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What is This?
Chinese SLE Treatment and Research group (CSTAR) registry: I. Major clinical characteristics of Chinese patients with systemic lupus erythematosus

M Li1,*, W Zhang1,*, X Leng1, Z Li1, Z Ye1, C Li4, X Li5, P Zhu6, Z Wang7, Y Zheng8, X Li9, M Zhang10, F Zhang1, Y Zhao1, X Zeng1 and CSTAR co-authors**

1Department of Rheumatology, Peking Union Medical College Hospital, Key Laboratory of Rheumatology and Clinical Immunology, Ministry of Education, Beijing, China; 2Department of Rheumatology, The Affiliated Hospital of Bengbu Medical College, Anhui, China; 3Department of Rheumatology, The Fourth People's Hospital of Shenzhen Affiliated to Guangdong; Medical College, Guangdong, China; 4Department of Rheumatology, Beijing Children's Hospital Affiliated to Capital Medical University, China; 5Department of Rheumatology, The Second Hospital of Shanshi Medical University, China; 6Department of Clinical Immunology and Rheumatology, Xijing Hospital affiliated to the Fourth Military Medical University, Shaanxi, China; 7Department of Rheumatology, Beijing Tongren Hospital Affiliated to Capital Medical University, China; 8Department of Rheumatology, Beijing Chao-Yang Hospital Affiliated to Capital Medical University, China; 9Department of Rheumatology, Anhui Provincial Hospital, China; and 10Department of Rheumatology, Jiangsu Provincial People's Hospital, China

The Chinese systemic lupus erythematosus (SLE) treatment and research group (CSTAR) provides major clinical characteristics of SLE in China and establishes a platform to provide resources for future basic and clinical studies. CSTAR originated as a multicentre, consecutive, and prospective design. The data were collected online from 104 rheumatology centers, which covered 30 provinces in China. The registered patients were required to meet four or more of the American College of Rheumatology (ACR) criteria for the classification of SLE. All CSTAR centers use the same protocol-directed methods to provide uniform evaluations, which included demographic data, clinical features, laboratory examinations, and disease activity evaluations. The patient samples, including DNA samples and sera, were also collected for further quality controls and additional studies. Preliminary analysis from 2104 baseline evaluations was available for this analysis. Of 1914 female and 190 male patients (F:M = 10.1), the mean age at onset was 29.2 y with confirmed diagnosis one year later at the age of 30.3 y. Eighty four (4.2%) of 2002 patients had a family history of rheumatic diseases, including 34 (1.7%) cases with SLE. In addition, one hundred and seven (5.2%) abnormal pregnancies were recorded among 2026 experiences. The characteristics of the CSTAR cohort were compared to similarly sized cohorts from other studies. We found that 56.1% of patients presented with concurrent hematological disorders compared to only 18.2% of European patients. Moreover, 47.4% of patients presented with nephropathy compared to 27.9% of European patients. Conversely, neurological manifestations were only seen in 4.8% of Chinese SLE patients compared to 19.4% of European patients, 12.1% of U.S. patients, 22.8% of Malaysian patients and 26.4% of Latin Americans. Pulmonary arterial hypertension and interstitial lung diseases were complications identified in 3.8% and 4.2% of Chinese lupus patients, respectively. The CSTAR registry has provided epidemiological data and phenotypes of Chinese patients with SLE, and has demonstrated several differences between ethnicities. Clinical data and biologic samples would be valuable resources for future translational studies with national and international collaboration. *Lupus (2013) 22, 1192-1199.

Key words: Systemic lupus erythematosus; registry; epidemiology

Introduction

Systemic lupus erythematosus (SLE) is the most complex disorder of systemic autoimmune diseases because it can affect any human organ and displays diverse phenotypes.1 However, it is well-accepted that SLE can be divided into several subgroups.
Age, gender, and the autoantibody pattern may have an impact on phenotypes of lupus, which can lead to different prognosis.2

SLE predominantly affects women, and particularly those from certain ethnic groups.3 Although the prevalence of lupus varies widely throughout the world, the highest prevalence has been reported in Italy, Spain, and populations with African or Asian ancestry.4 Therefore, the analysis of geographic variation among different SLE presentations and autoantibody associations may help in identifying genetic or environmental factors of the disease.5

To better understand this chronic disease, lupus registries and cohort studies have been created and maintained in the U.S. and Europe for more than twenty years, such as the Systemic Lupus International Collaborative Clinics (SLICC),6 Lupus Family Registry and Repository (LFRR),7 Lupus in Minorities: Nature vs Nurture (LUMINA),8 Euro-lupus project,9 the PROFILE10 and the GLADEL cohorts.11 In an attempt to clarify the natural history, evolution, co-morbidity, mortality, pathogenesis, and other difficult issues in patients with SLE, these registries have provided a plethora of valuable data, evidence, and biologic samples for studies.6–15 which guide the appropriate clinical practice and novel therapeutic development to improve the prognosis and quality of life for SLE patients.

Of the newly industrialized countries, China has the fastest growing economy in the world; however, there are limited epidemiological data on lupus in the Chinese population.16 Most studies that do exist were conducted retrospectively or at a single center. With the support of the Chinese National Key Technology R&D Program, the Chinese SLE Treatment and Research group (CSTAR) developed the first online registry of Chinese lupus in 2009, which is a multicenter observational study attempting to depict major clinical characteristics of lupus in Chinese patients and to explore any difference compared with other similar-sized cohorts.

Methods

CSTAR

CSTAR is an academic union that was first funded by the Chinese Ministry of Science & Technology in 2009. CSTAR is composed of 104 high-ranked rheumatology centers (see appendix) that cover 30 provinces in China. As the leading site, Peking Union Medical College Hospital (PUMCH) assumes substantial responsibility for training, communicating, and funding. The missions of CSTAR is to conduct clinical and basic research on SLE with coordinated efforts nationwide, to develop a platform of Chinese SLE research force in tandem with international protocols, and to create a self-sustaining research model.

Registry

The first project launched by CSTAR in 2009 was a registry of Chinese lupus patients, which was approved by the medical ethics committee of PUMCH. Other centers may receive their own ethics approval according to local regulations. National or regional training programs were set up for all investigators for diagnosis confirmation, history review, activity evaluation, mandatory laboratory examinations, data input and biologic sample collections. The online registry system, Chinese SLE information system (CSIS) version 1.0, was open to qualified investigators from different sites. In addition, newsletters of enrollment numbers, preliminary data, and quality controls are sent to all centers every month.

Patient recruitment

Our analysis of preliminary data was based on the CSTAR online registry. All Chinese patients with SLE were registered after informed consent forms were signed by themselves or their authorized guardians. The ongoing registry was launched in April 2009, and 2170 Chinese patients with SLE, who fulfilled four or more criteria for SLE diagnosis defined by the 1997 revised American College of Rheumatology (ACR) criteria,17,18 were registered by February 2010. After careful review, 66 cases (3.0%) with major incomplete data were removed from the database. Baseline data from 2104 patients were entered for the final analysis.

Data collection

All CSTAR centers use the same protocol-directed methods to provide uniform evaluations and record data. Demographic data were generally collected and included age at entry, gender, age at onset, age at diagnosis, family history of rheumatic diseases, and reproductive history. Socioeconomic status, education and marital status were also investigated.

Clinical information included the initial manifestation and systemic involvement. The initial manifestation of SLE is defined as symptoms
Results

Demographics

The baseline data consisted of 1914 (91.0%) female and 190 (9.0%) male patients (female to male ratio, 10.1). The mean age at onset of symptoms that were attributable to lupus was 29.2 ± 12.1 y (range, 1.4-68.9 y), mean age at diagnosis of lupus was 30.3 ± 12.3 y (range, 4-77 y) and mean age at entry was 32.7 ± 12.7 y (range, 5-78 y). Eighty four (4.2%) of 2002 patients had a family history of rheumatic diseases, including 34 (1.7%) with SLE and 50 (2.5%) with others including 30 cases of rheumatoid arthritis, 6 cases of primary Sjögren’s syndrome, 1 case of systemic sclerosis, 1 case of dermatomyositis, 4 cases of undifferentiated connective tissue disease, 1 case of vasculitis, 3 cases of ankylosing spondylitis, 1 case of psoriasis and 3 cases of rheumatic arthritis. One hundred and seven (5.2%) abnormal pregnancies were recorded among 2026 experiences, which included 49 cases of spontaneous abortion, 16 cases of fetal death, 4 cases of premature delivery, but 38 cases without detailed descriptions.

Socio-demographic data revealed that about one third (35%) of Chinese patients with SLE were in low-income families with average per capital income less than 1,000 China Yuan (CNY) month and only 15.9% of our patients were in relative high-income families with average monthly per capital income more than 3,000 CNY. Nearly one third (30.9%) of Chinese patients with SLE were well-educated with college degree, but still 14.3% of our patients were undereducated only with elementary education. Marital status showed that about two thirds (65.1%) of Chinese patients were married, one third (33.9%) were single and only 21 patients (1%) were divorced in our registry.

Clinical manifestations

The most common primary manifestations at onset were rash (53.8%), arthritis (53.5%), fever (37.5%), hematocytopenia (31.9%), or nephropathy (25.8%). However, a few cases presented with pulmonary (5.5%), gastrointestinal (3.6%), neurological (3.5%), cardiac (3.5%), or other (4.6%) manifestations.

As shown in Table 1, 1009 patients (47.9%) presented with malar rash, 118 (5.6%) had discoid lesion, 526 (25.0%) experienced photosensitivity, 466 (22.1%) had oral ulcers, 1147 (54.5%) had arthritis, 345 (16.4%) had serositis, 1181 (56.1%) had hematomocytopenia, 998 (47.4%) had nephropathy, and 101 (4.8%) had neurologic involvement. This analysis revealed important differences between this group and the other five cohorts. First, more than half of Chinese SLE patients (56.1%) presented with concurrent haematological disorders compared to 48.8% of Malaysian patients, 72.5% of Latin Americans and only 18.2% of European patients in the cohorts studied. Second, almost half of the Chinese patients (47.4%) were also diagnosed with kidney disease, which was in accordance with 40.2-55.6% of U.S. patients and 51.7% of Latin, compared to 27.9% of European patients and more prevalent in 74% of Malaysian patients. Thirdly, neurological manifestations were only seen in 4.8% of Chinese SLE patients compared to 19.4% of European patients and 12.1% of U.S. patients. 22.8% of Malaysian patients and 26.4% of Latin Americans. This prospective cross-sectional study revealed that the prevalence rate of PAH in Chinese SLE patients was 3.8% (74/1934) and the rate of ILD was 4.2% (86/2024).

Autoantibodies

The profiles of autoantibodies included the presence of ANA in 2063 (98.1%) cases, anti-dsDNA in 699 (33.2%), anti-Sm in 350 (16.6%), anti-RNP in 189 (8.9%), anti-SSA in 497(23.6%), anti-SSB in 224 (10.7%) and anti-rRNP in 255 (12.7%) cases. aPL were tested in 937 patients and were positive in 224 (10.7%) and anti-rRNP in 255 (12.7%) cases.
414 (44.1%). Among these cases, higher incidence of aPL was 36/54 (66.7%) in patients with abnormal pregnancy. But diagnosis of antiphospholipid syndrome (APS) could not be confirmed without additional information in the registry.

SLE disease activity

SLEDAI scores revealed that most patients had active SLE at the time of entry into the study. The patients were stratified by SLEDAI scores into groups, including 532 (25.3%) cases to a stable group (<5), 587 (27.9%) cases to a mild active group (5-9), 591 (28.1%) cases to a moderate active group (10-14), and 394 (18.7%) cases to a severe active group (>14).

Discussion

SLE has been recognized as a common, chronic, life-threatening disease that represents a serious threat to women’s health and an increasing burden on the patient’s family and society. SLE appears to be more prevalent in certain ethnic groups, such as the African-Americans, African-Caribbeans, and Asians.1 The prevalence of SLE in the Chinese population was estimated to be 40-70 cases per 100,000 persons (>100/100,000 among women),19 which represent a prevalence that is higher than Caucasians but lower than African-Americans. Based on an estimated Chinese population of 1.3 billion published in 2009, the number of lupus patients in China could reach 520,000-910,000, which would be the largest cluster of cases in the world. However, there are few epidemiological data available to date on lupus in the Chinese population. Most studies on phenotypes or survival of this population were from Hong Kong,20,21 and most studies conducted in mainland China were retrospective or regional analyses.22

CSTAR was the first to create a working group on lupus nationwide, and then launched the first multicenter registry of lupus cases in China. CSTAR sampled a representative and large-sized cohort of Chinese patients with SLE. Importantly, this prospective design, protocol-directed operation together with online data collection and quality controls make the information more reliable with minimal bias. The results of this approach could provide accurate information on the current situation of lupus in Chinese patients.

In our registry, SLE mainly occurred in childbearing women, coinciding with other studies. It is encouraging that most patients were diagnosed with SLE just one year after the onset of the disease, which suggests that both physicians (especially rheumatologists) and the general population are well informed of the disease. This situation is similar to the progressive development of rheumatology in China.23 In terms of genetic difference, we found that only 1.7% of all patients analyzed have a familial history of SLE, which is much lower than the 5.0% reported in the LUMINA cohort.24 Recently, newly detected susceptibility loci for Chinese SLE also showed a different genetic background between Chinese and other ethnic groups.25 Another important issue with lupus is pregnancy, and 5.2% abnormal experiences were recorded in our registry. This is in accordance with other studies that have shown a greater risk of still births, abortions, and premature delivery in SLE patients than in the general population.26,27 Therefore, further collaborative care is needed from obstetrics and rheumatology for these patients.

### Table 1 Comparison of cumulative main characteristics (%) related to SLE in several large cohorts

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of patients</th>
<th>Geographical area</th>
<th>Malar rash</th>
<th>Discoid lesions</th>
<th>Photosensitivity</th>
<th>Oral ulcers</th>
<th>Arthritis</th>
<th>Arthritis</th>
<th>Serositis</th>
<th>Hematologic involvement</th>
<th>Nephropathy</th>
<th>Neurologic involvement</th>
<th>ANA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petri, et al.</td>
<td>574</td>
<td>United States</td>
<td>331 (57.7)</td>
<td>162 (28.3)</td>
<td>335 (58.4)</td>
<td>219 (38.2)</td>
<td>NR</td>
<td>272 (50.5)</td>
<td>NR</td>
<td>319 (55.6)</td>
<td>123 (22.8)</td>
<td>NR</td>
<td>500</td>
</tr>
<tr>
<td>Wang, et al.</td>
<td>539</td>
<td>Asia, Malaysia</td>
<td>410 (76.1)</td>
<td>30 (5.6)</td>
<td>222 (41.2)</td>
<td>185 (34.3)</td>
<td>272 (50.5)</td>
<td>489 (88.1)</td>
<td>287 (51.7)</td>
<td>399 (74)</td>
<td>39 (74)</td>
<td>500 (98.9)</td>
<td>399</td>
</tr>
<tr>
<td>Alarcon, et al.</td>
<td>555</td>
<td>United States</td>
<td>322 (58)</td>
<td>107 (19.3)</td>
<td>334 (60.2)</td>
<td>293 (52.8)</td>
<td>489 (88.1)</td>
<td>481 (48.1)</td>
<td>160 (16)</td>
<td>404 (72.8)</td>
<td>223 (40.2)</td>
<td>67 (12.1)</td>
<td>538</td>
</tr>
<tr>
<td>Cervera, et al.</td>
<td>1000</td>
<td>Europe</td>
<td>311 (31.1)</td>
<td>78 (7.8)</td>
<td>229 (22.9)</td>
<td>125 (25.6)</td>
<td>481 (48.1)</td>
<td>481 (48.1)</td>
<td>160 (16)</td>
<td>182 (18.2)</td>
<td>279 (27.9)</td>
<td>194 (19.4)</td>
<td>538</td>
</tr>
<tr>
<td>Pons-Estel, et al.</td>
<td>1214</td>
<td>Latin America</td>
<td>744 (61.9)</td>
<td>143 (11.8)</td>
<td>681 (56.1)</td>
<td>506 (41.7)</td>
<td>481 (48.1)</td>
<td>506 (41.7)</td>
<td>268 (22.1)</td>
<td>880 (72.5)</td>
<td>628 (51.7)</td>
<td>321 (26.4)</td>
<td>NR</td>
</tr>
<tr>
<td>CSTAR</td>
<td>2104</td>
<td>Asia, China</td>
<td>1009 (47.9)</td>
<td>118 (9.5)</td>
<td>526 (25.0)</td>
<td>466 (22.1)</td>
<td>1147 (54.5)</td>
<td>1147 (54.5)</td>
<td>345 (16.4)</td>
<td>1181 (56.3)</td>
<td>998 (47.4)</td>
<td>101 (4.8)</td>
<td>2063</td>
</tr>
</tbody>
</table>

Abbreviation: NR, Not reported.
In this study, we described the frequency of primary manifestations attributed to lupus, which provides continuous medical education (CME) for primary care and other specialties. General physicians should pay attention to common symptoms of lupus, including an unknown origin of rash, arthritis, fever, hematocytopenia, or nephropathy, and attempt to refer suspected patients to a rheumatology consult for further investigation. Other specialties should also consider lupus as a differential diagnosis in complicated cases of cardiopulmonary, gastrointestinal, or neurological problems, and request a consultation from rheumatology. The information provided here may help improve early diagnosis of the disease in the future.

In our study, the main systemic involvement was comparable to other studies.9–11,15,28 We found that more lupus nephritis and haematological disorders and less neuropsychiatric lupus cases were detected in Chinese patients with SLE. These characteristics are in agreement with previous Chinese studies. CME for Chinese rheumatologists should emphasize precise monitoring and evaluation of renal and haematological parameters. Furthermore, we were the first report the prevalence of PAH and ILD associated with SLE in China, which have increasingly become major causes of death that will require great efforts to be managed in the future.29,30

We also assessed the profile of autoantibodies in patients of this study, but did not analyze the pattern of phenotypes associated with these antibodies. The ideal way to confirm the presence of antibodies is to test patient samples in a qualified central lab. According to our proposed protocol, all DNA and serum samples will be transported to the leading site at PUMCH. However, we were not able to accomplish a final analysis of the samples until the laboratory results have passed quality control. The presence of aPL was high in patients of this registry, especially with abnormal pregnancy. It is well accepted that aPLs are associated with adverse pregnancy outcome,31 to which we should pay more attention in the future study.

Disease evaluation was one of the important issues during our study design. SLEDAI scores showed that more active patients with SLE were enrolled in our registry, because new-onset and therapy-naive patients were encouraged to register. Regular follow-ups will benefit this group of patients, which will also help us establish a Chinese cohort of lupus patients in the near future. Other accepted tools, such as British Isles Lupus Assessment Group index (BILAG), Physician Global Assessment (PGA), and SLECC damage index are generally not applied in daily practice. However, Chinese rheumatologists are beginning to receive appropriate training of these assessment indices, and their implementation will be invaluable for an overall evaluation of lupus patients.

In summary, the CSTAR registry now provides preliminary data of Chinese patients with SLE at baseline, which has outlined the main characteristics of lupus in China and revealed several differences between ethnicities. The results here highlight the future direction of studies and CME. Clinical data and patient samples will be valuable resources for future translational studies with national and international collaboration. In addition, this registry and analysis will also be helpful for future management of patients with SLE using evidence-based medicine models.32

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There is no other disclosure.

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**Appendix**

**CSTAR co-authors**

1. Peking Union Medical College Hospital: Hongmei Song, Qian Wang, Qingjun Wu, Jimei Su, Qun Shi, Xin You, Wenjie Zheng, Ying Jiang, Dong Xu, You Hou, Min Shen, Hua Chen, Xiaodan Gan, Chaojun Hu, Juliang Zhao, Suzian Liu.
2. The Affiliated Drum Tower Hospital of Nanjing University Medical School: Lingyun Sun.
3. Anhui Provincial Hospital: Xiangpei Li, Xiaomei Li.
4. The Affiliated Hospital of Bengbu Medical College: Liqi Bi.
5. The First Affiliated Hospital of Sun Yat-sen University: Xiuyan Yang.
6. The Second Hospital of Shanxi Medical University: Xiaofeng Li, Jinli Ru.
7. Beijing Hospital Affiliated to the Ministry of Health of PRC: Cibo Huang, Bei Lai.
10. Xuanwu Hospital Affiliated to Capital Medical University: Xiaoxia Li.
11. Beijing Hospital Hospital Affiliated to Capital Medical University: Ting Duan.
12. Beijing Children Hospital Affiliated to Capital Medical University: Caifeng Li.
15. Changhui Hospital Affiliated to the Second Military Medical University: Dongbao Zhao.
16. Changzheng Hospital Affiliated to the Second Military Medical University: Huji Xu.
17. Huashan Hospital Affiliated to Fudan University: Hejian Zou, Haomin Qiu.
18. The First Affiliated Hospital of Anhui Medical University: Jianhua Xu, Li Mu.
19. Qilu Hospital of Shandong University: Xingfu Li.
20. The Second Affiliated Hospital of Zhejiang University School of Medicine: Huaxiang Wu.
21. The Third Affiliated Hospital of Sun Yat-sen University: Jieruo Gu, Ou Jin.
22. The Second Affiliated Hospital of Guangzhou Medical College: Yi Tao.
23. Guangdong Provincial People’s Hospital: Xiao Zhang, Guangfu Dong.
24. Xiangya Hospital, Central South University: Xiaoxia Zuo, Yisha Li.
25. The First Affiliated Hospital of Harbin Medical University: Zhiyi Zhang, Yifang Mei.
26. The First Hospital of China Medical University: Weiguo Xiao, Hongfeng Zhang.
27. Xijing Hospital Affiliated to the Fourth Military Medical University: Ping Zhu, Zhenbiao Wu.
29. West China Hospital Affiliated to Sichuan University: Yi Liu.
30. The Affiliated Hospital of North Sichuan Medical College: Guohua Yuan.
31. Sichuan Provincial People’s Hospital: Bin Zhou.
32. The People’s Hospital of Xinjiang Autonomous Region: Lijun Wu.
33. Jiangsu Provincial People’s Hospital: Miaojia Zhang.
34. The First Affiliated Hospital of Zhengzhou University: Shengyun Liu.
35. Shengjing Hospital Affiliated to China Medical University: Ning Zhang.
36. The First Affiliated Hospital of Shantou University Medical College: Qingyu Zeng.
37. Tianjin First Central Hospital: Wencheng Qi, Feng Han.
38. The Affiliated Hospital of Bengbu Medical College: Zhijun Li, Changhao Xie.
40. Peking University Shougang Hospital: Shuling Han.
41. Beijing Jishuitan Hospital: Hui Song, Shumin Yan.
42. Fuxing Hospital Affiliated to Capital Medical University: Wen Luo, Peilin Li.
43. Beijing Shunyi Hospital: Xiaomin Liu.
44. Peking University Third Hospital: Xiangyuan Liu, Xiaoli Deng.
45. South-West Hospital Affiliated to Third military Medical University: Yongfei Fang.
46. The First People’s Hospital of Foshan: Guoqiang Chen.
47. Fujian Provincial Hospital: He Lin.
48. The Second Affiliated Hospital of Fujian Medical University: Ling Lin.
49. Fuzhou General Hospital of Nanjing Military Region: Yinong Li.
50. Zhongshan Hospital Affiliated to Fudan University: Lindi Jiang, Lili Ma.
51. The First Affiliated Hospital of Guangxi Medical University: Cheng Zhao, Zhanrui Chen.
52. The People’s Hospital of Guangxi Autonomous Region: Jinying Lin.
53. The Affiliated Hospital of Guiyang Medical College: Long Li.
54. The Second Affiliated Hospital of Harbin Medical University: Yinhuang Zhao.
55. Hainan Provincial People’s Hospital: Feng Zhan, Shudian Lin.
56. Hebei Provincial People’s Hospital: Fengxiaozhang, Yonglong Yan.
57. Bethune International Peace Hospital: Zhenbin Li.
58. Henan Provincial People’s Hospital: Fengmin Shao, Wei Liu.
59. The First Hospital of Qiqihar: Xiaowei Gong.
60. Tongji Hospital Affiliated to Tongji Medical School of Huazhong University of Science and Technology: Shaoxian Hu.
63. The Affiliated Hospital of Inner Mongolia Medical College: Hongbin Li.
64. Nanfang Hospital Affiliated to Southern Medical University: Min Yang.
65. The General Hospital of Ningxia Medical University: Yi Gong, Hong Zhu.
66. The Affiliated Hospital of Qingdao University Medical College: Jibo Wang.
67. The Fourth People’s Hospital of Shenzhen Affiliated to Guangdong Medical College: Zhizhong Ye, Zhihua Yin.
68. The General Hospital of TianJin Medical University: Lu Gong.
69. Beijing Tongren Hospital Affiliated to Capital Medical University: Zhengang Wang, Li Cui.
70. The Second People’s Hospital of Wuxi: Tianli Ren.
71. The People’s Hospital of Wuxi: Yaohong Zou.
72. The Second Xiangya Hospital of Central South University: Jiweng Xu, Hi Mao.
73. The First People’s Hospital of Yunnan Province: Qin Li.
74. The First Affiliated Hospital of Zhejiang University School of Medicine: Jin Lin.
75. Sun Yat-sen Memorial Hospital, Sun Yat-sen University: Lie Dai, Baiyu Zhang.
76. The First People’s Hospital of Changzhou: Min Wu, Wen Xie.

77. The Affiliated Orthopaedic Hospital of Shandong Linyi People’s Hospital: Zhenchun Zhang.

78. Zhejiang Provincial People’s Hospital: Zhenhua Ying.

79. The First Affiliated Hospital of Baotou Medical College: Yongfu Wang.

80. The Affiliated Hospital of Nantong University: Zhiwei Zhang.

81. The First Affiliated Hospital of Suzhou University: Zhifeng Li.

82. Beijing Shiitan Hospital: Miansong Zhao.

83. Shandong Yantai Yuhuangding Hospital: Weiling Yuan.

84. The General Hospital of Daqing Oilfield: Xiangjie Bi.

85. First Affiliated Hospital of Medical College of Xi’an Jiaotong University: Lan He, Dan Pu.

86. Provincial Hospital Affiliated to Shandong University, Jinan, China: Yuanchao Zhang, Limin Zhang.

87. Jiang University 2nd Clinical Medicine College, Shenzhen People’s Hospital: Dongzhou Liu, Xiaoping Hong.

88. No.285 Hospital of People’s Liberation Army: Zhu Chen.

89. The First Hospital of Shanxi Medical University: Xiumei Liu, Yiqun Hao.

90. Kailuan Hospital Affiliated to North China Coal Medical College: Liufu Cui.

91. Peking University Shenzhen Hospital: Qingwen Wang, Yi-Sheng Zhu.

92. The First Affiliated Hospital of Fujian Medical University: Junmin Chen.

93. The First Hospital of Ningbo: Xiafei Xi.

94. Shanxi Provincial People’s Hospital: Lihua Fang.

95. The Second Hospital of Hebei Medical University: Hongtao Jin, Huifang Guo.

96. The First Affiliated Hospital of Wenzhou Medical College: Xiaochun Zhu.

97. The Third Affiliated Hospital of Hebei Medical University: Junmin Chen.

98. The First Affiliated Hospital of Xinjiang Medical University: Junmin Chen.


100. Wuhan Union Hospital Affiliated to Tongji Medical School of Huazhong University of Science and Technology: Lingxun Shen.

101. No. 264 Hospital of People’s Liberation Army: Jinli Ru, Xiaoxiang Xie.

102. Zhongda Hospital Affiliated to Southeast University: Meimei Wang.

103. The Central Hospital of Sichuan Mianyang: Jing Yang, yu Zhang.

104. The Seventh People’s Hospital of Shenyang: Zhen Wang, Tienan Li.