全部为卫生部“十一五”规划教材，其中22种为教育部规划的普通高等教育“十一五”国家级规划教材；配套教材25种，全部为卫生部“十一五”规划教材，其中3种为教育部规划的普通高等教育“十一五”国家级规划教材。本次修订编写出版的第七轮规划教材中主干教材共30种，其中修订第六轮规划教材28种。《生物制药工艺学》未修订，沿用第六轮规划教材；新编教材2种，《临床医学概论》、《波谱解析》；配套教材21种，其中修订第六轮配套教材18种，新编3种。全国高等学校药学专业第七轮规划教材及其配套教材均为卫生部“十二五”规划教材、全国高等医药教材建设研究会“十二五”规划教材，具体品种详见出版说明所附书目。

该套教材曾为全国高等学校药学类专业惟一一套统编教材，后更名为规划教材，具有较高的权威性和一流水平，为我国高等教育培养大批的药学专业人才发挥了重要作用。随着我国高等教育体制改革的不断深入发展，药学类专业办学规模不断扩大，办学形式、专业种类、教学方式亦呈多样化发展，我国高等药学教育进入了一个新的时期。同时，随着国家基本药物制度建设的不断完善及相关法规政策、标准等的出台，以及《中国药典》(2010年版)的颁布等，对高等药学教育也提出了新的要求和任务。此外，我国新近出台的《医药卫生中长期人才发展规划(2011—2020年)》对我国高等药学教育和药学专门人才的培养提出了更高的目标和要求。为跟上时代发展的步伐，适应新时期我国高等药学教育改革和发展的要求，培养合格的药学专门人才，以满足我国医药卫生事业发展的需要，从而进一步做好药学类专业本科教材的组织规划和质量保障工作，全国高等学校药学专业教材第三、第四届评审委员会围绕药学专业第六轮教材使用情况、药学教育现状、新时期药学领域人才结构等多个主题，进行了广泛、深入地调研，并对调研结果进行了反复、细致地分析论证。根据药学专业教材评审委员会的意见和调研、论证的结果，全国高等医药教材建设研究会、人民卫生出版社决定组织全国专家对第六轮教材进行修订，并根据教学需要组织编写了部分新教材。

药学类专业第七轮规划教材的编写修订，坚持紧紧围绕全国高等学校药学类专业(本科)教育和人才培养目标要求，突出药学专业特色，以教育部新的药学教育纲要为基础，以国家执业药师资格准入标准为指导，按照卫生部等相关部门及行业用人要求，强调培养目标与用人要求相结合，在继承和巩固前六轮教材建设工作成果的基础上，不断创新

和发展，进一步提高教材的水平和质量。同时还特别注重学生的创新意识和实践能力培养，注重教材整体优化，提高教材的适应性和可读性，更好地满足教学的需要。

为了便于学生学习、教师授课，在做好传承的基础上，本轮教材在编写形式上有所创新，采用了“模块化编写”。教材各章开篇，以普通高等学校药学本科教学要求为标准编写“学习要求”，正文中根据课程、教材特点有选择性地增加“知识链接”“实例解析”“知识拓展”“小结”。为给希望进一步学习的学生提供阅读建议，部分教材在“小结”后增加了“选读材料”。

需要特别说明的是，全国高等学校药学专业第三届教材评审委员会成立于2001年，至今已10年，随着教育教学改革的发展和专家队伍的发展变化，根据教材建设工作的需要，在修订编写本轮规划教材之初，全国高等医药教材建设研究会、人民卫生出版社对第三届教材评审委员会进行了改选换届，成立了第四届教材评审委员会。无论新老评审委员，都为本轮教材工作做出了重要贡献，在此向他们表示衷心的谢意！

由于众多学术水平一流和教学经验丰富的专家教授都积极踊跃和严谨认真地参与本套教材的编写，从而使教材的质量得到不断完善和提高，并被广大师生所认同。在此我们对长期支持本套教材编写修订的专家和教师及同学们表示诚挚的感谢！

本轮教材出版后，各位教师、学生在使用过程中，如发现问题请反馈给我们，以便及时更正和修订完善。

全国高等医药教材建设研究会

人民卫生出版社

2011年5月

卫生部“十二五”规划教材
全国高等学校药学类专业
第七轮规划教材书目

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Contents

Unit One Pharmacology

The word "pharmacology" derives from the Greek word for drug, pharmakon. It is the branch of medicine and biology concerned with the study of the actions, uses, mechanisms, and adverse effects of drugs. More specifically, it is the study of the interactions that occur between a living organism and chemicals that affect normal or abnormal biochemical function. If substances have medicinal properties, they are considered pharmaceuticals. The field of pharmacology encompasses drug composition and properties, interactions, toxicology, therapy, and medical applications and anti-pathogenic capabilities.

"Pharmacology"一词来源于希腊语药物 pharmakon,它是医学与生物学的分支,涉及研究药物的作用、用途、机制及不良反应。更具体地说,它是研究发生在活体和化学物质间的相互作用,该作用可影响正常或异常的生化功能。如果物质有药用价值,则认为它们是药物。药理学包括药物的成分和性质、相互作用、毒理学、治疗作用、临床应用及抗致病能力。

The two main areas of pharmacology are pharmacodynamics and pharmacokinetics. The former studies the effects of the drugs on biological systems, and the latter studies the effects of biological systems on the drugs. In broad terms, pharmacodynamics discusses the interactions of chemicals with biological receptors, and pharmacokinetics discusses the absorption, distribution, metabolism, and excretion of chemicals from the biological systems.

药理学的两个主要方面是药效学和药代动力学。前者研究药物对生物系统的影响,后者则是研究生物系统对药物的影响。广义上说,药效学讨论化学药物与生物受体的相互作用,而药代动力学讨论化学药物在生物系统中的吸收、分布、代谢和排泄。

Prehistoric people undoubtedly recognized the beneficial or toxic effects of many plants and animal materials. The earliest written records from China and from Egypt list remedies of many types, including a few still recognized today as useful drugs. Most, however, were worthless or actually harmful. Dioscorides' De Materia Medica is often said to be the oldest and most valuable work in the history of pharmacology. Pharmacology as a scientific discipline did not further advance until the mid-19th century amid the great biomedical resurgence of that period. Before the second half of the nineteenth century, the remarkable potency and specificity of the actions of drugs such as morphine, quinine and digitalis were explained vaguely with reference to extraordinary chemical powers and affinities to certain organs or tissues.

早在史前,人们毫不怀疑地认为许多动植物材料是有益或有毒的。中国和埃及的最早记载列出了许多种药物,包括一些迄今仍认为有用的药物,然而,大多数是毫无价值甚至是有害的。Dioscorides的《药物学》常被认为是药理学历史上最古老且最有价值的著作。

药理学作为一门科学学科直到19世纪中叶生物医学伟大复兴时期，才得到更好的发展。19世纪下半叶之前，对于一些药物（如吗啡、奎宁、洋地黄类）的显著的有效性和特异性仍解释不清，它们被表述为“对特定器官或组织有超凡的化学力量及亲和力”。

The study of drugs requires intimate knowledge of the biological system affected. With the knowledge of cell biology and biochemistry increasing, the field of pharmacology has also changed substantially. It has become possible, through molecular analysis of receptors, to design chemicals that act on specific cellular signaling or metabolic pathways by affecting sites directly on cell-surface receptors which modulate and mediate cellular signaling pathways controlling cellular function.

研究药物，需要详细了解受其影响的生物系统，随着对细胞生物学和生物化学的了解增多，药理学也已发生巨大变化。通过对受体的分子水平研究，设计通过直接影响细胞表面受体位点而作用于特定细胞信号或代谢通路的化学物质，从而调节和介导控制细胞功能的细胞信号通路，这些已成为可能。

Medication is said to have a narrow or wide therapeutic index or therapeutic window. This describes the ratio of desired effect to toxic effect. A compound with a narrow therapeutic index exerts its desired effect at a dose close to its toxic dose. A compound with a wide therapeutic index exerts its desired effect at a dose substantially below its toxic dose. Those with a narrow margin are more difficult to dose and administer, and may require therapeutic drug monitoring. Most anti-cancer drugs have a narrow therapeutic margin: toxic side-effects are almost always encountered at doses used to kill tumors.

药物具有窄或宽范围的治疗指数或治疗窗，它描述了所期望的效应和毒性作用之比。治疗指数窄的化合物发挥期望效应时用的剂量接近其毒性剂量，治疗指数宽的化合物发挥其期望效应时用的剂量远低于其毒性剂量。那些安全范围窄的化合物更难控制用药剂量，并可能需要进行治疗药物监测。大多数抗癌药物治疗范围窄：杀灭肿瘤细胞的剂量几乎接近产生毒副作用的剂量。

Pharmacokinetics describes the effect of the body on the drug. When describing the pharmacokinetic properties of a drug, pharmacologists are often interested in LADME:

- Liberation-disintegration, dispersal and dissolution
- Absorption-Is the medication absorbed through the skin, the intestine, or the oral mucosa?
- Distribution-How does it spread through the organism?
- Metabolism-Is the medication converted chemically inside the body, and into which substances? Are these active? Could they be toxic?
- Excretion-Is the medication eliminated through the bile, urine, breath, or skin?

药代动力学描述了人体对药物的作用，当描述一个药物的药代动力学特征时，药理学家通常关注“LADME”：

- 释放 - 崩解、分散和溶解
- 吸收 - 药物是通过皮肤、肠道还是口腔黏膜吸收的？
- 分布 - 药物是如何在有机体中分布的？
- 代谢 - 药物是在体内经化学转化的吗？转化何种物质？这些物质有活性吗？它们

Text A The Travails of Neuroprotective Drug Development for Acute Ischemic Stroke

(Abridged from *The Travails of Neuroprotective Drug Development for Acute Ischemic Stroke by MARC FISHER*)

The development of effective and safe therapies for acute ischemic stroke remains a difficult challenge for clinical investigators and the pharmaceutical industry. Currently, the only acute stroke trial to demonstrate unequivocal efficacy is the recombinant tissue plasminogen activator (rt-PA) trial conducted in the USA with a maximum time to patient enrollment of 3h.[1] The improved outcome in the rt-PA group in this study led to the approval of this drug for the treatment of acute ischemic stroke in the USA within 3h of onset. The 3-hour window and other stringent criteria for the use of rt-PA in acute ischemic stroke have limited its use to a very small percentage of the acute ischemic stroke population. Concerns about the hemorrhagic risk and how to best target this effective but potentially risky therapy have imposed another barrier to its widespread use. At this time, rt-PA for acute ischemic stroke is only approved for use by regulatory agencies within the USA but this situation may change soon, as might the effective time window, pending results of the second European cooperative acute stroke trial (ECAST-2) for rt-PA.[2]

Clearly the availability of rt-PA is only the first step in the quest for effective acute stroke therapies and other interventional strategies besides thrombolysis must be considered. The other major approach to acute stroke therapy is neuroprotective therapy that is designed to intervene upon the multitude of cellular and metabolic events that occur in the ischemic region as a consequence of a clot obstructing a cerebral vessel.[3] One type of neuroprotective strategy is to inhibit the recruitment and activity of polymorphonuclear leukocytes, because it is evident that these inflammatory white blood cells are recruited into the region of local ischemia and may contribute to the progression of tissue injury. In animal stroke models, therapies interfering with polymorphonuclear leukocyte adhesion reduce infarct size when given after reperfusion in temporary local ischemia. With permanent occlusion stroke models, there is little if any evidence that these interventions are effective.[4]

Schneider et al. report the results of a dose escalation safety study with enlimomab, an anti-ICAM-1[5] murine monoclonal antibody, in 32 acute, ischemic stroke patients. Subsequently, enlimomab underwent a much larger efficacy trial. Unfortunately, in this efficacy trial enlimomab proved to be ineffective and was associated with an increased rate of mortality and a poorer functional outcome than placebo treatment. What observations in the safety trial might have affected the design and implementation of the efficacy trial to potentially avoid the difficulties encountered? Additionally, what lessons are there from this safety trial that might be learned to improve future neuroprotective drug development for acute ischemic stroke?

This dose escalation safety study was conducted in an open-label manner and only included on overall total of 32 patients, not balanced among the 4 dose tiers. The lack of a

placebo group and blinded assessment of side effects and benefits is a cause for concern in such a safety trial. The investigators observed infections in 14 of the 32 patients (44%) but did not conclude that these were unexpected adverse events. Additionally, 1 patient experienced an anaphylactoid reaction, and cardiac arrest, cardiac failure and renal failure occurred in 4 other patients. All of these are potentially serious adverse events that might reflect the natural course of events in a population with a debilitating illness such as acute ischemic stroke. However, the lack of a control group makes the interpretation of these adverse events difficult, if not impossible. The issue of infection is particularly important with an agent such as enlimomab because its inhibitory effects on polymorphonuclear leukocytes function could reduce the immune system's ability to fight infection. A 44% rate of potentially serious infection appears to be somewhat higher than might be expected and this contention might have been proven, if a placebo group had been available for comparison. No comment is made about the development of increased body temperature related to enlimomab treatment and this complication occurred significantly more often in the treated patients during the efficacy trial. If this did occur in the safety trial, a potentially important confounder of the efficacy trial might have been appreciated at an earlier stage of drug development.[6]

Hopefully, effective and safe neuroprotective drugs to complement and enhance thrombolytic therapy will be available soon. The development of such efficacious neuroprotective therapies will require a carefully designed and implemented series of steps. If drugs are being developed for acute stroke treatment prior to the initiation of thrombolysis or independent of thrombolytic therapy, efficacy in permanent occlusion animal models with an extended time window is necessary. Additional efficacy in transient occlusion models is also desirable. Preclinical toxicology studies should show a wide therapeutic index, i.e. the plasma/brain levels that afford neuroprotection should be at least 5 times lower than the levels where early hints of serious side effects begin to occur. Neuroprotective drugs meeting all of these preclinical criteria should be given in a dose-ranging study to a group of healthy volunteers and, if safe in this group, then be tried in elderly, healthy volunteers to assess safety in a population reflecting the age of the stroke population. Demonstration of initial safety in healthy volunteers should then lead to a dose-escalation safety trial in stroke patients, such as reported by Schneider et al. However, this so-called phase 2 type trials should always include a placebo control group and be performed in a double-blinded and randomized manner with an adequate sample size to ensure with a reasonable probability that frequent, serious adverse events are realized before a much larger cohort of patients is exposed to the drug in an efficacy trial. One concern of pharmaceutical sponsors of phase 2 trials is the desire to detect some hint of efficacy even in these relatively small trials. Occasionally, some such signal is detected, but generally the sample size is too small and the traditional functional out-come measures too insensitive. The new approach of using diffusion-perfusion magnetic resonance imaging (MRI) techniques [7] may be able to provide evidence even with the samples sizes traditionally used in phase 2 stroke trials that neuroprotective agents affect ischemic lesion evolution. This effect on lesion development will then hopefully translate to improved clinical outcome when much larger efficacy trials powered to detect effects on functional outcome are performed. This hypothesis is

currently being tested and if correct may change how phase 2 safety trial of acute ischemic stroke therapies are performed. However, currently phase 2 safety trials of therapies being developed for acute ischemic stroke require a placebo-controlled, double-blinded, randomized design whether or not MRI or other surrogate markers are employed. The availability of such a trial supported by a surrogate marker suggesting potential efficacy will hopefully lead to an efficacy trial with an enhanced potential for success and one that will not have serious adverse events.

Word Study

1. anaphylactoid [ˌænəfi'læktɔid] *a.* 过敏的
2. cardiac ['kɑ:diæk,'kɑ:diˌæk] *a.* 心脏的,心脏病的
3. cardiac arrest 心脏骤停
4. cardiac failure 心衰
5. cerebral ['seribrəl,'serəbrəl] *a.* 大脑的
6. cerebral vessel 脑血管
7. clot [klɔt] *n.* 凝块 *v.* 凝结,阻塞
8. complement ['kɔmpliмənt,'kɔmpləˌment,'kɔmpləmənt] *vt.* 相辅相成,补充 *n.* 补足物
9. confounder [kən'faundə] *n.* 混杂
10. contention [kən'tenʃən] *n.* 争论,争辩,论点
11. criteria [krai'tiəriə,krai'tiriə] *n.* 标准,尺度,准则
12. debilitating [di'biliteitiŋ,di'bilə,teitiŋ] *a.* 使衰弱的
13. enlimomab 恩莫单抗〈免疫调节药,抗炎药〉
14. escalation [ˌeskə'leiʃən] *n.* 逐步增大
15. hemorrhagic [ˌhemə'rædʒik] *a.* 出血的
16. interventional [intəventional] *a.* 干涉的,干预的
17. ischemic [is'ki:mik] *a.* 缺血性的
18. lesion ['li:ʒən] *n.* 损害,损伤
19. leukocyte ['lu:kəˌsait] *n.* 粒性白细胞
20. metabolic [ˌmetə'bɔlik] *a.* 新陈代谢的
21. monoclonal [ˌmɔnəu'kləunəl] *a.* 单克隆的,单细胞繁殖的 *n.* 单克隆
22. mortality [mɔ:'tæliti,mɔ:'tæləti] *n.* 死亡率,死亡数目
23. obstruct [əb'strʌkt] *v.* 妨碍,阻塞
24. placebo [plə'si:bəu,plɑ:'tʃeibəu] *n.* 安慰剂
25. plasminogen [plæz'minədʒin,plæz'minədʒən] *n.* 血纤维蛋白溶酶原
26. polymorphonuclear [pɔlimɔ:fə'nju:kljə,ˌpɔli:ˌmɔ:fə'nju:kli:ə] *a.* (白细胞)多形核的
27. polymorphonuclear leukocyte 多形核白细胞
28. randomized ['rændəˌmaizd] *a.* 随机的
29. recruitment [ri'kru:tmənt] *n.* 征募新兵,募集,募集现象
30. renal ['ri:nəl] *a.* 肾脏的
31. renal failure 肾衰

32. stringent ['strindʒənt] *a.* 严格的
33. surrogate ['sʌrəgeit] *n.* 代用品 *a.* 可代替的
34. thrombolysis [θrɔm'bɔlisis] *n.* 溶栓
35. travail ['træveil] *n.* 阵痛,辛劳
36. unequivocal ['ʌni'kwivəkəl,ʌni'kwivəkəl] *a.* 明白的,确切的
37. vessel ['vesl,'vesəl] *n.* 血管,脉管

Notes

1. Currently, the only acute stroke trial to demonstrate unequivocal efficacy is the recombinant tissue plasminogen activator (rt-PA) trial conducted in the USA with a maximum time to patient enrollment of 3h. 目前,唯一能证明对急性脑卒中有确切疗效的临床试验是在美国进行的重组组织型纤维蛋白酶原激活剂(rt-PA)的试验,其要求病人入院诊治的最大时间窗为 3 小时。
2. At this time, rt-PA for acute ischemic stroke is only approved for use by regulatory agencies within the USA but this situation may change soon, as might the effective time window, pending results of the second European cooperative acute stroke trial (ECAST-2) for rt-PA. 当时,rt-PA 是唯一经美国管理机构获准用于急性缺血性脑卒中治疗的药物,但此情形不久就可能改变,这是由于有效时间窗问题以及第二次欧洲 rt-PA 临床试验结果尚不确定。
3. The other major approach to acute stroke therapy is neuroprotective therapy that is designed to intervene upon the multitude of cellular and metabolic events that occur in the ischemic region as a consequence of a clot obstructing a cerebral vessel. 另一个急性脑卒中治疗的主要方法是神经保护治疗,用它来调节栓块阻塞脑血管后引起的缺血脑区的细胞和代谢活动异常。
4. With permanent occlusion stroke models, there is little if any evidence that these interventions are effective. 用永久性闭塞脑卒中模型,无证据表明这些干预措施有效。
5. ICAM-1: intercellular adhesion molecule-1, 细胞间黏附分子 -1
6. If this did occur in the safety trial, a potentially important confounder of the efficacy trial might have been appreciated at an earlier stage of drug development. 如果在安全性试验中就发现了体温升高,则在药物研发早期就可获知这可能会是影响有效性试验的一个潜在的重要混杂因素。
7. diffusion-perfusion magnetic resonance imaging (MRI) techniques 磁共振扩散灌注影像技术

Exercises

1. Please paraphrase the following sentences.

1) The improved outcome in the rt-PA group in this study led to the approval of this drug for the treatment of acute ischemic stroke in the USA within 3h of onset.
2) Concerns about the hemorrhagic risk and how to best target this effective but potentially risky therapy have imposed another barrier to its widespread use.

3) What observations in the safety trial might have affected the design and implementation of the efficacy trial to potentially avoid the difficulties encountered?
4) All of these are potentially serious adverse events that might reflect the natural course of events in a population with a debilitating illness such as acute ischemic stroke.
5) If drugs are being developed for acute stroke treatment prior to the initiation of thrombolysis or independent of thrombolytic therapy, efficacy in permanent occlusion animal models with an extended time window is necessary.

2. Translate the following paragraph from Chinese into English.

局部脑缺血损伤引起的炎症反应是缺血性脑卒中发生后的重要病理生理特征，因此，抗炎治疗策略可能是治疗急性缺血性脑卒中的一种有效方法。恩莫单抗是一种抗细胞间黏附分子-1的鼠单克隆抗体，在实验性脑缺血模型上，能抑制多形核白细胞的募集和活化，减少其黏附，降低脑梗死范围。然而，一项由625例急性缺血性脑卒中患者参加的大规模的有效性临床试验却显示，使用恩莫单抗治疗，对缺血性脑卒中患者无效，且可能使病情恶化。rt-PA的治疗时间窗为脑缺血发病后3小时，超过3小时后用药则无明显治疗意义，并有可能增加出血性风险。一项在动物脑卒中模型上的研究表明，将抗炎治疗与rt-PA治疗联合应用，能显著减小梗死范围，改善神经功能结果，而不增加出血性风险，还可能延长溶栓治疗的时间窗。

3. Write a summary on the basis of the text with no less than 300 words on the safety and the efficacy trial of enlimomab as well as the lessons from the clinical trial when a neuroprotective drug is developed.

Text B Pharmacology of Dimethyl Sulfoxide in Central Nervous System Damage

(Abridged from *Pharmacology of dimethyl sulfoxide in cardiac and CNS damage by STANLEY W. JACO, JACK C. DE LA TORRE*)

Dimethyl sulfoxide (DMSO)[1] has a variety of biological actions that have made it the target of numerous pharmacological studies. Over the past 40 years, more than 10 000 articles on the biological implications and 30 000 articles on the chemistry of DMSO have appeared in the scientific literature. In the last 30 years, the most productive area of research and application in the use of DMSO has been in traumatic brain injury (TBI)[2] and in stroke.

As reported in literature, DMSO exerts neuroprotective effects on cellular and subcellular components associated with an assortment of tissue insults particularly involving brain and spinal cord trauma[3] and stroke. These neuroprotective effects have been shown in animal models of central nervous system (CNS) injury and in humans with TBI and ischemic stroke.

DMSO in experimental TBI

A traumatic brain injury is usually the result of a sudden, violent blow to the head. The severity of the injury can range from minor, with few or no lasting consequences, to major, resulting in profound disability or death. The severity of TBI is dependent upon the area of the