THE ROLE OF PHARMACIST-LED HYPERTENSION MANAGEMENT IN CHINA’S COMMUNITY MEDICAL CARE SERVICE: A RETROSPECTIVE ANALYSIS OF REAL-WORLD BIG-DATA SAMPLES

ARTICLE

HIGHLIGHTS

First report of retail pharmacy in-store hypertensive care led by pharmacists nationwide in China; Over 1.4 million patients served for 1.5 years; e-Health solution (Apps and cloud database) effective as a decision support tool for better BP control.

ABSTRACT

Objective: To explore the role of digital solution-associated hypertension management in the community service of hypertensive patients through a retrospective, observational analysis of the big data from retail pharmacy chains in China. Methods: We developed a digital healthcare solution, in which there are Blue-tooth-enabled blood pressure monitor, a mobile App, and a cloud database with special algorithms for healthcare decision support. This solution was commercialized and deployed in over 3,000 retail pharmacies of 78 brands in 48 cities in China to help pharmacists better manage hypertensive patients who were their pharmacy members. During the period of Jan 1st 2015 to Jun 30th 2016, a total of 1,441,755 pharmacy members received in-store hypertensive care using this digital solution. 11,778 of them were selected according to the specified inclusion criteria in this retrospective analysis. Dynamic changes of blood pressure, disease staging, and population distribution over time were the major end points measured. Results: Systolic and diastolic blood pressures were reduced on average by 11.4 and 6.6 mm Hg, respectively. Disease staging was improved across all three hypertension stages, and blood pressure of 5,036 patients (42.8% of the study population) was returned to normal. The predominant BP control effect occurred after the first-time intervention, but the BP remained stable throughout the whole follow-up period. Conclusions: The pharmacist-led hypertensive care, assisted with a digital healthcare solution, is effective in the management of hypertension at retail pharmacy stores.

KEY WORDS
hypertension management; digital healthcare solution; mobile App; big data; real-world study

Received 22 July 2016; Revised 29 July 2016; Accepted 31 July 2016; Published 2 Aug 2016

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INTRODUCTION

Hypertension is a major risk factor for cardiovascular diseases, stroke, and renal failure, affecting over 20% of the adult population in China according to a recent epidemiological survey [1]. A large number of clinical research studies have documented that better blood pressure (BP) control can decrease risk of developing life-threatening events [2,3]. Although various medical and lifestyle intervention initiatives have been implemented, hypertension remains more frequent in the adult populations worldwide.

As web- or mobile-based healthcare technologies advance, home BP tele-monitoring has been applied in various studies, and indicated effective BP control if healthcare providers were looped in to receive real-time vital sign data and feedback proactively [4-7]. This approach has been recommended as an adjunct to conventional outpatient hypertensive care to reduce the unnecessary clinic visits and to promote the adoption of a healthier lifestyle. Patient satisfaction was also enhanced because medication adjustment can be made more conveniently through phone consultation with physicians, avoiding time for clinic visit. However, scale-up of such an approach seems to be slow due to the following reasons. First, home BP tele-monitoring often requires the concomitant use of mobile Apps to submit or retrieve data, which may not be user-friendly to the elderly. Second, the devices are more expensive than regular BP monitors, and are not subject to payer’s coverage in China. And last but not the least, the number of available primary care physicians (PCP) who can offer e-healthcare services is still small.

Previous studies have suggested that, as an underutilized source for community healthcare delivery, pharmacists can improve the outcomes of chronic diseases, such as hypertension, diabetes, and dyslipidemia [8-13]. Furthermore, randomized controlled trials have demonstrated that an increase in BP control rate can be achieved through a collaborative pharmacist-physician team model (in which pharmacy care is under physician’s supervision), or another different model (in which clinical pharmacists can independently initiate and change medication regimens) [14-16]. However, little is known about whether retail pharmacists, when equipped with a digital healthcare solution, also could produce similar beneficial healthcare effects at the community pharmacy stores by taking the advantage of the vast number of available pharmacists and their geographical proximity to the end-users. In this study, we hypothesized that hypertension care could be supplied at the retail pharmacy stores by pharmacists using a pharmacist-customized digital healthcare management solution, and that such a free-of-charge service could be offered as a pharmacy membership benefit to local hypertensive patients to attract more store visits, consequently further increasing the contacts between patients and pharmacists to achieve higher hypertension control rate.

MATERIALS AND METHODS

Study Design and Setting

This was a retrospective, before-and-after analysis of pharmacist-led BP control service as a result of the commercialization of a digital healthcare system – CareLinker Health – at over 3,000 retail pharmacies of 78 different brands in 48 cities in China, in which 57 brands were ranked among the top 100 retail pharmacies released by a journal China Pharmacy (2016), including 5 of the top 10 brands – SinoPharm, DaShenLin, LaoBaiXin, ChengDaFangYuan, and YiFeng [17]. Hypertension care service was offered as part of the membership benefit program free of charge to their members, and each store formed a dedicated team of at least 1 pharmacist and 2-3 assistants to facilitate the care delivery.

In-store installation and pharmacist training supported by the CareLinker Health system began in November 2014, and the system was put into operation on December 1st, 2014. By the end of May 2015, a total of 2,660 retail pharmacies were using this system to provide hypertension care to their members on a “first come, first served” basis, with 7,121 services per day counted on average. The number of pharmacies covered by CareLinker reached 5,018 by June 2016, with a total of 1.44 million members recorded for service, including both hypertensive patients and those whose BPs were within the normal range but at higher risk of developing hypertension. The present study aimed to analyze the effects of BP control on the pharmacy members who were hypertensive at the baseline and received in-store hypertension care using the CareLinker Health system.

Study Instruments

The CareLinker Health system consists of a Blue-tooth-enabled BP monitor (Bliss BL918), a pharmacist-tailored App, and a cloud database that has two modules (personal healthcare record, and pharmacist decision support). The Blue-tooth BP monitor is synchronized to the mobile App which is only installed on pharmacist’s smart phone. Such setup allows auto BP submission to the cloud and data display or result sharing between pharmacists and patients. Pharmacists were asked to use the App to manually input users’ relevant healthcare information into the cloud-based personal healthcare records, including age, gender, height, weight, disease history, and medication regimens. The pharmacist decision support
module runs four algorithms for 1) risk scoring and screening to identify the hypertensive patients at higher risk of developing severe complications, such as cardiovascular accidents; 2) personalized meal planning to generate meal plans and menus that are tailored to one’s own metabolic condition; 3) personalized coaching that provides educational materials targeting the user’s disease stage; and 4) medication check that reminds drug refill and drug-drug interactions to avoid adverse drug reactions.

**Intervention by the Retail Pharmacists**
Each pharmacy member (i.e., hypertensive patients) who requested in-store hypertension care would receive 4 lines of intervention provided by the pharmacist: 1) BP measurements using the Blue-tooth BP monitor, 2) pharmacy consultation and medication adjustments if necessary after reviewing patient’s hypertension stage, disease history, and the risk assessment by the system’s risk scoring, 3) dietary advises according to the App-generated meal planning, and 4) personalized healthcare coaching based on the educational contents displayed in App’s coaching session. Pharmacists would urge patients whose BP remained uncontrolled to seek medical services.

**Patient Inclusion Criteria for Analysis**
During the period of January 1st 2015 to June 30th 2016, over 1.44 million pharmacy members received in-store hypertension care. To assess the BP control effect, we selected 11,778 patients in the retrospective and observational analysis following these 4 inclusion criteria: 1) baseline BP readings were hypertensive (≥ 140/90 mmHg), 2) the frequency of hypertensive care was ≥ 1 time per month, 3) the intervention duration between the first- and last-time hypertensive care was ≥ 1 month, and 4) baseline characteristics were complete. These patients were divided into 9 different groups according to the intervention duration: 2-month group (2M, n = 5,014), 3-month group (3M, n = 2,341), 4-month group (4M, n = 1,299), 5-month group (5M, n = 741), 6-month group (6M, n = 574), 7-month group (7M, n = 445), 8-month group (8M, n = 332), 9-month group (9M, n = 255), and over 10-month (10–18) group (10M+, n = 777).

These criteria allowed us to exclude those members who 1) were not hypertensive or had BP controlled; 2) visited pharmacy at a very low frequency; 3) stayed in the program for too short to draw appropriate conclusions; and 4) were not willing to share their healthcare information with pharmacists.

**Statistical Analysis**
Data collected from January 1st, 2015 to June 30th, 2016 were coded and entered into MATLAB version 2014a and SPSS version 22 for statistical analysis. Descriptive statistics were calculated on all variables. Categorical variables were described by proportion and the significance of group comparisons was estimated with the Chi-Square test. For metric variables, the normality of data was first assessed with the Kolmogorov-Smirnov and Shapiro-Wilk statistical tests to identify whether the metric variable was normally distributed. For normally distributed variables, a paired Student t test was performed to analyze the significance of group comparisons. The Related-Samples Wilcoxon Signed Rank test was used for the analysis of the non-normally distributed variables. All tests were controlled with 95% confidence interval (CI), and the reported P values and CI were two-sided.

**RESULTS**
A total of 11,778 hypertensive patients were included in this analysis. They had a mean age of 57.4 years, and 54.1% were male. The number of patients in each of the 3 hypertensive stages was 7,816 (stage 1), 2,954 (stage 2), and 1,008 (stage 3). The average BMI was 24.0, suggesting that they were on the threshold of being overweight.

The effect of hypertension care was first assessed by comparing the mean baseline and last-time BP values of each group which was categorized according to the duration of intervention of 2, 3, 4, 5, 6, 7, 8, 9, and 10-18 months, respectively. Mean improvements of systolic (SBP) and diastolic blood pressure (DBP) were 11.4 (P < 0.001) and 6.6 mmHg (P < 0.001), and the extents of BP reduction ranged from 10.6–12.2 mmHg in SBP [Figure 1A] and 6.1–7.0 mmHg in DBP [Figure 1B], respectively.

Population distribution demonstrated significant leftward shifts of both SBP and DBP when the baseline and last-time BPs were compared. As illustrated in Figure 2A, the population median BP values were 141.7–124.0 mmHg and 93.7–77.0 mmHg, respectively. As shown in Figure 2B, cumulative distribution identified an increase of 33.7% and 22.6% in patient population whose SBP was < 140 mmHg (baseline, 44.5%; last-time, 67.1%), and the extents of BP reduction was also improved, and the number of patients was reduced by 44.4% in the stage 1, 38.2% in the stage 2, and 43.6% in the stage 3 (all P < 0.001). In addition, the BP levels of 5,036 subjects (42.8% of the whole patient population) returned to normal.

[Note: Additional information and context would be added here, but due to the length of the text, only a portion is provided for this example.]
To better establish the relationship between the outcomes of the hypertension care and the times of service, we chose the subgroup of patients who received 5 times of care. We found that the most significant drop of SBP and DBP occurred following the first-time intervention and the BP control effect remained steady but at a smaller extent during the period of the follow-up [Table 1]. Comparison of mean SBP and DBP at baseline with those after each intervention indicated that BP reduction was statistically significant (all P < 0.001).

Table 1. The effects of hypertension care on patients receiving care of one to five times. Mean ± SD, in the rows of "stage 1, stage 2, and stage 3"

<table>
<thead>
<tr>
<th>SBP</th>
<th>1st time</th>
<th>2nd time</th>
<th>3rd time</th>
<th>4th time</th>
<th>5th time</th>
<th>Patient No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval (d)</td>
<td>14.6</td>
<td>18.2</td>
<td>21.0</td>
<td>28.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 1</td>
<td>144.6±8.4</td>
<td>138.2±16.0</td>
<td>138.8±16.1</td>
<td>137.5±15.4</td>
<td>137.0±16.8</td>
<td>711</td>
</tr>
<tr>
<td>Stage 2</td>
<td>160.7±10.4</td>
<td>150.7±18.4</td>
<td>145.3±19.1</td>
<td>144.4±17.5</td>
<td>143.5±18.5</td>
<td>284</td>
</tr>
<tr>
<td>Stage 3</td>
<td>174.1±16.5</td>
<td>156.1±24.2</td>
<td>153.1±23.1</td>
<td>150.2±25.3</td>
<td>145.8±21.2</td>
<td>108</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DBP</th>
<th>1st time</th>
<th>2nd time</th>
<th>3rd time</th>
<th>4th time</th>
<th>5th time</th>
<th>Patient No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval (d)</td>
<td>14.6</td>
<td>18.2</td>
<td>21.0</td>
<td>28.6</td>
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</tr>
<tr>
<td>Stage 1</td>
<td>86.9±8.7</td>
<td>83.2±11.6</td>
<td>83.7±11.2</td>
<td>82.7±11.7</td>
<td>82.7±11.4</td>
<td>711</td>
</tr>
<tr>
<td>Stage 2</td>
<td>96.7±9.3</td>
<td>90.9±13.5</td>
<td>88.5±13.2</td>
<td>88.0±12.2</td>
<td>87.5±12.7</td>
<td>284</td>
</tr>
<tr>
<td>Stage 3</td>
<td>109.7±13.8</td>
<td>96.5±16.8</td>
<td>94.9±16.2</td>
<td>93.1±16.6</td>
<td>91.5±15.1</td>
<td>108</td>
</tr>
</tbody>
</table>

Fig 1. Time course of the baseline and last-time SBP and DBP after receiving the in-store hypertension care. (A) SBP: *P < 0.001; (B) DBP: *P < 0.001. Patients were divided into 9 different groups based on the duration of their receiving intervention (in months).

To further develop a broader view about the trend of population BP change, we performed simulation of all the SBP and DBP data points (154,808) collected from the 11,778 patients in the first 180 days. As shown in Figure 4, both SBP and DBP exhibited a linear descending over time, with the predicted BP range being moved towards normal as well. The linear fitting functions were: for SBP, Y = -0.05x + 144.12; and for DBP, Y = -0.04x + 87.61.

DISCUSSION

This is the first report of the nationwide hypertension care service delivered by retail pharmacy in China. The results suggest that integration of the CareLinker Health system is effective in BP control for hypertensive patients at pharmacy stores. In this study, we found that the average reduction of SBP and DBP across all intervention duration groups was estimated at 11.4 and 6.6 mmHg, respectively, that the distribution of BP population displayed significant shift leftward over time, and that hypertension staging was improved in all three stages. In addition, hypertension care exhibited more potent effect after first time intervention than other times, and the BP levels remained stable throughout the whole follow-up period. As a result, the BP levels of approximately 42.8% of patients returned to normal after this intervention.
Fig 2. (A) Leftward shift of population distribution when BP was measured at the last-time point compared with at baseline. The medians of SBP and DBP were shifted by 9 and 7 mmHg, respectively. (B) Changes of cumulative distribution of patients who had SBP < 140 and DBP < 90 mmHg, respectively.

Fig 3. Patient distribution of hypertension stages at baseline (left) and last time (right).

These results suggest that healthcare professionals, such as clinical pharmacists, nurses, or dieticians, regardless of them alone or in combination with physicians, are valuable resources in the management of chronic conditions of hypertension and diabetes, and that tele-monitoring of BP can help achieve better BP control, consistent with previous findings [18-26]. Our approach goes one step further by demonstrating that BP control can be accomplished by retail pharmacists when their healthcare decision is supported by a digital solution that integrates BP monitoring, risk scoring, medication support, and lifestyle enhancement together.

This study had several strengths. First, this was a true real-world study as all 11,778 patients included in the present analysis were managed at retail pharmacies where the hypertension care took place and the data were collected.
We relied on a large number of retail pharmacists who offered free-of-charge hypertension care to their members who walked into the pharmacy store with such a request. This model can be easily replicated and promoted throughout the whole country by mobilizing over 250,000 licensed pharmacists nationwide to serve the underserved hypertensive population as pharmacies can benefit most from enhanced member loyalty and recurring store visits. Second, all data were produced electronically and stored in a real-time manner at the cloud, eliminating mistakes in otherwise manual data processing and ensuring nearly 100% data accuracy. It also provided for the first time a generalized view of the dynamic changes of population BP in China, which can be instrumental for public health policy makers in formulating new guidelines for community healthcare. Third, it circumvented the challenges that e-medical services were often facing high price and low user acceptance by the elderly who did not use the mobile Apps. The entire procedure of the hypertension care was provided by the trained pharmacists, and patients did not need to purchase or operate the system by themselves. This design could be particularly impactful in China to narrow the “digital divide” which referred to the subgroup of population who were older, did not have mobile internet access, and had less education [14,27]. And last, the system generated personalized decision support for pharmacists based on each patient’s latest healthcare profile updates and helped streamline the interventional procedures which pharmacists conveniently resort to and focus on. This function improved the hypertension care efficiency and the auto-generated health report assisted pharmacists to review progress when patients re-visited the pharmacy store.

We believe that improved BP outcomes resulted from the following reasons. First of all, the system enhanced pharmacists’ expertise by providing tailored decision support covering the whole spectrum of hypertension management, from BP monitoring to lifestyle and medication advices. Pharmacists may adjust medication plans by changing dosages, adding or discontinuing drugs according to the knowledge library of the system. Next, patient’s medication adherence was increased. This readily available service that was offered at locations proximal to patients’ residence increased the number of store visits and contacts between patients and pharmacists. This helped pharmacists monitor more closely both the therapeutic effects and side effects, or recommend clinic visit and lab tests when necessary. The frequent pharmacy consultation and better knowledge of the medication being taken, could contribute to improved compliance. Finally, coaching on dietary plans and exercise may also lead to better BP control. Pharmacists were required to interpret some concerns to patients based on the App contents, the meal plans, nutrition guidance, and exercise suggestion when they were receiving care. A healthier lifestyle was expected particularly with regard to restraining the daily salt and fat consumption.

We acknowledge several limitations. The main concern would be lack of a randomized control group that did not receive pharmacist care. The reason of not including a blank control arm was mainly due to the unavailability of data as the partnering pharmacies were only sharing the information of patients who received hypertension care using the CareLinker Health system. We also did not control for the healthcare services that the study patients might receive additionally if they went to clinics. It was possible that those who demonstrated more BP reductions may have sought more medical services and the better BP control could have resulted from their increased hospital visits and medical interventions by physicians. The other limitation came from the incompleteness of patients’ medication records and lack of knowledge of their compliance to the lifestyle intervention. Data of such categories would help us draw more precise conclusions for the mechanisms underlying the significant BP control observed in this retrospective analysis.
CONCLUSIONS

The present analysis demonstrates that a pharmacist-led hypertension care, enabled with a digital healthcare solution and offered at retail pharmacies, can improve BP control for hypertensive patients. Further studies of medication adherence and lifestyle interventions in the setup of randomized controlled trials are needed to identify essential elements underlying the observed outcomes. Future research may also include applying the intervention to other chronic conditions and assessing cost-effectiveness.

CONFLICT OF INTEREST

The authors declare no competing interests.

ACKNOWLEDGEMENT

The authors thank Drs. Jian-Yong Wang and Yao Zheng for their advices on data analysis, and Charles Ying and Lisa Wei for helping conduct the study, as well as the pharmacists and their assistants for providing hypertension care to the patients. In addition, the authors thank Dr. Hong-Guang Xie, General Clinical Research Center, Nanjing First Hospital, Nanjing Medical University, China, for his critical reading of manuscript and English editing.

FINANCIAL DISCLOSURE

The hypertension care services were funded by all 78 retail pharmacies and CareLinker.

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