

An Intellectual Stroke Database

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ABSTRACT

According to data definition of Case Record Form in the project which is termed “High-risk factors of stroke screening and intervention” from National Health and Family Planning Commission of the People’s Republic of China, we develop the stroke database network based on various kinds of clinical needs at clinical data registry, data mining and analyses. From November 2012 to January 2015, a total of 43468 screening population was completed, the two-way referral was 14754 cases, three months follow up 13561 cases, six months follow up 11563 cases, and one year follows up 8565 cases with the high-risk and stroke, meanwhile five research projects were registered. All data can be quickly and accurately uploaded to “China Stroke Data Center”, there was good relevance among the indexes through statistic by SAS software. In short, our database is advanced idea, integral functions, superior performance and simple operation. It is an advantageous data management platform for stroke prevention and therapy, clinical registries research and the establishment of biological specimen bank.

Keywords

stroke, database, registry study, biological specimen bank

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1. INTRODUCTION

The Multicenter Clinical Registry Study or The Real Word Study is emerging recently as a clinical research pattern in international academic circles. [1, 2] Under the premise of strict top design, clinical registry study is a multicenter, multitask, prospective study based on the network database to research the etiology, symptoms, auxiliary examination features, diagnosis and treatment plan, follow-up and prognostic information of target disease. It is characterized by detailed and accurate clinical data, standardized data definition, low criteria of selected cases, few extrapolation problems, high-quality research; meanwhile it can conduct vertical or cross-sectional studies. So, it make up the limit of excessively strict randomized controlled trial because of it’s high criteria of case selection, outstanding extrapolation issues, limited observation of adverse events, and difficult research on etiology and diagnosis[3,4]. Therefore, it has been getting more and more attention in the contemporary international academic circles. In the current situation, China has rich case resources but advanced research facilities and methods are relatively insufficient, especially in provincial and municipal hospitals. To carry out clinical registration study will play important role in accelerating discipline construction, promoting the connotation of hospital management and research level, ordering medical behavior, improving medical quality and safety. Because of needing a large quantity of data in clinical registration studies, it can’t be well conducted without the establishment of network database. Thus, it is the primary mission that building network database for carrying out clinical registration studies and creating biological specimen bank in China.

2. BASIC FUNCTIONS

We develop the stroke database network successfully according to the contemporary evidence-based literatures and data definition of Case Record Form in the project which is termed “High risk factors of stroke screening and intervention” from National Health and Family Planning Commission of the People’s Republic of China. The stroke database was placed on the website of The First People’s Hospital of Lianyungang, Jiangsu Province (website: <http://100.100.100.200:82/stroke/login.aspx>), and linked the external network (website: <http://123.138.180.70 /stroke/login.aspx>) on August 2012. At same time, it was also installed in the official network of The Affiliated Hospital, Yan’an University (website: <http://123.138.180.70/stroke/login.aspx>). The two hospitals simultaneously connect to “Chinese stroke data center”, it was practical implementation for three years from 2012 to 2014 on the project that is termed “High-risk factors of stroke screening and intervention”. This database with dozens of times of modifying and upgrading through constantly collecting users’ feedback advice has become increasingly perfect and mature because of meeting various kinds of clinical registry research and research project management, data mining and analyses. The basic functional units and the data flows of the database are shown in Figure 1. Its main functions are as follows:

2.1 Research projects registration.

According to the design of scientific research projects, the system can register either Randomized Controlled Trial, or Real World Study and data management of biological specimen bank. While a project is registered, the system can be designed such as blinded design, randomized, inclusion and exclusion criteria, research teams, informed consent, CRF, data selection mode (manual entry or use of the existing research cohort in this database), additional indexes added, drugs and surgical intervention methods, follow-up period and frequency, specific follow-up content and time-points, and so on. Once you have set the above parameters, the system will auto-run based on the corresponding parameter setting.

2.2 Data entry.

According to the requirements of project design or index definition of biological specimen bank, the system can set many functions, such as premised of researchers, numbering for cases and specimen, grouping and randomization, generating informed consent, the first record CRF and the follow-up CRF, etc. After researcher entry data, these functions will automatic operation.

2.3 Data reuse.

After the strict top design and data quality control, to reveal the underlying rule behind large amount of data annually generated from the project which is termed “High risk factors of stroke screening and intervention project” from National Health and Family Planning Commission of the People’s Republic of China is difficult for doctors busy with clinical work. Once "Default-mode" of our system is set according to parameters of the project registration, and what we need can be extracted efficiently from the basic database. If the number of cases is mismatch in each group, the system can randomly select cases to meet the match of cases number among groups. At this time, researchers can add indexes arbitrarily on the basis of the research demand, directly export data used for statistical analysis, and also add indexes for long-term observation and study.

2.4 Data quality control.

The system can check out data by the logic relation between indexes that project designer defined. The system can make tips and restriction of the errors of entry data automatically and inspect logical relation. For example, body height in adults can’t exceed 1 meter in one year, and glomerular filtration rate can directly calculate accord to the serum and urinary creatinine level, etc. For some constant indexes, such as family history, past history, and so on, the system can automatically search all basic cases according to the ID number, if those indexes were filled previously, the system would default directly.

2.5 Data retrieval.

When searching data, as long as we select the project title, various indexes will be present in line with the grouping, the basic information, the continuous variables, and the non-continuous variables. According to the need of the forthcoming written papers, researchers can optionally combine them from thousands of indexes, and extracted the best ideal data set for statistical analysis.

3. APPLICATION EFFECTS

From November 2012 to January 2015, a total of 43468 screening population was completed, the two-way referral was 14754 cases, three months follow up 13561 cases, six months follow up 11563 cases, and one year follows up 8565 cases with the high-risk and stroke, meanwhile five research projects were registered. All data can be quickly and accurately uploaded to “China Stroke Data Center”, there was good relevance among the indexes by SAS statistical software. In 2014, we successfully applied for two stroke research projects. Both of them were based on the database supporting. One is a study on the value of optimize antihypertensive scheme in patients with acute cerebral infarction (project number: H201461, Unique identifier: ChiCTR-TRC-14004804) , the other is a study on multidimensional “J shape rules” between the regulation of blood pressure controlled level and stroke risk (project number: BL2014062, Unique identifier: ChiCTR-TRC-13003408). These funds are approval respectively by the general program of Jiangsu Provincial Health Bureau and the clinical medical science and technology special-project in Science and Technology Agency of Jiangsu Province. These projects are being conducted successfully with supporting of our database. Some papers were published in Stroke, [5] International Journal of Stroke [6] in 2014 and Neurological Sciences [7] in 2015, and another some paper will be published in international academic journals.

4. SUPERIORITY COMMENT

Database is a platform as a common vehicle for clinical research from the traditional case series analysis to demographic-based research. The database provides a detailed and comprehensive description of integrated information sources, and it also provides a systematical analysis sets through collection, storage, analysis of clinical information. [8] Through the large sample, consecutive and prospective long period of follow-up registration, it provides characteristics of stroke classification, clinical subtype, diagnosis and the law, enhances the ability of understanding disease, and improves the accuracy rate of diagnostic. [9, 10] Since WHO Stroke Registry Program was established in 1971, many countries have established their own stroke database, which plays an increasingly important role in the analysis and research of the pathogenesis of stroke, development of disease, clinical

characteristics, and classification of diagnosis, prognosis of disease. For instance, the Swedish National Diabetes Register, [11] the Swedish National Patient Register, [12] Norway National register data [13] and the population register of the Killifish Health and Demographic Surveillance System. [14] There are five points for the purpose and significance of the establishment of the stroke database: First, to understand the course and outcome of stroke. Second, to provide research information and classification of clinical assessment that can be diagnosed. Third, to determine the prognostic factors of stroke. Forth, to provide information of stroke therapy for randomized control trial. Last, to study the etiology and risk factors of stratification. [15-18] Therefore, the establishment of SDB and the related research has been drawn widely international attention and has become of a new trend in clinical research domain of stroke.

However, we still have not a suitable stroke database for the use of the nationwide hospital at all levels, it not only hinders the process of clinical registration study in China, but also it is inconvenient for data management of stroke prevention. Since 1992, Nanjing General Hospital of Nanjing Military Command has developed "Nanjing stroke registry system" (website: <http://www.stroke.net.cn>). The system is especially for vascular imaging indexes of stroke described in full detail, and suitable for use in developed neural interventional hospitals. Beijing Tiantan Hospital has also developed the database [19] for record of stroke thrombolysis, post stroke depression and cerebral hemorrhage. 2012, National Health and Family Planning Commission of the People's Republic of China authorized "China stroke data center" (web site: <http://cnstroke.com/Userinfo/login.aspx>) according to "Stroke Screening and Prevention Engineering Guide Specifications ". This database provides a convenient platform for data management of stroke in high-level hospital of our country, but it still can not meet the needs of stroke data management and research in various hospitals. Therefore, "China Stroke Conference 2014" clearly pointed out that the Regional Network Center of Stroke Study at nationwide should be established in the future. Therefore, it is urgently needed to develop a multifunctional stroke database that can meet the need of data management of stroke prevention and intervention, and also which can meet the needs of user's special science project management. Meanwhile, it can record the current condition of illness, and it can be used for follow-up data registration of the future conditions as well. In other words, it can not only bring into play the leading effects of high-rank hospital, but also mobilize the participation enthusiasm of all level hospitals and be applied extensively in different levels of nationwide hospitals. We develop the "Chixun Stroke Database" matching the needs of stroke research data management in Regional Network Center in the future, and there are several characteristics as follows:

4.1 Data entry is quick and easy.

After every patient was recorded from preliminary screening platform, the system automatically determines the degree of risk. The information of low risk population was retained the preliminary screening platform, while the information of high risk population and stroke cases were deposits automatically in the high-risk platform and stroke registry platform, respectively. At the same time, due to the relevance of these input indexes, the system automatically generates screening results and intervention items. And then doctors make related intervention and avoid wrong choice to refer automatically selected items by computer. Furthermore, because the system is connected with HIS and LIS,

some information can be directly extracted through the admission number and patient name, and it greatly reduces the burden of doctors to input data, avoids error, and improves efficiency and quality of work.

4.2 Public health education was personalized.

In view of preliminary screening, high risk and stroke registry platform has the function of printing reports, and we set related health education contents according to the specific risk factors of participants. The response is very good because they can get a suitable recommendation for health education contents base on their own conditions.

4.3 The data is guaranteed uniqueness and authenticity.

Because there is a special entry platform of inspection and testing data, the data is only recorded and saved by the qualified personnel who is confirmed by the system through the examine and test platform, or else the entry data by unauthorized persons will be limited. At the same time, the data can be saved while inputted correctly ID number and this demographic information is unique in the system as the restriction of uniqueness of the ID card.

4.4 Uploading and browsing image data is convenient and intuitive.

As each work platform can upload pictures simultaneously, while evaluate or follow-up patients, doctors can refer these imaging data.

4.5 Management function of research data is powerful, scientific and convenient.

In order to meet the needs of scientific research data entry, the function of research project registration realized multiple functions of automatic selecting study case, automatic exclusion, automatic numbering and random grouping, etc. Because there are the functions of any CRF generation and index amplification, it is well met the needs of a various kinds of data management of clinical research project.

4.6 File management mode of three-level linkage realized the new ideas of stroke screening and intervention.

There are three-level (municipal, town and village) of administrative organization within the corresponding administrative areas in our country. Accordingly, we proposed the management mode of three-level linkage of stroke. The two-way transfer is very perfect in our database through connects with the Internet. Therefore, preliminary screening information input in our city is all finished by inquest, physical examination and data entry contemporaneously at the side of villages. We print screening report on the spots, the information of high-risk population is transferred to the hospital-base platforms immediately. Subjects hold this report to the hospital-base for further blood test and carotid ultrasound. After further rescreening, those patients with arterial stenosis stay directly in the hospital-base for further intervention, while those subjects with non-artery stenosis, their information were returned back local county or township hospitals for drug intervention and

follow-up. Its process of document management and screening are shown in Figure 2.

In short, our database is advanced idea, integral functions, superior performance and simple operation. It is an advantageous data management platform for stroke prevention and therapy, clinical registries research and the establishment of biological specimen bank.

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Appendix:

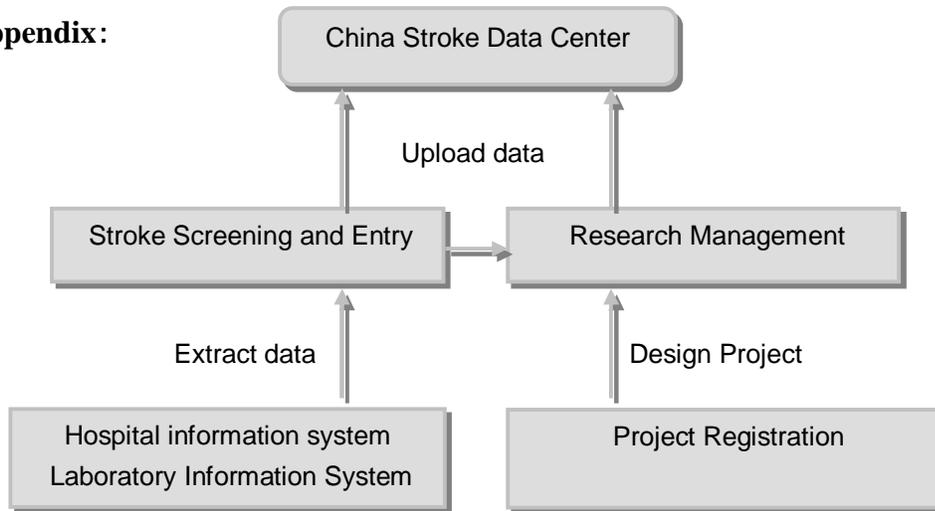


Figure 1: The basic functional units and the data flows of the database

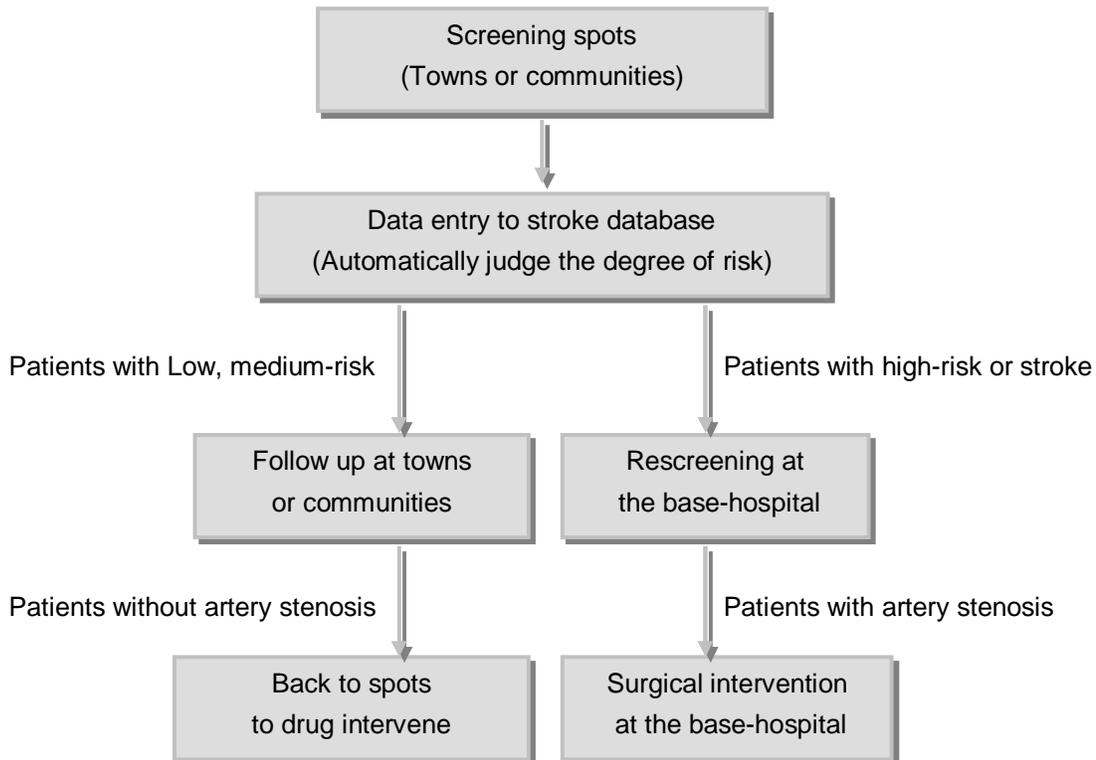


Figure 2: File management mode of three-level linkage