Novel and Effective Medicine for the Treatment of Kidney Diseases

Tianjin Renji Hospital
Tianjin, China
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I. Our Founding Doctors Invented Medicine for Treating Kidney Disease

The medical doctors, Drs. Hongyin Ji and Wei Ji, in Tianjin Renji Hospital invented and developed a safe and highly effective pharmaceutical composition for the treatment of various kidney diseases. In the last 20 years, thousands of kidney patients have been treated with the composition. Many patients fully recovered. And many patients stopped further loss of kidney function and avoided kidney failure and dialysis.
II. **The Efficacy of Our Medicine**

We kept detailed medical records of several hundred kidney patients who had been treated in our hospitals and provide the following preliminary statistics:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Patients who achieved kidney function improvement (measured by protein in urine or serum creatinine)</th>
<th>Patients who fully recovered (measured by normal protein and serum creatinine)</th>
<th>Average treatment course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nephrotic syndrome (including pediatric nephrotic syndrome)</td>
<td>80%</td>
<td>70%</td>
<td>3 years</td>
</tr>
<tr>
<td>IgA nephropathy</td>
<td>80%</td>
<td>60%</td>
<td>3 years</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>90%</td>
<td>80%</td>
<td>2-3 years</td>
</tr>
<tr>
<td>Diabetic nephropathy</td>
<td>90%</td>
<td>80%</td>
<td>2-3 years</td>
</tr>
<tr>
<td>Kidney failure (serum creatinine &lt; 200umol/L (2.3mg/dL))</td>
<td>90%</td>
<td>50%</td>
<td>3 years</td>
</tr>
<tr>
<td>Kidney failure (serum creatinine &lt; 400umol/L (4.5mg/dL))</td>
<td>80% patients achieved stable creatinine level; 60% patients can resume normal life with stable</td>
<td></td>
<td>&gt;3 years</td>
</tr>
<tr>
<td>creatinine level</td>
<td>Kidney failure (serum creatinine &gt; 400(\mu)mol/L (4.5mg/dL))</td>
<td>70% patients achieved stable creatinine level, and reduced dependency on dialysis; 50% patients can resume normal life with stable creatinine level</td>
<td>&gt;4 years</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
</tbody>
</table>

Creatinine level

Kidney failure

(serum creatinine > 400\(\mu\)mol/L (4.5mg/dL))

70% patients achieved stable creatinine level, and reduced dependency on dialysis; 50% patients can resume normal life with stable creatinine level

>4 years
III. The Safety Profile of the Our Medicine

The composition has not shown any toxic side effect. We have followed up with some patients for 5 years and none has shown any long term- side effect. Many of the kidney patients we treated also had diabetes, high blood pressure, lung or heart disease. The composition does not affect any of those medical conditions, or have drug interaction with other medicines the patients took.

IV. The Ingredients and Biological Mechanism

The composition includes natural medicinal ingredients e.g., *semen cuscutae* and *polyporus umbellatus* that are known to be safe for human use. The most effective combinations have been tested in human patients over the years and optimized to achieve the best therapeutic results.

We believe that the composition achieves its therapeutic effect for kidney disease by activating and further strengthening the patient’s remaining healthy kidney tissues. The activated healthy kidney tissues can bring the patient’s kidney function to normal or close to normal level. TYK Pharmaceuticals, a research based pharmaceutical company, is planning and performing experiments in animal models to study the therapeutic mechanism of the composition.

V. Our Medicine Was Approved for Treating Kidney Patients

Our medicine was approved in 1996 by Tianjin Health Administration (the highest authority in Tianjin to approve pharmaceutical products) for treating kidney patients after sufficient proof was presented to show safety and efficacy.
天津市医疗单位新制剂申请表

申报单位

申请时间

天津市卫生局制
一九九六年版
<table>
<thead>
<tr>
<th>年 月 日</th>
</tr>
</thead>
<tbody>
<tr>
<td>市卫生局审查意见</td>
</tr>
<tr>
<td>同意委托制备壹年，按法律规定在本院使用。</td>
</tr>
</tbody>
</table>

制剂批准文号：
(97)津卫药制第 W1试第 8号
VI. Collaborations With International Kidney Disease Experts

Over the years, many patients outside of China, including the U.S., Middle East, Africa and Europe have reached out to the hospital and been treated successfully. Some of those patients’ attending physicians were very impressed by the therapeutic effect of the composition. We are currently treating kidney failure patients in North America, Middle East and Africa via online consultation and mail order of our medicine.

To bring this novel treatment to more patients worldwide, TYK Pharmaceuticals is in the process of filing an Investigational New Drug Application for the composition with the United States Food and Drug Administration. TYK intends to seek orphan drug status for the treatment of pediatric nephrotic syndrome, nephrotic syndrome, and IgA nephropathy, and hopes to receive fast track review and approval from the FDA.

We are looking for partners in the U.S. and other countries to collaborate in doing further research and study on this composition and its clinical pathways, so that we could expedite the process of bringing this composition to the overseas patients.

VII. Access to the Treatment

In 2016, the inventors of the composition launched Tianjin Renji Hospital, a state of the art modern hospital in China, to serve the international kidney patients. The patients are encouraged to visit Renji Hospital for consultation and treatment. The visit generally lasts no more than a day and includes initial consultation, blood and urine tests, and recommendation for treatment. If the patient is suitable for the treatment, we will prescribe a three-month supply. The patient would not need to visit our hospital again during the treatment course unless she desires to do so. We compound the pharmaceutical composition in our hospitals pursuant to the local permits issued by the healthcare authority.

Foreign patients can also receive diagnosis and consultation remotely. The patient can send all prior medical records and test results (either in English or Chinese)
electronically to Renji Hospital. Within 48 hours we will arrange for telephone or video conference consultation. If the patient is suitable for the treatment, we will arrange to ship a two-month supply to the patient upon full payment. The patient should confirm that such treatment does not violate any local laws or regulations permits.

 VIII. Frequently Asked Questions

1. **Dosage form and administration**

   The medicine is compounded into round shaped pills. The recommended dose is three times per day, and 12 g of pharmaceutically effective ingredients per administration.

2. **How does it take for the patient to see improvements**

   In general, the patient should experience improved physical symptoms after 1-3 months of treatment, including reduced swelling (edema), improved appetite, reduced fatigue, and improved rigor.

   The majority of the patients should experience improved kidney function test results in 3 to 6 months, including e.g., reduced creatinine and blood urea nitrogen levels.

3. **How long do patients need to be on the medicine?**

   Patients need to be treated for 1 to 3 years to fully recover from kidney disease or to achieve a stable kidney function level. There are some patients who have taken the medicine for over 5 years to maintain sufficient kidney function to avoid dialysis.

4. **Relapse**

   Relapse is very rare. There are a few instances in which patients, after a successful treatment, suffered kidney disease again due to other medical problems. Generally a second course of treatment would be sufficient to stop the
loss of kidney function.

5. **Dietary restrictions**

Avoid plant protein or soy-based protein, and food high in phosphorous (e.g., certain type of cheese, salmon). The daily protein intake should be limited to 0.6-0.8g/Kg.

6. **Drug interactions**

Many of our kidney patients have diabetes, high blood pressure, lung problems, and heart disease. During treatment, they can maintain all their other medications. We have not observed any negative effective of the composition on other medical conditions, or any drug interaction.
IX. Clinical Trial Results Reported by the Hospital

Clinical Trial I

The founders of the hospital reported the result of a clinical trial of our medication among 46 patients in the Eighth National Nephrology Conference in China. The cohorts included three groups (1) initial stage of kidney failure, 16 patients; (2) moderate kidney failure, 14 patients; and (3) late stage kidney failure, 9 patients; and (4) end stage kidney failure, 7 patients. The treatment period is 6 months. Endpoints for effective: either reduction of urea nitrogen by 7.14 mmol/L (20 mg/dL), or reduction of creatinine by 88.4 umol/L (1 mg/dL), and improvement in physical symptoms, including reduced fatigue, swelling, vomiting, headache or itchy skin. Results: (1) for initial stage of kidney failure the effective rate was 72.2%; (2) for moderate kidney failure the effective rate was 71.4%; and (3) for late stage kidney failure the effective rate was 62.5%; and (4) for end stage kidney failure the effective rate was 50%.

Clinical Trial II

This clinical trial included 120 kidney patients who had protein in urine due to kidney disease. The endpoint for effective is defined as (1) full recovery from swelling, and (2) protein in urine is reduced to 0.3g/24 hours (normal level is <0.15 mg/24 hours). The treatment course is 6 to 9 months and includes two years follow up period. The comparison group included 42 patients who were given another standard kidney disease medicine. The trial is single blind. The effective ratio in the group that took our medicine was 75.8% (91 patients). The effective ration in the comparison group was 14.3% (6 patients).

X. News Reports in China about Our Novel Treatment

Our novel and successful treatment for kidney disease were reported by China’s official news agency XINHUA and the official local newspaper Tianjin Daily in 1998 and 1997 respectively.
XINHUA reported on January 3, 1998 that we have successfully developed a new medicine for the hard to treat kidney disease. The treatment has reached thousands of patients and our early stage empirical statistics analysis showed over 60% patients treated responded to the medicine.

Tianjin Daily reported on October 28, 1997 our discovery of the novel and effective medicine for kidney disease and the empirical data of 60% patients responded well to the treatment.

The original reports in Chinese are attached below:

报 摘

新华每日电讯 1998年1月3日 星期六 第2版

天津开创肾病四脏兼治法

新华社天津1月2日电（张齐）一种治疗肾炎的新方法在天津临床获得成功。这种一改过去肾病治肾、采用四种脏器兼治的新方法，较有效地解决了肾炎反复发作的难题，受到了患者和专家的好评。

他们在长期临床实践中发现，肾与肺、脾、肝等脏器的关系极为密切，肾的阴阳失调会导致这些脏器的失调，而这些脏器功能改变后，天长日久必又累及于肾，因而肾病不单是肾本身的疾病，而是各脏器同时虚损的综合症。他们依据祖国医学辨证施治的理论，研究出对四种脏器同时施治的一整套治疗方案，应用于临床后，效果明显。据对千余例患者的临床观察，这种方法在解决肾炎的反复发作上有所突破，临床治愈率达到了百分之六十七。
创治疗肾炎新方法

本报讯一种治疗肾炎有效的新方法，在本市临床获得成功。受到了患者的欢迎和专家的肯定。

他们在长期临床实践中发现，肾与肺、脾、肝等脏器的关系极为密切，肾的阴阳失调会导致肺、脾、肝的阴阳失调；其他脏器的阴阳失调，日久必又累及于肾，因而肾病不单是肾本身的疾病，而是各脏器同时虚损的综合病症。新兴医院的医生依据中医辨证论治研究出对肺、脾、肝、肾四脏同时施治的一整套有效的治疗方案，称为“四脏兼治法”。这种疗法在肾病治疗中取得突破性进展，经过对千余例患者的临床观察，四脏兼治法有效地解决了肾炎反复发作的难题，临床治愈率达67%。
XI. The Founders of Tianjin Renji Hospital

Dr. Hongyin Ji

Dr. Ji has been practicing medicine in China for over 40 years. Dr. Ji invented the highly effective pharmaceutical composition for the treatment of kidney disease. In the last 25 years, Dr. Ji has successfully treated several thousand kidney patients including a number of international patients. Dr. Ji is the founder of Tianjin Yikang Hospital and Tianjin Renji Hospital, both focus on kidney diseases. Despite having a fully staffed kidney disease department working for him, Dr. Ji still sees his patients on a daily basis. Many patients request to be seen by him in person. And it is common that the patients Dr. Ji successfully treated 10 years ago come back and refer new patients to him. Dr. Ji is leading the efforts to make the medicine available for patients outside of China.

Dr. Wei Ji

Dr. Ji has been practicing medicine in the last decade under the guidance of Dr. Hongyin Ji focusing on the treatment of kidney disease. He has treated many patients successfully with our pharmaceutical composition. Dr. Ji also made significant contributions to the improvement of the pharmaceutical composition. He is the head of
Yikang Hospital and Tianjin Renji Hospital. Dr. Ji has a B.S. degree in Chinese Medicine from Beijing Chinese Medicine University and is pursuing a graduate degree in Tianjin Chinese Medicine University.

Gary Ji, esq.

Mr. Ji is a U.S. lawyer registered with the New York state bar. Mr. Ji was Of Counsel in the global law firm Paul Hastings’ Life Sciences group. In his 14 years law practice, Mr. Ji was counsel to numerous international healthcare companies including Astrazeneca, Pfizer, Merck, Eisai, Helsinn, Sunovion, Amgen, Takeda, Mitsubishi Tanabe Pharma. Mr. Ji’s law practice included work on numerous highly successful pharmaceutical products in the United States. In 2016, Mr. Ji helped launch Tianjin Renji Hospital, a brand new state of the art hospital, to attract international kidney patients. Mr. Ji also founded TYK Pharmaceuticals to seek the FDA approval for the pharmaceutical composition. Gary holds a J.D. degree from Columbia law school and a M.S. in chemistry from the University of Toledo.
XII. Pictures of Our Medicine
XIII. Pictures of Tianjin Renji Hospital

Entrance

Lobby

Standard Exam Room

Lab
Standard Inpatient Room

Waiting Area

Infusion Facility

Tianjin Renji Hospital
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https://www.facebook.com/rjkidneyhospital/