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Analysis on Current Status and Plights of Translational Medicine

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ABSTRACT

Translational medicine, which is a new concept appearing in the field of international medical health in the past three or four years, forms a discipline of the system medicine (including systematic pathology, diagnosis and comprehensive treatment as well as pharmacology, etc) synchronizing with personalized medicine and predictable medicine. It is a branch of medical research trying to build a better bridge between the basic studies and the clinical medical treatment. It can promote the predicative, prognostic and personalized medicines by the evaluation and application of molecular markers, the individual therapies based on molecular subtypes and the evaluation and predication of therapeutic responses and prognosis. And its purpose is to build a direct connection between basic research and clinical practice so as to transform the knowledge and achievements of basic research into new therapeutic methods in clinic, which can be used to serve the clinic and solve clinical problems. Nevertheless, the study on translational medicine is limited, and there are few review articles about the progress of translational medicine in English. With the development of innovative and new technology, the therapeutic methods become more accurate and diverse, and the translational medicine will make outstanding advances and provide more space for the future treatment of various diseases so as to better serve the clinical practices and the patients. In addition, except the outstanding achievements, there are still multiple plights in the translational medicine research. Therefore, this study aimed to review the current status and the present problems in translational medicine, hoping to expand the study outcomes in China to the whole world.

Key words:
Translational medicine
National Institutes of Health
Current status
Plight
Hepatocellular carcinoma
Myocardial infarction

Introduction

With the development of human society, the medical model has been transformed from biology-medicine model to biology-psychology-social medicine model, along which the corresponding medical heath service has also turned to 4-P models (preventive, predicable, personnel and participatory). The life science research has entered into the proteomics era, which, in return, helps make marvelous achievements in the life science research, continuously disclose the essence of life activity, appeal to more attention to the basic scientific research from the whole world, increase the fund on research, produce abundant research and scientific fruits and accumulate plenty of research data. However, the input in the research and scientific field does not provide appropriate solutions to the problems in clinical practice, the transformation rate from basic research to clinical practice is low, and the speed of solving the clinical scientific problems is far behind the step of basic researches. How to fast and effectively transform the basic research results into theories, techniques, methods and drugs that are applicable in clinical practice has become an urgent issue, which stimulates the development of translational medicine, a new medical research field[1]. The purpose of translational medicine is to build a direct connection between basic research and clinical practice

so as to transform the knowledge and achievements of basic research into new therapeutic methods in clinic, which can be used to serve the clinic and solve clinical problems. The patient-centered translational medicine focuses on severe diseases in order to propose scientific problem from clinical practice for the development of correlative basic research, whose achievements will then be used in clinic to collect more clinical data to be fed back to clinical physicians[2]. Therefore, this study aimed to introduce the current status and the plights in translational medicine, hoping to expand the study outcomes in China to the whole world.

Definition of Translational Medicine

Concept of Translational Medicine

Translational medicine, also named as translational research, was proposed by American EA., Zerhouni in American *National Institutes of Health (NIH) Roadmap* in 2003, whose aim was to establish a rapid channel from bench to bedside by fleetly and effectively transform the basic research results of medical biology to theories, techniques, methods and drugs that could be practically applied in clinic. And then it has become an important part and a hot topic in the field of biological medicine.

Translational medicine is bi-directional and open instead of single-directional and close research process in the transformation from basic research to clinical practices, which means that translational medicine can not only fleetly and effectively apply the experimental research results to clinical practices, but also make deeper basic research when the problems in clinical practices are timely back-traced to the laboratories[3]. It is a constantly circulating, up-warding and endless research progression. It is not only the roadmap of American NIH, but also the roadmap of medical development. It is an inevitable way that should be passed by the medical research development and it will become the primary model and the promising pathway for present and future medical research.

Translational medicine, which is a new concept appearing in the field of international medical health in the past three or four years, forms a discipline of system medicine (including systematic pathology, diagnosis and comprehensive treatment as well as pharmacology, etc) synchronizing with the personalized and predictable medicines[4]. It is a branch of medical research attempting to build a better bridge between the basic studies and the clinical medical treatment. It is also known as modern medicine constructed under the basis of systematic biology and techniques such as genetics and omics chips, in which the interaction between systematic scientific theory and automatic communication techniques is so close that the industrialization process from scientific research to electrical engineering technology can be rapidly implemented and the distance between basic and clinical medicines due to the application of systematic science on medical science and techniques is greatly shortened[3].

Extensive definition of translational medicine

Translational medicine is extensively defined as the development and application of new techniques for patients, which focus on the early examination of patients and the early evaluation of diseases. In modern medical treatment, translation medicine is processed in a more open and patient-centered direction and it also includes the medical clinical practices derived from researches.

It can be seen from the above definition that translational medicine advocates the patient-centered therapeutic methods in clinical practices where multiple issues can be discovered and proposed. Deep research on basic medicine is conducted by the researchers, whose results are then transformed into clinical application fast. The integration of basic and clinical technical workers can increase the medical treatment to a higher level. Therefore, research on translational medicine advocates to break the single-disciplinary or limited cooperation models in previous research subjects and emphasize the constitution of project research team by multi-disciplinary experts.

Essence of translational medicine

The essence of translational medicine is the combination of theory and practices; the integration of basic and clinical medicines; the systematic analysis of molecules, cells, structures, functions, phenotypes, pathogenesis, physiology, pathology, environmental heredity, warning, diagnosis, prevention, treatment and the medical information; and the multi-disciplinary, multi-target and multi-level intersection and integration of microscopic view and macroscopic view, static state and dynamic state, structure and function, physiology and pathology, prevention and treatment as well as humanism and science[5-8]. Translational medicine us a great medical revolution, which not only involve each exclusive disciplinary reform in basic and clinical medicines, but also influence the cultivation of medical talents at present and in the future.

Developmental Background of Translational Medicine

Disjunction between basic medicine and clinical practices

With the development of scientific technology, great achievements have been made in resolving healthy problems. However, the obtained achievements are not proportional to the devoted human and material resources. The more resources input, the less obtained. From 2003 to 2005, American NIH had invested 1.5 billion dollars into genetic researches, which was returned by 25 000 research articles. Yet, it is still a long way to go to use this technology into clinical treatment. As to tumors, the studies on their molecular mechanism are fast, but the long-term survival of patients with solid tumors has not been prolonged, and the survival rate is still depended on the early diagnosis and treatment[9-10]. E.g., among the 25 years from 1976 to 2000, the 5-year survival rate of patients with lung cancer and colon cancer had been improved by only 25% and 28%, respectively. In the near 2 decades, America has devoted more than 200 billion dollars and abundant human resources into the scientific research and development of tumors, and is returned by 1.56 million research articles. In 1986, Nobel prize winner Renato Dulbeco reported in a article that serious diseases (such as tumors) could not be cured only by scattered studies, for which the decoding of genomics were still important. After joint efforts, Human Genome Project (HGP) was started in 1990 and the human genome sequencing was finished in 2003. However, after the sequencing, the expected cognition on autologous secrets is still not achieved. Obviously, there is significant disjunction between the basic scientific research and the clinical practices, so how to set up a bridge to improve the combination of basic medicine and clinical application had become the focus of human researches.

Increase of medical cost after changes of disease spectrums

There are significant differences in the disease spectrums in different countries due to the changes of industrialization and life styles. In developed countries, chronic diseases play a dominate role while in developing countries, infectious diseases and nutritional deficiency diseases are in the lead. As in China, with the development of economy, the disease spectrum had changed from acute diseases to chronic diseases, and the rate of latter is increasing annually with ages, which can promote the medical consumption and burdens. Therefore, the prevention and early intervention of diseases become a critical topic. The prevention and treatment of chronic diseases need the combined researches of multiple subjects including basic and clinical medicines and the application of multi-variance study model because the one-way analysis of variance cannot meet the demands of many chronic diseases[11]. Considering the significant differences in genetic background and the specificities of diseases, individual therapies based on molecular subtypes are clearly proposed due to the completely distinguished clinical efficacy and adverse responses of different therapeutic methods on one same disease.

Massive data in basic scientific research

Massive data have been accumulated in the development of Genomics and Proteomics, which will become useless if they cannot be used effectively. How to use these data to resolve medical problems is a challenge around the corner, which needs the effective combination and the interdisciplinary research of bioscience, mathematics, computers and the experts of medical fields[12]. The scientific research has changed from microscopic view into macroscopic view and the era of integrated systematic biological science is coming, which raises a claim in changing the medical research models.

Combination of basic research, medicinal development and medical practices

The prolonged longevity and improvement of quality of life are indisputable, but the traditional three separating situation has wasted lots of resources with low efficacy in resolving the problems. Though the medical cost is rising annually, the primary problems have not been tackled. So the essential purpose of translational medicine is to develop medical scientific practices with patient driven research process. And the most effective routine to resolve the medical fundamental issue is to combine the basic research, medicinal development and medical practices.

Current Status of Translational Medicine

Translational medicine is an inevitable product of history development, which received higher attention from various countries after it developed, in which America, English, Italy, Germany and France, are the principal subjects in the research of translational medicine. It will not ignore the basic research, but attaches great importance in the basic research aiming to solve the problems in clinical practice. In addition, translational medicine research centers, being composed of members from

basic and clinical research, have been set up in many countries, hoping to develop the translational medicine more purposefully. Some core journals open up the column for translational medicine in succession, including *Translational Research, J Translational Medicine* and *Science Translational Medicine*. In 2003, NIH formulated a long-term plan for the development of biological medicine, which planned to set up more than 60 translational medicine centers in 10 years. *American National Heart, Lung and Blood Institute* also finished a strategic plan for the future 5 ～ 10-year scientific work in 2007, which focused more on the translational research including the transformation from the laboratory to clinical bedside and from clinical bedside to community. Translational medicine also receives great improvements in English, where 450 million pound has been planned to fund the establishment of translational medicine centers in the future 5 years. In 2007, translational medicine was determined by *European Community* as a research and scientific field to be prioritized in the future 5 years, for which the funds was up to 6 billion Euro cents.

Translational medicine in China is in its initial step and many universities, medical science and technology institutes as well as pharmacological agent companies also develop close cooperation. In 2006, *Shanghai Jiaotong University* established cooperative relation with famous pharmacological enterprise *AstraZeneca Company* and set up *AstraZeneca Chinese Innovation Center*. Translational research centers have been established gradually by Chinese famous universities and scientific institutes to carry out translational medicine, such as *Xiamen University, Fudan University, Zhejiang University* and *Central South University*, etc[13-16]. In 2010, *Union Translational Medicine Center* was set up, which organized the medical elites from all parts of our country to drive and improve the development of Chinese translational medicine research and establish a platform for the communication and resource share with high-level translational medicine research institutes at home and abroad, hoping to forge an international high-end translational medicine research platform. In 2011, *Cyrus Tang Foundation* funded 100 million RMB to build the *Translational Medicine Institute of Shanghai Jiao Tong University School of Medicine*. At present, in China, many hospitals and research institutes have set up translational medicine research centers aiming to accelerate the spread and development of translational medicine, change the conventional concepts of basic researchers and clinical physicians and actively establish communication and relationship so as to play the function of scientific research in guiding the human health[17-18].

Additionally, international conferences on translational medicine increase gradually and international communication deepened continuously. In order to improve the development of translational medicine, multiple columns have been opened in many core journals across the world and three international journals have been published, namely *Science Translational Medicine*, *Translational Research* and *Journal of Translational medicine*. In 2011, the *12.5 Plan for Medical Science Development* promulgated by Chinese government focused on establishing 30 ～ 50 clinical/translational medicine centers on cardiovascular and cerebrovascular diseases, diabetes, malignant tumors, psychological diseases, mental diseases, respiratory diseases and birth defects[19-20]. Moreover, the "*12.5 Developmental Plan*" of *National Natural Science Foundation* also proposes to support the research of translational medicine and integration medicine.

Application of Translational Medicine

Development of translational medicine in experimental surgery

Experimental surgery, as a branch of surgery, focuses on exploring and verifying the unknown issues in surgical field by methods of laboratory medicine. Firstly, it aims to verify the clinical efficacy of surgical methods via animal experiments and the rationality of clinical diagnosis, treatment and application by various laboratory techniques and methods. Secondly, it is the principle content for the pathogenesis, diagnosis, prevention and prognosis of surgical diseases, in which evidence-based medicine is used for the determination.

From the foregoing, it is believed that experimental surgery is the important pivot for basic medicine and clinical medicine, especially for the interrelation between the surgical clinical medicines, so it belongs to the translational medicine[21-22]. During the clinical diagnosis and treatment of surgical diseases, issues are discovered and corresponding available solutions are diagnosed and verified by correlated contents in basic medicine of experimental surgery so as to apply the basic research results in clinical diagnosis and treatment in clinical practices.

In recent 30 years, though experimental surgery has made astounding achievements in domestic, it is still far behind the

world advanced level, which is mainly marked by[23-25]: (1) There are few advanced achievements with marked influence on international development; (2) Though articles published annually on SCI are numerous, few of them can transform basic medicine into clinical practices for repeated verification; (3) Notable physicians who are good at diagnosis and treatment of diseases are numerous, few of them can discover problems in clinical practices and turn to experimental surgical research; (4) The innovation on clinical surgeries is deficient and the achievements and application of advanced techniques are rare, in which the foreign new techniques are usually traced, imported and repeatedly applied and some important techniques and apparatus are controlled, so the innovative index and evidence degree of clinical research are needed to be further improved. In addition, the development of surgery in China is incomparable in world high-tech field, therefore, the experimental surgery, which belongs to translational medicine, should emphasize the inter-disciplinary transformations of medical science, improve the whole medical level, apply the translational medicine rationally and culture comprehensive talents of "experiment-clinical-laboratory" so as to make China a great country in the field of innovative and technology[26-32].

Translational medicine research on hepatocellular carcinoma (HCC)

HCC is one of the malignant tumors commonly seen in clinic. According to clinical statistics, HCC ranks the second of tumor-related death in China, and the third in the world. In recent 10 years, research on the techniques for treatment of HCC is increasingly expanded. The representative research methods include genomics, protrinology, metabonomics and transcriptomics, etc., which bring about great achievements for the development of basic medicine on HCC and leading position in HCC development and progression associated molecular mechanism and key molecule[33]. However, according to the diagnosis and treatment of HCC in clinic, the total prognosis is still poor, which is far behind of the rapid development of basic medicine.

The same situation is also found in China. HCC morbidity is high in our country and the number of patients account for more than half of the HCC patients all over the world. Therefore, relevant researches on the diagnosis and treatment are more outstanding, but the therapeutic condition is not positive. Hence, as to translational medicine research on HCC, though relevant basic medicine develops fast and innovative and new technologies updated continuously, the development of translational medicine is slow, and its application in clinical practices of treating HCC is not ideal, and the basic research on HCC has not achieved the expected aim of improving the prognostic survival time for HCC patients. Compared with research results in foreign countries, though the number of HCC patients is higher, the relevant molecular biological research has not provided effective therapeutic methods for clinical treatment through translational medicine, and the real significance of translational medicine is hard to achieve its expected efficacy.

Translational medicine research on myocardial infarction (MI)

At present, clear consensus has been made in the treatment of MI ischemic heart disease through translational medicine practices after years of clinical practices, summarization of therapeutic experiences and transformation from basic research to clinical practice. It is commonly believed that the placement of endovascular stent is the most effective method for the treatment of ischemic heart disease, so the application of endovascular stent shows excessive growth trend in treating ischemic heart disease. According to statistics, the application rate of endovascular stent increases annually by 60 thousand cases for continuously 3 years, but the mortality of patients with cardiovascular diseases is still increasing. The efficacy of a therapeutic method is diagnosed by the prognostic effect, which means the survival time of patients. Coronary stent and/or bypass surgery only reduce 3% ~ 5% of the mortality for patients with cardiovascular disease[13]. It is known from the above cases that in the 10-year application, translational medicine is still in exploration stage in the treatment of MI, and satisfactory efficacy has not been achieved[34-35]. Although coronary stent is considered as the principle therapeutic method for patients with MI in that it can quickly smooth the coronary artery, the diagnosis of a clinical applicable technique is not only based on the short-term recovery condition, but also on the long-term follow-up after treatment so as to make an objective evaluation. However, the prognosis of MI is unsatisfactory, so is the efficacy of translational medicine, which needs the collaboration of relevant researchers in basic medicine and clinical practices so as to promote the development of translational medicine and seek the optimal diagnostic and therapeutic protocols.

Plights of Translational Medicine

Although world translational medicine research has obtained great development and success, the development of transforming

basic biomedical research into effective clinical application is rather slow, which means that the success of translational medicine is limited. Because of the rapid development of scientific techniques and increasingly complex negotiatory problems in supervisory and business environment, translational medicine has faced the unprecedented challenges with multiple obstacles that inhibit its development. It is noteworthy that though translational medicine is bi-directional in transformation, the transformation from basic medicine to clinical application receives more attention, which is the biggest difficult that involving multiple factors like time, funds and ethnic, etc..

Funding profile and achievement publications contrary to the original intention of translational medicine

In the last 30 years, American National Oncology Institute has cost more than 200 billion dollars on relevant studies of basic medicine, in which 80% of the fund is used for the basic medicine on mice, drosophila and worms, with 1.56 million articles being published. However, the cancer-related mortality has no significant improvement. The same situation is also found in China, where article about basic medicine published on journals such as Nature, Science and Cell, are considered as the major and top research findings by physicians for a long time. Most clinical physicians, who are not good at basic medicine research due to their limited knowledge and are less sensitive to the challenges in clinic, are accustomed to solve clinical problems by experience; even in teaching hospitals, cooperation between clinical physicians and workers on basic medicine is more formal than practical, which lacks effective communication and integration, thus inhibiting the development of translational medicine. As to clinical physicians, to realize the new model of translational medicine, traditional thoughts on clinical science and technology should be changed, and the nature of diseases should be studied based on the innovative and new technologies, such as genomics, protrinology, metabonomics and transcriptomics, bioinformatics, etc., so as to search new therapies for the diagnosis and types of disease, provide new medicinal targets for treatment and explore new techniques for target therapy[36-38].

Organizational structure and mechanism of translational medicine research institutes

In traditional medical research organizations, mechanisms that can improve translational research is deficient and the basic scientists and clinical physicians are separated, which limit the opportunity of mutual inspiration, leading to academic obstacles between researchers. And translational medicine center can better support the research on translational medicine.

Lacking of workers

The present medical research emphasizes more on model organs and cells instead of human body, so the professionalization of translational medicine scientists is critical. The lacking of scientists involves the medical education problems, which needs the translational medicine researchers who can combine the basic and clinical medicine be equipped with Master's Degree (M.D.) or Doctor's Degree (D.D.) in clinical and basic fields. However, it is not easy for a researcher to get the M.D. or D.D. So to speak, the lacking of translational medicine researchers is a systematic issue threatening the medical academy.

Huge cost

Though the funding origins for translational medicine research are diverse, every channel has its limitation. American NIH is an important funding origin for translational medicine research, but does not establish the competitive mechanism between translational medicine and basic medicine research, and the patient-oriented clinical research has not been equally concerned as basic medicine. The partialness of these major fund systems on basic medicine has leaded to the consequences as follows: when human disease-associated research subjects are selected, the studies lack of sufficient closeness and most of stage Ⅰ clinical research only produce data without provide useful information to resolve the problems in medical treatment. Another fund origin of translational medicine is the earnings of medical treatment, but it will increase the operating costs of the medical organizations, and the cost of hospitals specialize in research is 30% ～ 40% higher than that of non-research hospitals. Some private foundation is also a fund origin, but its proportion of funds is small[39-40].

Complexity of translational medicine

Continuous research in clinic and laboratory is needed in translational medicine. Translational medicine has started for not long, so there are no typical cases for reference. How to scientifically and effectively develop the programs is still in exploration stage. The operation and education mechanisms of translational medicine are in fumble period, so how to integrate the powers of each department and discipline so as to cooperatively resolve the issues including translational medicine

associated target verification, intellectual property, transforming protocols, preclinical works, clinical trial design and fund preparation, etc., needs to be further explored and discussed.

Prospects of Translational Medicine

In the recent decade, translational medicine has developed quickly with numerous successful cases, such as the application of imatinib in the treatment of patients with gastrointestinal stromal tumor (GIST) can effectively prolong the patients' survival time from the 10 ~ 20 months to more than 57 months. In the future translational medicine research, infectious disease will become one of the important parts in clinic, in which lots of disease are agent to be resolved, such as acquired immune deficiency syndrome (AIDS), hepatitis B and C as well as influenza, etc.[41]. Though relevant research mechanisms have been proposed, the great and fast variation of influenza virus brings about dramatic challenge to the medical researchers. Additionally, it will also involves many other diseases like diseases of metabolism, psychology, movement disorders, retina, heredity, organ transplantation, with corresponding research contents including new agents for Alzheimer's disease, application of artificial spleen for type 1 diabetes, genetic therapies in treating spinal muscular atrophy and stem cell on patients with Parkinson's disease, and the pathogenesis mechanism of insomnia and its influence on human body, etc.. However, there are still many diseases waiting to be resolved by the research and application of translational medicine, which needs more effective communication between basic and clinical researchers. It is noteworthy to be mentioned that the most critical reason for the standstill of translational medicine is lacking of professional talents, so the author of this article advised that a huge number of professional talents on translational medicine should be cultured first to get proper practical techniques and theoretical knowledge and then research objective be made before basic medicine research, after which certain examination be conducted in clinic so as to determine whether the new technique is positive in treating corresponding diseases[42]. With the development of innovative and new technology, the therapeutic methods become more accurate and diverse, and the translational medicine will make outstanding advances and provide more space for the future treatment of various diseases so as to better serve the clinical practices and the patients.

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