ERCP development in the largest developing country: a national survey from China in 2013

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Background and Aims: The ERCP volume in developed countries has decreased recently, whereas the ERCP trend is unknown in developing countries. This study aimed to evaluate the ERCP development in China between 2006 and 2012.

Methods: All hospitals performing ERCP in mainland China in 2012 participated in an online survey. Data on ERCP infrastructure, volume, indication, and adverse events were collected and compared with those in a previous national survey and in developed countries.

Results: From 2006 to 2012 the number of hospitals performing ERCP in China increased from 470 to 1156. The total ERCP volume increased from 63,787 to 195,643, of which >95% were therapeutic. The ERCP rate in China (14.4 per 100,000 inhabitants) in 2012 was still much lower than that in developed countries. There was significant imbalance between different regions (1.3-99.1 per 100,000 inhabitants). The median ERCP volume per hospital decreased from 80 (interquartile range [IQR], 31-150) in 2006 to 52 (IQR, 20-146) in 2012. The median volume of the 686 hospitals that started ERCP after 2006 was 31.5 (IQR, 11-82). The post-ERCP adverse event rate in 2012 was comparable between hospitals in terms of volume (≥500 or <500 per year: 5.8% vs 5.6%) and practice durations (starting ERCP before or after 2006: 5.5% vs 5.6%).

Conclusions: ERCP has developed considerably in China in recent years. Despite low annual volume, the hospitals starting ERCP after 2006 have acceptable adverse event rates and will be promising and important sources of ERCP development in China. (Gastrointest Endosc 2016;84:659-66.)

ERCP is an important technique for pancreaticobiliary disease and has continued to develop for more than 4 decades.1 In developed countries, the role of ERCP has gradually changed from a diagnostic to a therapeutic modality, and the total volume has decreased in more recent years.3,5 However, reliable data on the trend of ERCP growth in developing countries are sparse, especially in China, India, and other emerging market countries where ERCP is still a relatively new and rising technique.

According to the national survey conducted by the Chinese Society of Digestive Endoscopy (CSDE) in 2007, a total of 63,787 ERCP procedures were performed in 470 hospitals across mainland China in 2006, with an estimated annual ERCP rate of 4.87 per 100,000 inhabitants, thereby suggesting that ERCP use needs substantial improvement. Recently, the economy of China has developed dramatically. Thus, ERCP use may also be significantly improved. To address this issue, the CSDE conducted another survey.
in 2013 to evaluate the development over 6 years and to investigate the potential problems in ERCP use in China. This study may also provide useful information for other developing countries.

METHODS

Conduct of the survey
The present study was initiated and organized by the CSDE and supervised by the Chinese National Ministry of Health as part of the Chinese Digestive Endoscopy Census 2012. All 31 provincial branches of the CSDE in mainland China participated in the survey. Hospitals that could provide ERCP service were confirmed through local health authorities by CSDE branches. Online predesigned structured questionnaires were completed by a senior endoscopist in each hospital. Data were collected by CSDE headquarters and analyzed in Shanghai.

After returning the questionnaires to the organizer, 1 of 10 hospitals involved were selected through simple random sampling. From November 2013 to February 2014 the involved individual branches of the CSDE covering these selected hospitals collected the official annual reports from the hospitals and independent personnel of the CSDE branch checked the data on the questionnaires and then returned the results to the organizer. If significant discrepancies were present in the data between 2 data sources, the questionnaire was considered invalid and excluded in the analysis by the organizer.

Contents of the questionnaire
The contents were completed according to the data in 2012. The questionnaire included data on the general status of hospitals; infrastructure for ERCP; volume, indication, and anesthesia method for ERCP procedures; and post-ERCP adverse events. The general status of hospitals included hospital ownership and grading. In China the Chinese Ministry of Health graded the hospitals as III, II, and I, which is in descending order. Grades III and II hospitals are tertiary and secondary referral hospitals, and ERCP could be performed in these hospitals. Post-ERCP adverse events in this survey included post-ERCP pancreatitis, bleeding, perforation, and cholangitis. The definition of adverse events was consistent with Cotton et al’s ERCP adverse event consensus.

Data collection and analysis
Data from returned questionnaires were extracted and summarized in a database for further analysis. The ERCP rate in a year was used as a main index to evaluate the adequacy of ERCP use. The gross domestic product (GDP) per capita was used as the main index to represent the economic development of a provincial region. The data in this survey were compared with those retrieved or estimated from the previous national survey in 2007 and published reports from developed countries.

Statistical analysis
Categoric data are shown as percentages. The nonparametric correlation statistical test (1-sided Spearman test) was used to analyze the correlations between regional GDP per capita and ERCP rate. The Student t test was used to analyze the association between the adverse event rate and an individual hospital’s ERCP volume or duration of ERCP service. Simple random sampling and statistical analyses were performed using SPSS version 17.0 for Windows (SPSS Inc, Chicago, Ill). A 2-sided P < .05 was considered to be statistically significant.

RESULTS

General status and ERCP infrastructure of hospitals
In 2012, 1156 hospitals performed ERCP in mainland China, which was 2.46-fold the number in 2006 (n = 470). All of these hospitals responded to this survey. The data check was performed in 117 hospitals (10.1%), and no check revealed significant discrepancies in these hospitals. Table 1 lists the general status of these hospitals performing ERCP. In the 1156 hospitals, more than half

| Table 1. General status of hospitals providing ERCP in China in 2006 and 2012 |
|----------------------------------|------------------|------------------|
| Hospital grading                 | 2006 (n = 470)   | 2012 (n = 1156)  |
| Tertiary referral hospitals      | 75.5 (339)       | 76.5 (884)       |
| Secondary referral hospitals     | 24.5 (110)       | 22.7 (262)       |
| Ungraded hospitals               | 0.0 (0)          | 0.9 (10)         |
| Hospital ownership               |                  |                  |
| Government-administered hospitals| 47.7 (214)       | 52.2 (603)       |
| University-affiliated hospitals   | 47.0 (211)       | 35.5 (410)       |
| Military hospitals               | 4.0 (18)         | 6.6 (76)         |
| Private or foreign-invested hospitals| 1.3 (6)       | 5.8 (67)         |
| Department performing ERCP       |                  |                  |
| Department of Gastroenterology   | 68.6 (308)       | 68.0 (786)       |
| Department of Endoscopy          | 16.3 (73)        | 26.9 (311)       |
| Department of General Surgery    | 6.7 (30)         | 1.5 (17)         |
| Other departments*               | 8.5 (38)         | 3.6 (42)         |
| Owning established endoscopy unit| 76.0 (341)       | 96.9 (1120)      |
| Owning x-ray fluoroscopes        | 15.6 (70)        | 32.2 (372)       |
| exclusive for ERCP               |                  |                  |

Values are percents, with total number of cases in parentheses.
*Such as the Department of Interventional Radiology or Oncology.
Figure 1. ERCP rates of China and developed countries.

Figure 2. Development of ERCP rate (the number of ERCP procedures per 100,000 inhabitants) in the 31 provincial regions of mainland China between 2006 and 2012 (Northeast: Heilongjiang, HL; Jilin, JL; Liaoning, LN. East: Beijing, BJ; Fujian, FJ; Guangdong, GD; Hainan, HaN; Hebei, HeB; Jiangsu, JS; Shandong, SD; Shanghai, SH; Tianjin, TJ; Zhejiang, ZJ. Central: Anhui, AH; Henan, HeN; Hubei, HuB; Hunan, HuN; Jiangxi, JX; Shaanxi, ShX; Sichuan, SC; Tibet, XZ; Xinjiang, XJ; Yunnan, YN; Chongqing, CQ. Hong Kong, HK; Macau, MAC; Taiwan, TW). This map does not show the complete territory of China.
(52.2%) were government-administered and most (76.5%) were tertiary referral hospitals, which was similar to the status in 2006. In 2012, 1120 hospitals (96.9%) providing ERCP services had an established endoscopy unit, and 372 (32.2%) had x-ray fluoroscopes owned by the endoscopy unit, which was higher than the number in 2006. Across mainland China, 85 hospitals provided ERCP in the Northeast, 535 in the East, 229 in the Central, and 307 in the Western regions.

ERCP volume and its distribution

In 2012 the total ERCP volume in mainland China was 195,643, with an estimated ERCP rate of 14.4 per 100,000 inhabitants. The ERCP rate in 2012 was significantly increased from that in 2006 (4.9 per 100,000 inhabitants) but was still much lower than the rates of developed countries (Fig. 1).

The development of ERCP rates in various regions between 2006 and 2012 is presented in Figure 2. Significant imbalance still existed in the regional distribution of ERCP use in 2012, but the ERCP rate increase was more obvious in the less-developed Western (4.34-fold) and Central (3.14-fold) regions. A significant correlation existed between the ERCP rate and GDP per capita in 2006 and 2012 (2006: \( r = .871, P < .001 \); 2012: \( r = .452, P = .005 \)) (Fig. 3).

Significant variation was observed in the annual ERCP volume between different hospitals (Fig. 4). In 2006 the median ERCP volume in each hospital was 80 (range, 2-1303; interquartile range [IQR], 31-150), and 29.1% of hospitals performed fewer than 50 ERCPs throughout the year, whereas in 2012 the median ERCP volume decreased to 52 (range, 1-3478; IQR, 20-146), and 46.8% of hospitals performed fewer than 50 ERCPs throughout the year. Among the 686 hospitals that started ERCP after 2006, the median ERCP volume in 2012 was 31.5 (range, 1-1000; IQR, 11-82). In 2012, 262 secondary referral hospitals performed 7.8% of all procedures (15,188/159,966), and the median annual ERCP volume was 25 (range, 1-422; IQR, 11-55).
Indication and adverse events

In 2006 and 2012, the proportions of therapeutic ERCP were 95.2% and 96.9%, respectively. The detailed ERCP indication is shown in Figure 5. In both 2006 and 2012, cholelithiasis was the most common indication. Overall, 47,643 ERCP procedures (24.4%) were performed with the patient under conscious sedation in 644 hospitals (55.7%) in 2012.

In 2012 the reported post-ERCP adverse events in China included 8471 (4.33%), 1016 (.52%), 352 (.18%), and 1285 (.66%) cases with post-ERCP pancreatitis, bleeding, perforation, and cholangitis, respectively. The adverse event rate was similar between high-volume (≥500/y) and low-volume (<500/y) hospitals and between hospitals that started ERCP before or in 2006 and hospitals that started ERCP after 2006 (Table 2).

DISCUSSION

This is the first report about nationwide ERCP development from a developing country. The overall ERCP use improved significantly in China between 2006 and 2012, with the annual ERCP rate almost tripled. However, the absolute volume of ERCPs still needs to be substantially increased in China compared with developed countries. Low-volume hospitals constituted a considerable proportion, especially for hospitals that started ERCP after 2006.
Nevertheless, the adverse event rates in those hospitals were acceptable, and these emerging ERCP providers may offer a feasible solution for China’s large demand for ERCP.

ERCP is an important technique for the diagnosis and treatment of pancreaticobiliary diseases. Because CT, MRCP, and other imaging modalities partly replaced ERCP as a diagnostic tool, temporal changes in ERCP volume have been observed in many countries in more recent years, and the total volume has decreased in some developed countries.\textsuperscript{16-18} However, this phenomenon may not be the reality in developing countries. In China, India, Brazil, and other rising developing countries, ERCP is still at the early development stage with rapid growth along with the economy. There are large-volume ERCP centers located in less-developed and remote regions. The median ERCP development stage of a technique, with an expected narrowing gap as the economy developed (Fig. 2), some measures could be transferred to high-level hospitals in developed and remote regions instigated our concern in this area. The most developed region in China, Shanghai, had an ERCP rate of 99.1 per 100,000 inhabitants, which was comparable with that in developed countries. Meanwhile, the ERCP rate in Tibet was only 1.3 per 1,000,000 inhabitants, which was substantially increased. To date, there is no consensus on the optimal ERCP rate for a country, but the ERCP rates of developed countries can be adopted as suboptimal references, which basically ranged within 70 to 100 per 100,000 inhabitants, almost 5-fold that of China in 2012 (Fig. 2). Furthermore, China is a region with a high prevalence of pancreaticobiliary diseases.\textsuperscript{20,21} The ERCP rates of developed countries may not be the benchmark for China in the recent period, but the significant shortage in less-developed and remote regions instigated our concern in this area. The most developed region in China, Shanghai, had an ERCP rate of 99.1 per 100,000 inhabitants, which was comparable with that in developed countries. Moreover, the total ERCP volume in 262 secondary referral hospitals, most of which were located in small and medium-sized towns, only constituted 7.8% (n = 15,188) of all procedures. Although this distribution seemed reasonable to some extent during the early development stage of a technique, with an expected narrowing gap as the economy developed (Fig. 2), some measures could be taken currently to alleviate this shortage and maximize the benefits of ERCP. We believe that patients with indications for elective and challenging ERCP procedures could be transferred to high-level hospitals in developed regions, whereas patients who need emergency ERCP (eg, acute cholangitis) should be managed in the local community hospital. Therefore, we suggest that health authorities, especially in less-developed and remote regions, should consider some targeted measures, such as promoting multisite practice by experienced ERCP practitioners and establishing ERCP centers mainly for emergencies and procedures with low difficulty.

Second, the proportion of hospitals with low-volume ERCP was high. In 2012 nearly half of the hospitals (46.8%) performed fewer than 50 ERCPs throughout the year. This result could be attributed mainly to the 686 hospitals that started ERCP after 2006, most of which were located in less-developed and remote regions. The median

### TABLE 2. Reported post-ERCP adverse events from Chinese hospitals in 2012

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Overall (n = 65)</th>
<th>Hospitals with ERCP volume ≥ 500/y (n = 1091)</th>
<th>Hospitals with ERCP volume &lt;500/y (n = 686)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>4.33</td>
<td>4.65</td>
<td>4.18</td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>.26</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>.52</td>
<td>.38</td>
<td>.59</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>Perforation</td>
<td>.18</td>
<td>.23</td>
<td>.16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>Cholangitis</td>
<td>.66</td>
<td>.69</td>
<td>.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.54</td>
<td></td>
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<tr>
<td>Total</td>
<td>5.69</td>
<td>5.79</td>
<td>5.64</td>
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<td></td>
<td></td>
<td>.43</td>
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</table>

From 2006 to 2012, ERCP use in China has seen considerable improvement. The total number of hospitals performing ERCP increased from 470 to 1156, and the annual ERCP rate increased from 4.9 to 14.4 per 100,000 inhabitants. The development trend of ERCP in China today is fairly different from that in developed countries but is consistent with the economic growth and increase of medical input in China, which promoted both the renewal of ERCP infrastructure and the training of ERCP practitioners. Compared with common digestive endoscopy, ERCP needs relatively more human and material resources, and economic factors influence its use to a large extent. As shown in this study, a significant association exists between the ERCP rate and the local GDP per capita (P < .05). From 2006 to 2012 the GDP per capita of China increased from $2083 to $6264, and the health expenditure per capita increased from $94 to $326,\textsuperscript{18} both of which are parallel with the growth of the ERCP rate. More and more hospitals have established endoscopy units and exclusive x-ray fluoroscopes. Meanwhile, the total number of ERCP practitioners in China increased from 1155 (.88 per million) to 3345 (2.47 per million).\textsuperscript{19} This is mainly because standard ERCP training programs have been widely conducted in China’s large endoscopy centers, and more continuing medical education programs, including academic conferences and endoscopy workshops, are now available.

Although the ERCP development in China is inspiring, the following 3 aspects should be considered further. First, the absolute volume of ERCP procedures still needs to be substantially increased. To date, there is no consensus on the optimal ERCP rate for a country, but the ERCP rates of developed countries can be adopted as suboptimal references, which basically ranged within 70 to 100 per 100,000 inhabitants, almost 5-fold that of China in 2012 (Fig. 2). Furthermore, China is a region with a high prevalence of pancreaticobiliary diseases.\textsuperscript{20,21} The ERCP rates of developed countries may not be the benchmark for China in the recent period, but the significant shortage in less-developed and remote regions instigated our concern in this area. The most developed region in China, Shanghai, had an ERCP rate of 99.1 per 100,000 inhabitants, which was comparable with that in developed countries. Meanwhile, the ERCP rate in Tibet was only 1.3 per 1,000,000 inhabitants. Moreover, the total ERCP volume in 262 secondary referral hospitals, most of which were located in small and medium-sized towns, only constituted 7.8% (n = 15,188) of all procedures. Although this distribution seemed reasonable to some extent during the early development stage of a technique, with an expected narrowing gap as the economy developed (Fig. 2), some measures could be taken currently to alleviate this shortage and maximize the benefits of ERCP. We believe that patients with indications for elective and challenging ERCP procedures could be transferred to high-level hospitals in developed regions, whereas patients who need emergency ERCP (eg, acute cholangitis) should be managed in the local community hospital. Therefore, we suggest that health authorities, especially in less-developed and remote regions, should consider some targeted measures, such as promoting multisite practice by experienced ERCP practitioners and establishing ERCP centers mainly for emergencies and procedures with low difficulty.

Second, the proportion of hospitals with low-volume ERCP was high. In 2012 nearly half of the hospitals (46.8%) performed fewer than 50 ERCPs throughout the year. This result could be attributed mainly to the 686 hospitals that started ERCP after 2006, most of which were located in less-developed and remote regions. The median
ERCP volume of these 686 hospitals in 2012 was only 31.5 (range, 1-1000; IQR, 11-82). Although the hospitals with low-volume ERCP have been a concern for a long time, we still consider these hospitals as a feasible solution for the large demand for ERCP in China in recent years. On one hand, encouraging hospitals and endoscopists to start an ERCP service is necessary for ERCP development, especially in less-developed regions, even though their volume may not be high in the beginning. On the other hand, the adverse event rate did not significantly increase in these hospitals, suggesting an acceptable quality of procedures. The association between the ERCP volume of a hospital and the quality and outcome of ERCP has not been conclusive. Several studies showed that only if the endoscopists are technically competent and the indication is appropriate, low-volume hospitals could also complete ERCPs with high success rates and low adverse event rates. In fact, most hospitals with low ERCP volumes (or during the initial years after starting ERCP) would select patients who required low-difficulty procedures and would invite experienced ERCP practitioners from large ERCP centers to guide or live-demonstrate procedures, both of which are beneficial for increasing ERCP quality. In our opinion, balancing quality improvement and quantity increase has been a difficult problem for a long time in the development of China’s healthcare system, because the gap has always been large but human and material resources are limited. Seemingly low-level modifications, such as barefoot doctors (farmers who received basic medical and paramedical training and worked in rural villages) decades ago, may also be a feasible method. Therefore, we recommend that these low-volume hospitals should continue their ERCP service but should manage patients with appropriate indications and risk levels according to the practice status.

Third, a number of large ERCP centers have emerged. During the past decade, a large number of hospitals in China experienced a new round of rapid expansion. In 2012, 20 top ERCP centers completed 20% of the total volume in China (individual ERCP volume, 1069-3478). These centers have become the main referral centers and training centers for ERCP and completed most studies and practice guidelines on ERCP in China. However, the core principle of healthcare reform in China is to provide basic health care as a “public service” to the people; healthcare facilities at the community level are the priority for financial input. Considering that ERCP is a challenging and important technique, we still believe that these large ERCP centers need continuous support in developing personnel and increasing ERCP volume to lead ERCP development nationwide in the future.

This study has several limitations. First, this study is retrospective, and recall bias could not be avoided. A national prospective survey or registry is necessary for subsequent study. Second, this study is the first online national survey on digestive endoscopy in mainland China, and some data, such as detailed indication, anesthesia methods, and successful rate of cannulation, were not included, which precluded further analysis about the quality control. In conclusion, ERCP has developed considerably in China in recent years. Although most have low annual volumes, the hospitals starting ERCP after 2006 have acceptable adverse event rates and will be the essential growth point for ERCP development in China, which should be the priority for support in the future.

REFERENCES