

COST-EFFECTIVENESS ANALYSIS OF LAPAROSCOPIC SURGERY VERSUS OPEN  
SURGERY IN RENAL CELL CARCINOMA AT INNER MONGOLIA MEDICAL UNIVERSITY  
SUBSIDIARY HOSPITAL IN INNER MONGOLIA, CHINA



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A Thesis Submitted in Partial Fulfillment of the Requirements  
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บทคัดย่อและแฟ้มข้อมูลฉบับเต็มของวิทยานิพนธ์ตั้งแต่ปีการศึกษา 2554 ที่ให้บริการในคลังปัญญาจุฬาฯ (CUIR)

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การวิเคราะห์ต้นทุนประสิทธิผลของการผ่าตัดผ่านกล้องและการผ่าตัดแบบเปิดของมะเร็งที่ไตที่โรงพยาบาลมหาวิทยาลัยการแพทย์อินเนอร์มองโกเลีย ในเขตปกครองตนเองมองโกเลียในประเทศจีน



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CHULALONGKORN UNIVERSITY

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## ABBREVIATION

LAP	laparoscopic surgery
OPE	open surgery
CEA	cost-effectiveness analysis
Retro	retrospective
Perpe	perspective



# CHAPTER I

## INTRODUCTION

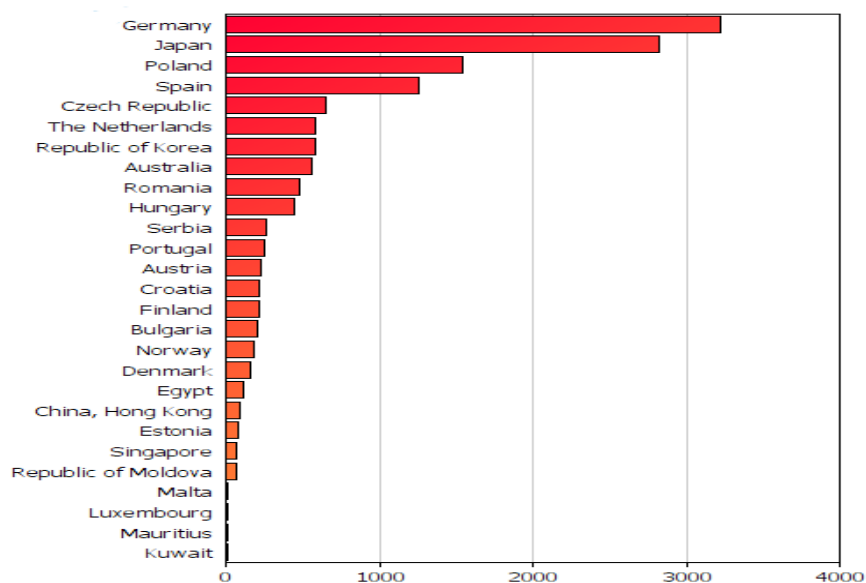
### 1.1 Problems and Significance:

With the improving of modern medical technology all over the world, the application of the machine also gradually applied in clinical surgery. The minimally invasive treatment of laparoscope is one of the cases. This new technology and traditional open operation apply in lots of clinical surgery fields, for example: Aspects of department of gynecology of breast cancer treatment, general surgery treatment of cholecystitis as well as the urology field kidney cancer treatment.

Kidney cancer is a kind of typical urinary system disease. It is also one type of the tumor which threatens human health in recent years. There are quite different incidence and death number around the worldwide in different countries. In United States, malignant tumors of the urinary system comprise slightly more than 2% of new cancer cases and deaths with an estimated 31,200 new cases causing approximately 11,900 deaths in 2000. Annual mortality-to-incidence show a significantly higher ratio of associated with renal cell carcinoma compared with other common urological malignancies. (Pantuck 2011)

Figure 1 kidney cancer deaths

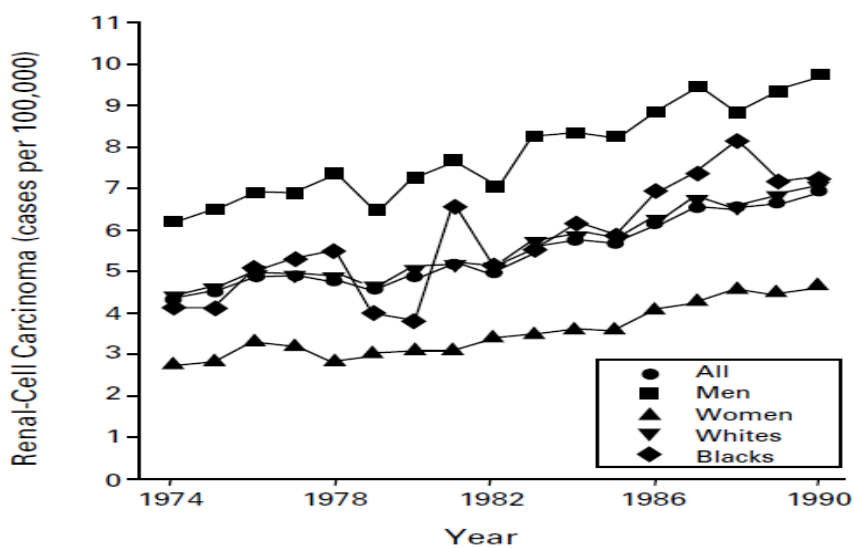
range



(Source: International range of deaths for males with kidney cancer in select countries according to 2011 estimate from WHO-IARC)

Renal cell carcinoma as main component of the kidney cancer, Incidence rates and mortality have been increasing steadily year by year, especially in Europe and the United States. (Loren 2006) There are also different incidence and death number around the worldwide. It is the 12th most common site in male and 17th in female. In less developed countries, rankings for the incidence is 16th, About women it ranks 12th and 17th in developed and developing countries respectively, The highest rates in both men and women were observed in the Czech with 20 and 10 annual new cases per 100,000 population. (John 2004)

Figure



(Source: Cancer statistics of the Surveillance, Epidemiology, and End Results Program in United States)

In China, According to the National Cancer Prevention and Control Research Office, and the Ministry of Health Center for Health Statistics publish the data of our pilot cities and counties which are information of morbidity and mortality shows that there is an upward trend in renal cell carcinoma incidence. 1988-1992, 1992-1998, 1998-2002, the incidence of kidney and other urinary system cancers are 4.26, 5.4 and 6 per thousand population respectively. According to incidence, the number of the infected are 28447, 36594 and 49007 respectively. The number of women is half of the number of male patients. Urban areas higher than rural areas. And there are big difference in incidence among different areas.

The investigation of renal cell carcinoma is controversial, in the western developed countries, laparoscopic is widely used in many years, but in China, this technology treatment introduced in hospital just few years, and the first time, this treatment just take account into the The department of obstetrics and gynecology disease surgery. Moreover, compared with laparoscope, open operation remains the advantages of cheap.

In China, the traditional open operation has been widely used. In recently years, with minimally invasive surgery which use laparoscope gradually promotion the usage, the two treatments gradually become the most widely treatment to cure the renal cell carcinoma. But the two treatments have different cost and effectiveness. And according to a lot of related literature, there are a lot of research pay attention on the clinical effectiveness comparison with undergo the two treatments, in views about length of the stays in hospital, length of the operation time, and so on, there are less research analysis the two treatment from the economics and economic evaluation. This study want to analysis this two different methods use the cost effectiveness analysis to find which treatment is more reasonable. For patients, this study can provide the decision evidence for patients choose which treatments are more reasonable. For hospital, in order to use reasonable treatment in clinical and provide evidence to develop scientific treatment, and make more reasonable policy suggestions.

This study has many significants. For hospital, The hospitals want to provide decision-making basis to establish the reasonable treatment costs payments and



standards. This research not only solves the cost problems but also find the short run effectiveness which in terms of not have the complication, like burst pleural rupture , renal nest bleeding , anesthetic accident. Moreover, medium effectiveness which is 2-years disease-free period situation. On this account to achieving rational allocation of health resources.

## **1.2 Questions:**

### **Primary question:**

What is the most cost-effectiveness treatment of renal cell carcinoma between laparoscopic surgery and open surgery at Inner Mongolia Medical University Subsidiary in Inner Mongolia, China?

### **Secondary questions:**

1. What is the cost of the two treatments of renal cell carcinoma?
2. What is the outcome of the two treatments of renal cell carcinoma in term of the number of complications avoided and 2-years disease free survival rate?
3. What is the most cost-effectiveness treatment of renal cell carcinoma between laparoscopic surgery and open surgery at Inner Mongolia Medical University Subsidiary in Inner Mongolia, China?
4. Does the cost-effectiveness analysis comparative result stability?

## **1.3 Objectives:**

### **Primary objective:**

To compare the cost-effectiveness between the two treatments which is laparoscope surgery and open surgery in renal cell carcinoma.

### **Secondary objectives:**

1. To find the total cost of the two treatments from provider perspective.
2. To calculate the effectiveness between the two treatments, according to the decision tree to find the short term outcome in terms of postoperative complications and intraoperative complications avoided; and the long term outcome in terms of 2-years disease free survival rate.

3. To calculate cost-effectiveness ratio between the two treatments and compare the cost-effectiveness of the two treatments of renal cell carcinoma.
4. According to the systematic review find other effectiveness in terms of the range of the complications avoided rate and 2-years disease free survival rate which from other papers to do sensitivity analysis check the stability of the comparative analysis results.

#### **1.4 Scope**

This study collects data from the history patient's records and the medical care bills from the department of urology in one public hospital in Inner Mongolia, China. This study extract patient documents during January 2010 - December 2011. Renal cell carcinoma minimally invasive surgery group of patients with the same period of traditional operation in patients, and they are all patients which do the laparoscopic radical nephrectomy, age among 20—84 years old.

#### **1.5 Possible Benefits**

This study may has some possible benefits: firstly, it can provide more effective, safe, economic treatment which from the cost perspective and effectiveness perspective; secondly, for hospital, it can make policy recommendations, the two treatments can do some reform or improvement, provide reasons and evidence on establish disease charge criteria and achieve rational allocation of health resources, improve the utilization.

In conclusion, cost-effectiveness of a treatment takes account into not only the contributed benefit expended from the clinical effectiveness which from short term to long term, but also think of the monetary perspective. Thus, this study can provide evidence and suggestion for hospital decision makers.

## CHAPTER II

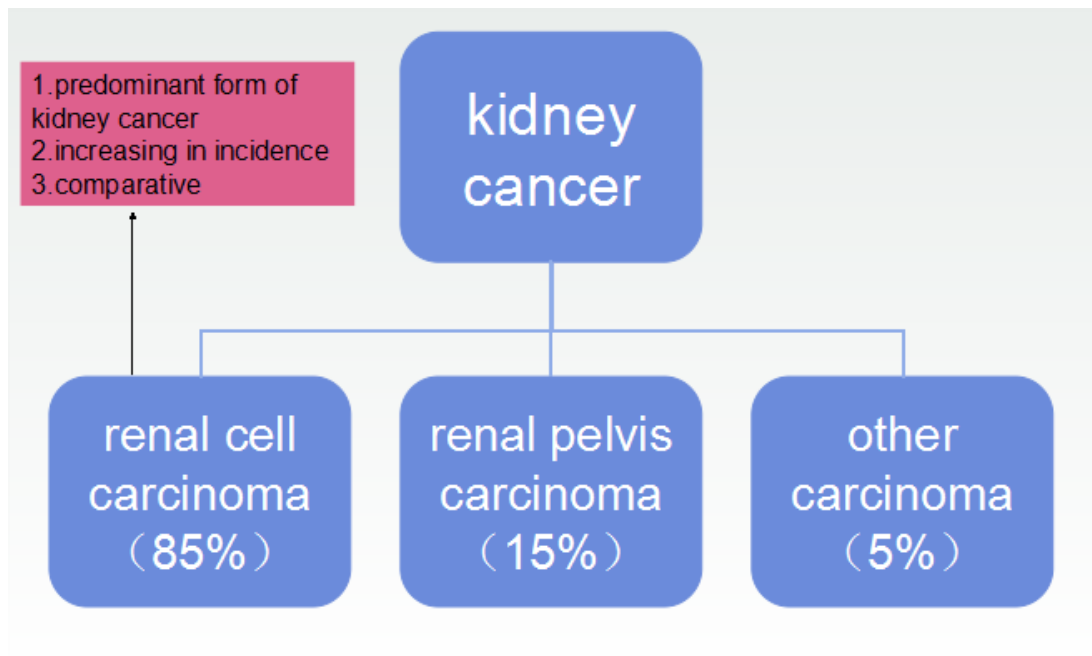
### BACKGROUND

#### 2.1 Kidney cancer and renal cell carcinoma

About the concept of kidney cancer, academic has many different understanding on this field. The National Cancer Institute at the National Institute of Health in America give a definition of kidney cancer is includes renal cell carcinoma (cancer that forms in the lining of very small tubes in the kidney that filter the blood and remove waste products) and renal pelvis carcinoma (cancer that forms in the center of the kidney where urine collects). It also includes Wilms tumor, which is a type of kidney cancer that usually develops in children under the age of 5. (National Cancer Institute at the National Institute of Health, America). But the book “We Have Kidney Cancer” which introduced by Kidney Cancer Association says kidney cancer’s medical name is renal cell carcinoma (Kidney Cancer Association, 2012). This study adopt the definition which WHO’s International Agency for Research on Cancer (IARC) introduced, namely renal cell carcinoma.

According to the concept about renal cell carcinoma. Renal cell carcinoma is a group of malignancies arising from the epithelium of the renal tubules. (John 2004) Overall the developed countries higher than developing countries, urban areas higher than rural areas, men more than women. Renal cell carcinoma takes the percentage of 85% in kidney cancer. Others are renal pelvis carcinoma and others category. This study will use the renal cell carcinoma to analysis the two treatments. Because renal cell carcinoma is the predominant form of kidney cancer. And regardless of the world or some countries, the incidence of the renal cell carcinoma presents increasing tendency. The last is to achieve comparability.

Table 1 the types of kidney cancer



## 2.2 Treatments rationale

Laparoscopic like electronic gastroscopy, which is a kind of instrument with a miniature camera, laparoscopic surgery is a kind of operation that use the laparoscopic and its associated equipment, It uses cold light to provide illumination, take the laparoscopic into the abdominal cavity, use the digital camera technology to take photo and transform to signal handle system by optical fiber, and display in the special monitor on time. Anesthesia is general anesthesia. The advantage of the laparoscope are small wound trauma, postoperative patients with rapid recovery, shorter postoperative diet time, small wound pain, shorter hospitalization time. But also has some disadvantage: Operation cost is higher, and have some limitation, because it is a new treatment, for security reasons, so do not have a high level of patients want to choose it (Jeffrey 1998).

Open operation is a normally treatment in renal cell carcinoma all the time, Open surgery didn't has limit conditions. Anesthesia is local anesthesia. After more than ten years of clinical research, Compared with the laparoscope, open operation of kidney cancer patients are bigger trauma and longer hospitalization time, the patient

recovery time is slowly. But the cost of open operation is more cheap, for some related poor families, choose which way is also a difficult decision.

**Table 2 the summary of advantages and disadvantages in two treatments**

	<b>LAP</b>	<b>OPE</b>
<b>Advantages</b>	small wound trauma , postoperative patients with rapid recovery, shorter postoperative diet time, small wound pain, shorter hospitalization time.	bigger trauma, longer hospitalization time, recovery time is slowly, longer postoperative diet time, wound pain,
<b>Disadvantages</b>	Cost expensive, have some use limitation, security reasons (new technology)	Cost cheap, Not have use limitation Anesthesia risk low

About the conditions of use the different treatments, it related to the size of tumor and the limited of stages, according to the literature, open operation not has limited condition, all types of tumor can do this operation; but the laparoscope, compared with open operation, patients are required to have a good heart and lung function, and also has some conditions of size of tumor and the limited of stages. It is generally believed that small malignant tumor, cancer should be less than 5 cm in diameter, but some literature also written that 12 cm and 9 cm in diameter also can do the laparoscope, and this situation more based on the patients who has good heart and lung function.

1990, Clayman, the university of Washington in the United States was successful in launching its first laparoscopic radical nephrectomy. Thus introduces laparoscopy in renal cell carcinoma treatment. In 1993, Winfield, completed the first laparoscopic partial nephrectomy. With the development of new materials and new equipment, the doctors are more skilled in laparoscope operation. After more than ten years of clinical research, laparoscopic technique is more and more widely used in surgical treatment of renal cancer.

The laparoscopic technique has been introduced to the hospital in Inner Mongolia, China since 2006. The region include 12 cities and pledges, up to now, the union city hospitals, including private hospitals and public hospital, urology laparoscopic surgery technology has basic mature.

In this study, which use one case of a public hospital in Inner Mongolia, China. This hospital introduced the laparoscopic treatment in 2006, which is the earliest hospital introduced the treatment in Inner Mongolia province. This study use this hospital to define database, because this hospital is one of the largest public hospital whole Inner Mongolia region, number of outpatient visits are 6000 per day, and uropoiesis surgical department related field is also the most leading worker compared with other hospitals in Inner Mongolia.

### **2.3 Operation methods in renal cell carcinoma**

Due to the different cancer stages, there are two different operation methods which have been use in clinic, radical nephrectomy and partial nephrectomy. This two methods using is depending on the tumor size and stage. 1963, Robson put on radical nephrectomy, laid the basic categories and elements of kidney cancer surgery. After about 50 years, renal cell carcinoma surgery has to be used. In recent years, some doctors put forward partial nephrectomy, Fundamentally changed the so-called standard of small renal cancer or early kidney cancer surgery. Although at present on the use of the two kinds of surgery remains controversial, according to the Renal Cell Carcinoma Treatment Guidelines (Chen 2012), radical nephrectomy is the classical operation method, partial nephrectomy has good effect on small tumors (<4cm) (Uzzo 2001). No matter what methods, they can both use laparoscope and open operation.

## CHAPTER III

### LITERATURE REVIEW

According to literatures, There are 4 types of literatures consist of this study's literature review. First is cost-effectiveness analysis applied in different medical fields and diseases. Secondly, is about the decision tree application in different treatment and diseases. Thirdly, is previous research about the comparison of the laparoscope and open operation.

Many people use cost-effectiveness analysis which the economic evaluation tools to evaluate one or more of the intervention of disease, some people only do the cost analysis, some people do analysis of clinical effect and some people do cost effect analysis of other diseases. And some literatures also use the decision tree analysis the different state about postoperative.

#### **3.1 Economics evaluation in health fields and clinical fields**

Economics evaluation as the comparative analysis of many alternative courses of action in terms of both their costs and consequences (Drummond 2005) In clinical economics, economics evaluation plays an important role, Normally, with the the development of medical technology, disease treatments and interventions constantly innovation, it is difficult for decision makers to choose which treatments or interventions are much better, so economic evaluation can help decision makers to evaluate the new treatments or interventions compared with the old one. This study use the economics evaluation method to analysis the treatment about the renal cell carcinoma is also based on the new technology which is laparoscopic surgery were introduced into clinical fields, and decision makers not have more comparison information with traditional surgery, so this study will analysis this problems and give more suggestions to decision-makers. There are three analysis tools consist of the economics evaluation research in health and clinical fields which are cost-effectiveness analysis (CEA), cost-benefit analysis (CBA) , cost-utility analysis (CUA).

### 3.2 Cost-effectiveness analysis in health fields

Cost-effectiveness analysis is a kind of health economics and clinical economics evaluation method which assesses the interventions results in health or clinical activities. Normally use comparison about two or more treatments or interventions. (Gerelt 2011) This evaluation method is based on the limited resource and the unsatisfied demand of human beings. It can provided evidence of decision-making to manager.

Cost effectiveness analysis has two parts, the first is use the monetary measure input, generally speaking, there are three types perspective, the one is provider, like hospital, government. Second is receiver, like patients, public which accept the invention. And the last is some third party, like insurance or community. When finish the cost measure, next is effectiveness, this evaluation method need some index to stand for effectiveness, like survival rate, number of cure. After the measure, the ratio of the cost and effectiveness is our result; it means the unit cost can get the effectiveness.

This study will use the CEA because of two reasons, first is in clinical research, using effectiveness index could reflect the results more directly, because this study will reflect the short run outcome and long run outcome, so using effectiveness index can give more completely results. Another reason is this study is hard to use monetary method to measure the conclusion. So this study used the CEA.

### 3.3 systematic review and meta-analysis

System review and Meta-analysis is a kind of analysis which uses the statistic concept and methods, collect and finish the scholars and experts have done many empirical studies for a theme previously. This analysis hope to be able to find out the problem or the relationship between the variables of explicit relational schema (Glass 1976). This analysis first time applied to the medical field in 1955, the author combines 15 separate research results, did the placebo effective analysis to different situation 1000 patients. Got the conclusion the placebo effect with 35%.

This study use Meta-analysis because the health records resource is limited, and the research samples are very few, so results maybe has clinical significance, but without



statistical significance, if collect the similar research cases, sample size, may be get other conclusions.

In clinical research, if the sample size is small, the results are greatly influenced by accidental factors, and difficult to eliminate these accidental factors, if statistically to eliminate these factors, it requires a lot of sample size. The biggest drawback is just to look at the paper, rather than the experimental investigation, and with the different quality of the papers, Meta-analysis also will have some deviation analysis results

Christine(1999) did the Internal derangements of the shoulder: decision tree and cost-effectiveness analysis of conventional arthrography, conventional MRI, and MR arthrography, this study want to analysis which diagnosis way is more accurate and low cost. This study used the method of using clinical assumptions, use the system review and Meta-analysis gather the data about the cost and effectiveness, used decision tree to analysis the different diagnosis conclusion. This study use cost-effectiveness analysis and decision tree solved the clinical problems, but this study use the data which is not real, and not combine the reality in which place, what kind of patients, not have the real significant.

### **3.4 Laparoscope and open operation analysis**

Laparoscopic surgery and operation surgery can be used in a lot of clinical fields, no matter which kind of fields, there are general same characteristics in laparoscopic surgery, which are short hospital stays, wounds heal quickly, less postoperative pain. And compared with the open surgery, the effectiveness is better than open surgery, but in economics analysis, there are some debates, although the laparoscopic surgery is expensive in equipment, but the short time hospital stays and quick recovery time, which can lead less cost compared with open surgery.

Mocahill (1996) did the clinical outcome and cost analysis of laparoscopic versus open appendectomy, all patients operated on for suspected acute appendicitis at the University of Washington Medical Center (UWMC) from January 1, 1991 through January 1, 1995 were analyzed. They use hospital length of stay, operative time and the postoperative complications as the

effectiveness index, operating room charges, and total hospital charges as the cost. The conclusions are laparoscopic appendectomy, while safe, was more expensive and were not associated with better clinical outcome compared with open appendectomy patients. This study just analysis in two different perspective, and divided into the cost and effectiveness, so my study want to use this as a starting point, combine the cost and effective, find more comprehensive results.

William (1995) did the prospective cost analysis of laparoscopic cholecystectomy, this study use the basic of hospital data in operation room , radiology, pharmacy, anesthesia supplies and hospital room, and this study use the hospital perspective to find which department take more cost during laparoscopic cholecystectomy, this study put some suggestions of improving the surgical value package, like decrease cost while maintaining quality. But this study just analysis the cost, and just put the suggestions in hospital cost, not give the guideline to patients, so my study will pay attention on the patient perspective.

Dennis (1999) did the cost analysis of laparoscopy versus laparotomy for early endometrial cancer, this study choose the target population and do t-test, Variables analyzed included age, Quetelet index (QI), surgical stage, number of lymph nodes, surgical time, estimated blood loss, postoperative complications, number of days in the hospital, and costs. After divided two groups. The cost analysis was divided into room and board, pharmacy, ancillary services, operating room equipment, operating room services, and anesthesia. Because the total costs for each surgical approach are not statistically different, so the results is laparoscopic surgical management of early stage endometrial cancer is feasible with minimal morbidity. This study considers the morbidity.

Zengshu Xing (2011) did A comparison of the clinical effects between retroperitoneal laparoscopic and open partial nephrectomy for the treatment of renal tumor, they compared open partial nephrectomy in clinical effect and after laparoscopic partial nephrectomy clinical effect, they use the blood loss, postoperative intestinal function recovery time, usage of painkiller, postoperative hospitalization days and the incidence of postoperative complications as the effectiveness index. The conclusion is laparoscopic partial nephrectomy on renal tumor, compared with the

traditional open partial nephrectomy, with little trauma, quick recovery, curative effect and a lot of other advantages. But this study just look at the effectiveness not has cost analysis.



## CHAPTER IV

### METHODOLOGY

#### 4.1 Study Design

This study compared the laparoscopic surgery and open surgery in treatment about renal cell carcinoma by economic evaluation method which is cost-effectiveness analysis. This study used retro perspective, by means of medical records and the hospital cost accounting bills (January 2010-December 2011).

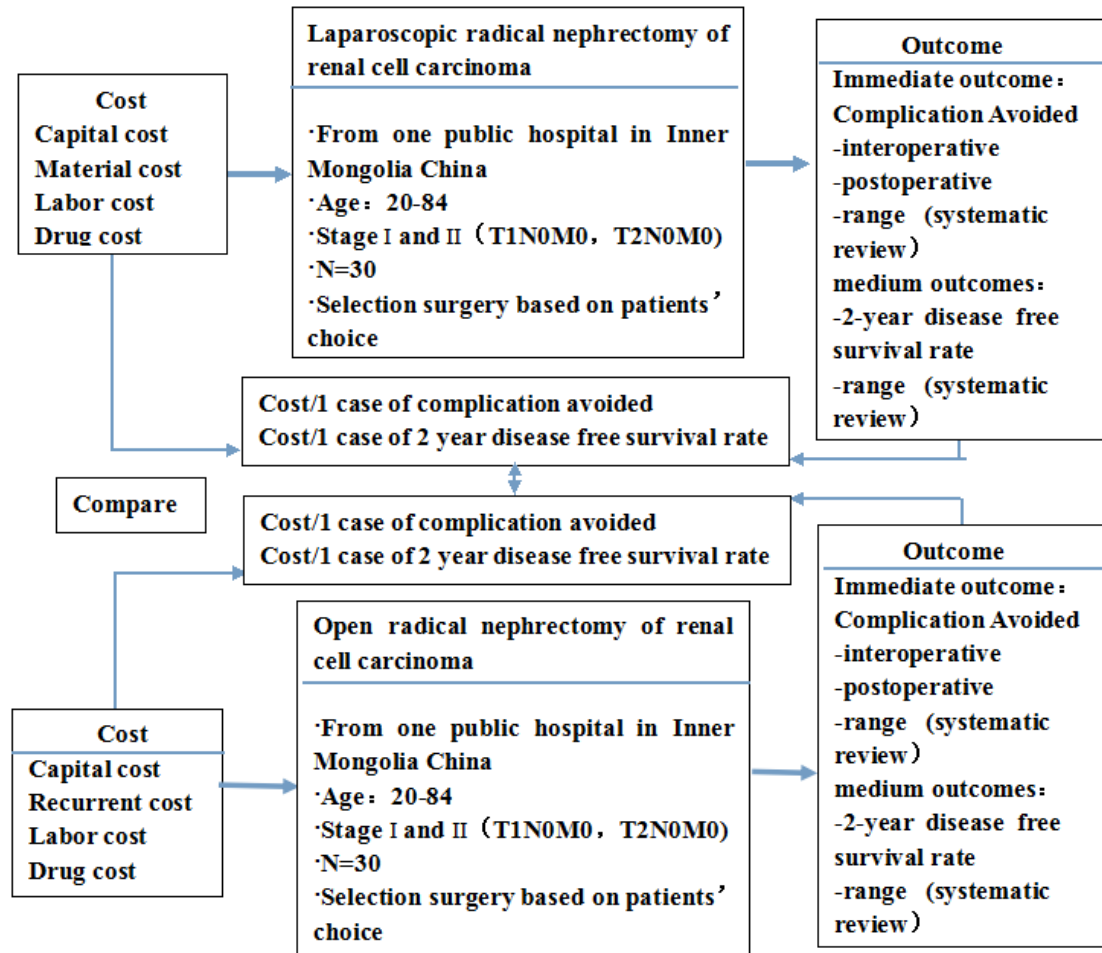
In order to complete the patients different status after treatments, this study choose postoperative complications and intraoperative complications avoided rate as short term effectiveness and 2-years disease free survival rate as medium term effectiveness according to decision tree. And do system review to find the comparable studies, do the sensitivity analysis.

## 4.2 Conceptual framework:

Provider perspective

Hospital Cost Accounting Bills

(January 2010-December 2011)



### 4.3 Target population

Target population were the renal cell carcinoma patients which do the radical nephrectomy using two treatments respectively in 2 years. According to the eligible criteria select the patients and find the information about their treatment cost and the treatment effective.

This study used radical nephrectomy patients because different methods have same situations, in order to make sure the same level of two groups ' patients. This study not uses partial nephrectomy because this method is just for a few people who tumor is less than 4 cm. The data were not representative.

### 4.4 Data source

This study chooses data were the history patient's records and the medical care bills from the department of urology of one public hospital in Inner Mongolia, China. So the data is patient level data. This study extract patient documents during January 2010 - December 2011 in one public hospital in Inner Mongolia, uropoiesis surgical department. The patients did the radical nephrectomy using two treatments respectively, age are among 20—84 years old.

Basic patient information investigation: Including name, age, and the number of inpatient, contact information, discharge time, history of previous abdominal surgery, and the MRT check situation (tumor stages and size).

Clinical patient information investigation : Including hospital stays, recovery time, blood loss, complications, wound healing, the cure rate, etc.

### 4.5 Inclusion criteria and exclusion criteria

#### 4.5.1 Inclusion criteria:

1. Without concomitant disease patients with renal cell carcinoma ;
2. According to the TNM Classification of Renal Cell Carcinoma by WHO, based on different stages, patients have different influence in terms of cost and effectiveness. So this study limited the stages are T1N0M0 and T2N0M0. T1N0M0 means tumor 7cm or less in greatest dimension, limited to the kidney. No regional lymph node metastasis and no distant metastasis. T2N0M0 means tumor more than 7cm in greatest dimension, limited to the kidney.

3.Doctors not have clinical recommendations about the treatment, surgical procedure for patients based on their own choices.

#### 4.5.2 Excluding condition:

- 1.Patients with obvious concomitant disease.
- 2.Patients not include in TIN0M0 and T2N0M0.
- 3.Patients were advised to choose the treatment by doctors.

Table 3 summary of the inclusion criteria and exclusion criteria

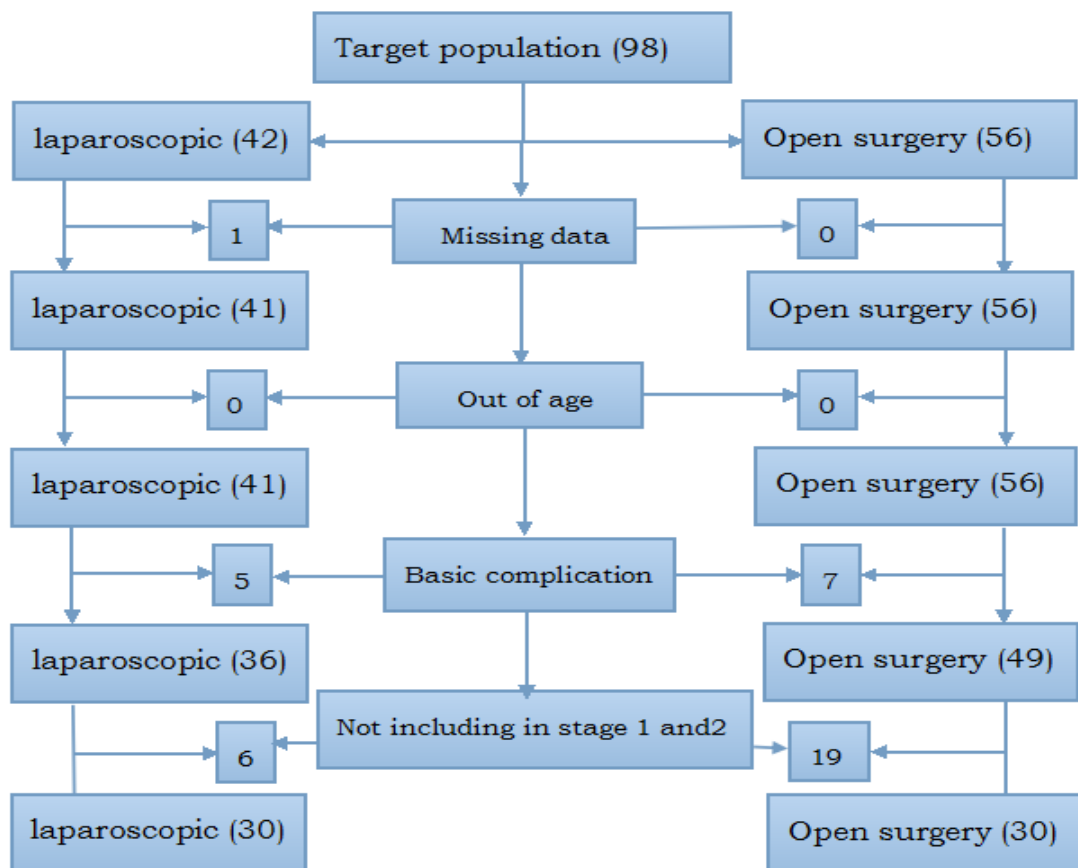
	<b>inclusion</b>	<b>exclusion</b>
<b>inclusion</b>	<ol style="list-style-type: none"> <li>1.Without concomitant disease</li> <li>2.TIN0M0 and T2N0M0</li> <li>3.Without clinical advices</li> </ol>	
<b>exclusion</b>		<ol style="list-style-type: none"> <li>1.With concomitant disease</li> <li>2.exclude TIN0M0 and T2N0M0</li> <li>3.With clinical advices</li> </ol>

According to the operation treatments, patients is divided into two groups after select samples from target population, And do the postoperative follow-up until they leave hospital. After operation, normally patients without complications, and wound healing in good condition, the indicators reaction is normal, 12 days later can be discharged from hospital. If the patients have the complications, study will according to the situation of the patients do the corresponding treatment.

#### 4.6 Samples selection

There were 98 target population of renal cell carcinoma patients which do the radical nephrectomy using two treatments respectively in 2 years. According to the eligible criteria, the laparoscopic patients are 30, the open surgery patients are 30, table 4.2 show the sample process in more details.

Table 4 Sample data screening process





## 4.7 Data analysis

### 4.7.1 Database diagram:

Step 1: design database diagram

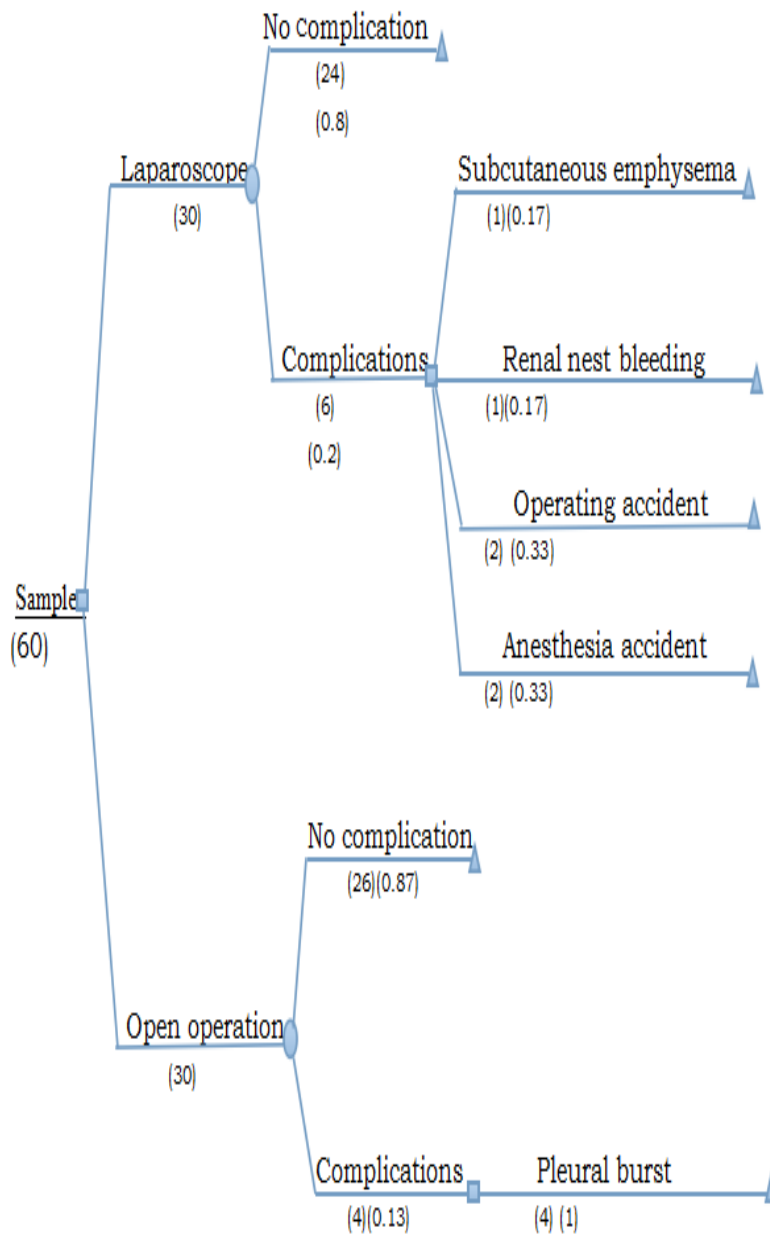
Database diagram is designed to estimate the cost of treatment and follow up for different outcome after treatment. The diagram algorithm is built on account of the available data and the actual effect of treatment. After doing the screen according to the eligible criteria from the target population, according to the samples build the database diagram.

Based on the available medical records, after did the treatments, they have been come out some complications, and two treatments has different complications, the complications can be divided into 2 types, Inoperative complications and postoperative complication. Inoperative complication means the process of the operation, generate the complications, postoperative complications means the complications which occurred after the operation

**Table 5 summary of the complications in two groups of patients**

Name	type	LAP (n)	OPN (n)
Subcutaneous emphysema	intraoperative	1	—
Renal nest bleeding	postoperative	1	—
Operating accident	intraoperative	2	—
Anesthesia accident	intraoperative	2	—
Pleural burst	intraoperative	—	4

Figure 3 Database diagram



block node1: the two treatments  
 patients choices  
 block node2: complications which  
 induced by treatments  
 circular node: treatment results  
 triangle nodes: outcomes

### Step 2: probabilities calculation

To analysis the overall cost-effectiveness of laparoscope treatment relative to open operation of renal cell carcinoma, this study will estimate the probabilities of different health states after did the operation, this study will do retro perspective find the number of different states after operation, the formulas are:

probabilities of no complication after laparoscope=the number of no complication after laparoscope/total patient undergo laparoscope

probabilities of complication after laparoscope=the number of complication after laparoscope/total patient undergo laparoscope

probabilities of burst pleural rupture after laparoscope=the number of burst pleural rupture /total patient have complications

probabilities of operative bleeding after laparoscope=the number of operative bleeding /total patient have complications

probabilities of anesthetic accident after laparoscope=the number of anesthetic accident /total patient have complications

probabilities of no complication after open operation=the number of no complication after open operation/total patient undergo open operation

probabilities of complication after open operation=the number of complication after open operation/total patient undergo open operation

probabilities of burst pleural rupture after open operation=the number of burst pleural rupture /total patient have complications

probabilities of burst pleural rupture after open operation=the number of postoperative pain /total patient had complications

probabilities of each treatments successful or failure about complication =the number of treatments successful or failure about complication /total patients took in treatment about complications

### Step 3: estimated cost calculation

Estimated cost of no complication=probabilities of no complication after two treatments\*cost of two treatments

Estimated cost of complications=probabilities of complications after two treatments\*cost of two treatments+probabilities of each treatments successful or failure about complication\*cost of treatments about complications

Total estimated cost=estimated cost of no complication+estimated cost of complications

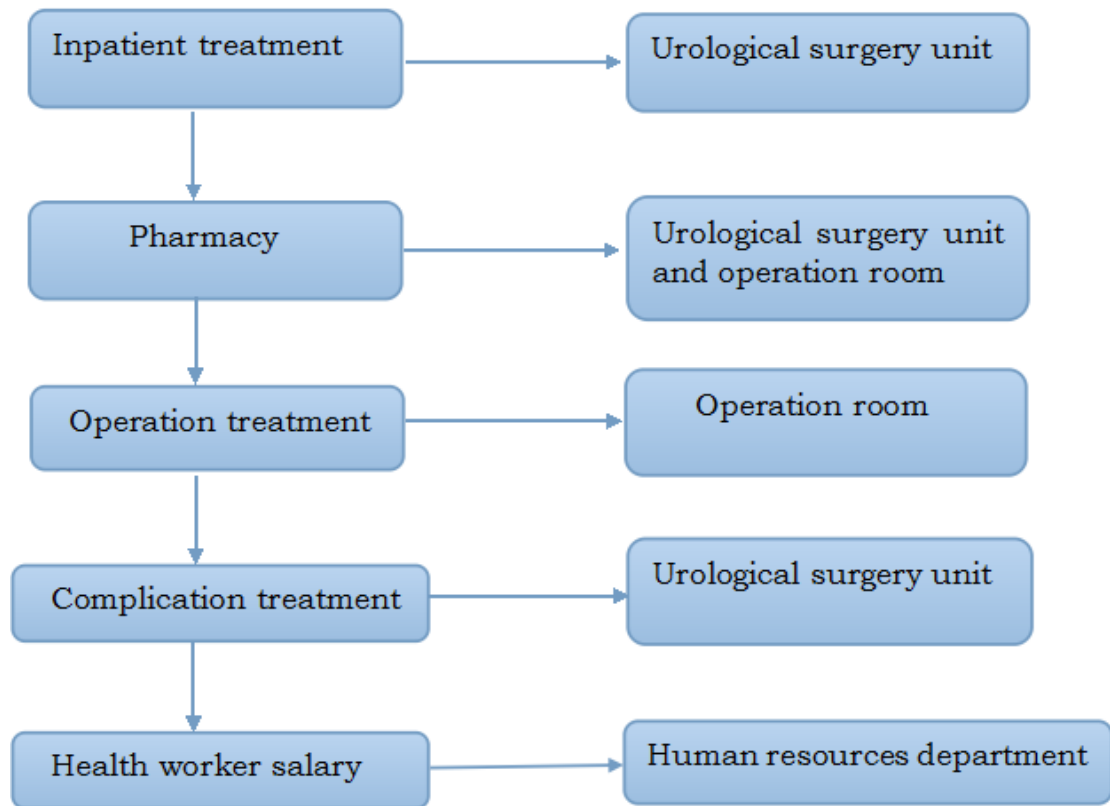
#### 4.7.2 Cost analysis:

From the retrospective analysis, this study uses the provider perspective to analysis the cost. This study calculates the cost from the day the patients did live in hospital until they leave the hospital. Because this study will summarize 2 years data, in order to analysis in the same money value. So cost in 2010 and 2011 were converted in present value.

**Table 6 Costing steps during different treatments**

Steps	Costing category	laparoscope	open operation
1	inpatient treatment	including	including
2	pharmacy	including	including
3	operation treatment	including	including
4	complication treatment	including	including
5	total cost	sum of 1, 2,3,4,5,	

Table 7 data collection department



#### Step 1: inpatient treatment

Inpatients treatment cost means the cost about hospital days except of operation treatments until patients leave the hospital. According to the finding of the patient record status, this study cost will divide into ward cost and operation cost. ward cost including the capital cost, which are medical facility, like oxygen table, pneumatic pump and electrocardioscanner. Variable cost including one-time consumables, like gloves, needles; health worker salary.

#### Step 2: pharmacy

Pharmacy cost means the drug cost used in intraoperative and postoperative. According to the National System for Basic Drugs rule, drugs price on the basis of the input price increased by fifteen percent.

So the cost of pharmacy can be identification as:

$$\text{Cost of drug} = \text{drug price} * (1 - 15\%)$$

### Step 3: complication treatment

Complication treatment cost means the cost that the patients generate intraoperative complication and postoperative complication. The cost of doctors and nurses take some measure to treat. And according to different patients has different complications, so the part of cost included in every patients cost.

#### 4.7.3 Effectiveness analysis

This study defines the short term outcome and medium term outcome. About short run outcome, despite the minimally invasive surgery character of laparoscopic radical nephrectomy and its superiority, it is still a major significant that promote research on postoperative complications. (Matthew 2004). Therefore, the short run use the number of complication avoided. According to the differences in the process of two kinds of treatments, this study also takes account into the intraoperative and postoperation complications.

About medium run outcome, While the immediate benefits of laparoscopic are clearly proved in terms of estimated blood loss, postoperative painkiller requirements, length of hospitalization and duration of convalescence.(Andrew 2002) But the long term oncological effectiveness which is 2-year disease free period also need to be considered. In 2-year disease free period, the number of patients not have the cancer survival in 2 years, means patients have effectiveness in this treatment.

About the index of short-run effectiveness, this study will choose the number of complication survival, the standard is not have the complication until leave the hospital. Like burst pleural rupture, renal nest bleeding, anesthetic accident.

According to the concept of the complication, the complication divided into two types of situations, the one is one disease caused by another disease, for example, chicken pox cause pneumonia. The second is caused in the process of disease diagnosis and treatment, like complications after the operation, but both of two types complications is not the reason of medical staff negligence, so calculate the rate of not have complication, this study will eliminate the complications which due to the medical staff negligence. Doctors according to the regulation of the operation

do treatments, the patient's family signs the documents of responsibility, if complications, means not doctors mistakes.

#### 4.7.4 Cost-effectiveness:

$$\text{CER} = \text{cost} / \text{effectiveness}_{\text{short}}$$

$$\text{CER} = \text{cost} / \text{effectiveness}_{\text{long}}$$

After calculating the cost and effectiveness, doing the cost-effectiveness analysis, compare the two ratios about the cost divided effectiveness, the less ratio, the more cost effectiveness treatment.

#### 4.7.5 Systematic review:

Due to the small size of samples, this study use systematic review to increase the reliability results. Sensitivity analysis will use the range of Incidence of complications and the situation in 2-year disease free period after or in the two treatments to find the stability of the results.

Analysis question:

What are clinical outcomes that renal cell carcinoma patients undergoing laparoscopic surgery and open surgery? What kind of complications were they occurred? How about the situation in 2-year disease free period.

Retrieval strategy:

This review used one databases which is Science Direct, retrieval strategy are “renal cell carcinoma” AND “laparoscopic” AND “open surgery”. Paper types include journals from countries, books, professional web site, etc. And because of the developed of the clinical technology, so this study limited the review year, limited year is from 1990 to 2014.

Inclusion criteria

To enter the analysis, studies has to (1) comparative research from renal cell carcinoma underwent laparoscopic surgery and open surgery. (2) Report on at least one of the outcome measures mentioned below or other outcome, and (3) clearly document treatment as either an “radical nephrectomy” or “renal cell carcinoma

resection''. (4) This study is retrospective research, but this study is also cooperate the clinical trial on the part of the clinical outcome, in this study is effectiveness, so this system review included the literature which are retrospective study and prospective study.

#### Exclusion criteria

Patients must be matching with this study database, means the patients are matching the eligible criteria of patients which included age, basic complications, staging. If the review analysis's samples not match the criteria, these study exclude in this analysis.

#### Statistical analysis

Using the Review Manager 5.2 to do the statistical analysis, draw the forest figure and funnel plots, do the heterogeneous test and test for overall effect, get the range of the incidence of the total complications and 5-year disease free survival rate.

#### **4.7.6 Sensitivity analysis:**

Sensitivity analysis in views of the uncertainty when dealing with data collection. By changing some of the uncertainty of the variables in the data within a certain range estimates, to find the views whether has influence in stability of outcome. It can reduce the offset.

About variable, This study changed effectiveness index to do analysis. This study did the Meta-analysis, refer to other related literature to find the complication incidence after operation and the situation 2-year disease free period, and find the range of the different probabilities, and change the complication rate into the range's highest value and lowest value. Then does the sensitivity analysis find the result was stability or not.



## CHAPTER V

### RESULTS

#### 5.1 Basic patients' information data statistics

This study analysis the statistics data by IBM SPSS Statistics 21, by means of the basic information about sample patients from target population. The content include age, gender, tumor diameter, hospital stays, kidney disease, and therapeutic effect. More details in continued tables. And the null hypothesis is two groups of data difference not have the statistic significant, alternative hypothesis is two groups of data difference have the statistic significant.

(1) Patients' age: Patients' age means the patients age when they check in the hospital and accept the treatments. Based on the patients' medical records the first page recorded, compare the 2 groups' age statistic difference by independent sample t test. Significance level is 95%. The table shows the test results, the p bigger than 0.05, accept the null hypothesis. The difference between two groups of age not have the statistic significant. More details in table 8.

**Table 8 Age information of the LAP group and OPE group**

	LAP (30)	OPE (30)	P
Mean	55.1333	54.7000	0.886>0.05
SD	11.03203	12.18294	

(2) Patients gender : Based on the patients' medical records the first page recorded, compare the 2 groups gender statistic difference by Chi-square test. Significance level is 95%. The table shows the test results, the p bigger than 0.05, accept the null hypothesis. The difference between two groups of age not have the statistic significant. More details in table 9.

**Table 9 Gender information of the LAP group and OPE group**

	LAP (30)	OPE (30)	$\chi^2$	p
Male	19	20	0.073 <sup>a</sup>	0.787
Female	11	10		

(3)Tumor diameter : according to the B-ultrasonic examination, get the tumor diameter. Based on the patients' medical records the first page recorded, compare the 2 groups' tumor diameter statistic difference by independent sample t test. Significance level is 95%. The table shows the test results, the p less than 0.05, reject the null hypothesis. The difference between two groups of age have the statistic significant. More details in table 10.

**Table 10 Tumor diameter (cm) information of the LAP group and OPE group**

	LAP (30)	OPE (30)	P
Mean	4.96	5.7533	0.016<0.05
SD	1.54241	0.82325	

(4)Hospital stays: means the time patients check into the hospital accept treatment until they check out of the hospital. Based on the patients' medical records the first page recorded, the situation about post-operation complication, record the sum of twice the hospital days. Significance level is 95%. The table shows the test results, the p bigger than 0.05, accept the null hypothesis. The difference between two groups of age not have the statistic significant. More details in table 11.

**Table 11 Hospital stays (days) information of the LAP group and OPE group**

	LAP (30)	OPE (30)	P
Mean	14.8000	15.4000	0.696>0.05

SD            7.24640                      4.17381

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(5) Kidney site: means the right kidney and the left kidney. Based on the patients' medical records the first page recorded, compare the 2 groups' kidney disease statistic difference by Chi-square test. Significance level is 95%. The table shows the test results, the p bigger than 0.05, accept the null hypothesis. The difference between two groups of age not have the statistic significant. More details in table 12.

**Table 12 Kidney site information of the LAP group and OPE group**

	LAP (30)	OPE (30)	$\chi^2$	P
Left	20	18	0.298 <sup>a</sup>	0.585
Right	10	12		

(6) Recovery time : means after doing the operation, the patients check out of the hospital time. Some researches got the laparoscopic surgery recovery time is faster than open operation, because the open operation patients need more time to exhaust. Based on the patients' medical records the first page recorded, compare the 2 groups' recovery time statistic difference by independent sample t test. Significance level is 95%. The table shows the test results, the p less than 0.05, reject the null hypothesis. The difference between two groups of age have the statistic significant. More details in table 13.

**Table 13 Recovery time (days) information of the LAP group and OPE group**

	LAP (30)	OPE (30)	P
Mean	6.3333	8.7333	0.039<0.05
SD	5.89759	2.01603	

(7) Therapeutic effect: means the success rate of surgery, based on the Patients postoperative information table, compare the 2 groups' therapeutic effect statistic difference by Chi-square test. Significance level is 95%. The table shows the test

results, the p bigger than 0.05, accept the null hypothesis. The difference between two groups of age not have the statistic significant. More details in table 14.

**Table 14 Therapeutic effect information of the LAP group and OPE group**

	LAP (30)	OPE (30)	$\chi^2$	P
Success	29	30	1.017 <sup>a</sup>	0.313
Fail	1	0	(8) Summary:	

**Table 15 summary of patients' information**

Characteristic	Average. (SD) Of recipient		p value
	Laparoscope (n=30)	open surgery (n=30)	
1. Sex			
Male	19	20	0.787
Female	11	10	
2. Age	55.1(11)	54.7(12.2)	0.886
3. Hospital stays	14.8(7.2)	15.4(4.2)	0.696
4. Recovery time	6.3(5.9)	8.7(2)	0.039
5. Tumor diameter	4.9(1.5)	5.8(0.8)	0.016
6. Tumor size			
Left	20	18	0.585
Right	10	12	
7. Effect			
Success	29	30	0.313
Fail	1	0	

## 5.2 Costing

This study divided two types of the cost centers, which have the directly relationship to the two treatment. So this study will be the provider perspective, and the data type are patient-level data. Which including the disposable materials cost, pharmacy cost in terms of patients in ward and in operation room. As well as the building and equipment cost in operation and in ward of a hospital, otherwise, the labor cost is also included.

According to this study's property, analysis the treatment cost of the every patients, so this study just include the cost centers related to the surgery directly, which are operation room and ward room.

According to the cost analysis for every patients, disposable materials, drugs and heating costs were got by the hospital designated standard price. Because this study calculate the cost include capital cost and recurrent cost which are take advantage over years, so the cost in 2010 will be convert into 2011 by inflation-adjusted method. Based on the formula:

Cost in year 2011=cost in 2010\*(1+inflation rate of year 2011)

$$\text{Inflation rate of year 2011} = \frac{CPI_{2011} - CPI_{2010}}{CPI_{2010}}$$

According to Inner Mongolia Statistical Yearbook in 2011 and 2012, the CPI in 2010 is 103.2, 2011 is 105.6. According to the formula, the inflation rate in 2011 based on the benchmark year in 2010, is 0.0232.

**Table 16 Cost centers**

Step	cost center	LAP	OPN
1	ward room	√	√
2	operation room	√	√
3	total cost	sum of 1 and 2	

### 5.2.1: Ward cost

**Table 17 ward cost type**

Step	cost type	LAP	OPE
1	disposable materials	√	√
2	pharmacy	√	√
3	salary	√	√
4	building and equipment	√	√
5	total ward cost	sum of 1,2,3,4,	

Firstly. Disposable materials cost and pharmacy cost calculation, this part of cost calculation will use the price charge ratio according to the patients' records.

**Table 18 Disposable materials cost in two treatments**

	LAP	OPE	data source
Total cost	87607.7	26487.9	patients documents
Unit cost	2920.3	882.9	

**Table 19 Pharmacy cost in two treatments**

	LAP	OPE	data source
Total cost	101705.3	96721.8	patients documents
Unit cost	6561.6	3224.1	

Secondly. Salary cost calculation

The labor cost in ward were divided into two categories which were nurse work in ward and physician. And according to the different professional qualifications, every rank of the medical staff can support services to patients, so this study will take the

total salary every year in nurses and physician. And about the trainee, hospital not send the salary to this part of workers, so this study not consider the trainee cost.

About this hospital's human resources allocation, the ward nurses are managed by the ward, and the nurse just provide the medical service to the inpatient patients in the ward. And the physicians not just work for ward, they also work for the outpatient and the operation room. So about the nurse salary, they just related to the ward room or operation room, which are two independent department. But the physicians' salary included in inpatients, outpatients and operation.

When calculate the salary cost for the nurse and physician in inpatients in ward, there is a assumption, about the inpatient service, the nurse and the doctors provide the same service to every patients, no matter renal cell carcinoma patients or other urological diseases patients. In another word, salary in every patients are the same, the difference are the hospital stays. The ward has 15 nurses, the work days are 20 days, and the average inpatients are 42 per day in this ward. So this study will take the formulas, and firstly is ward nurses salary.

Step 1

Ward nurses total salary per month =sum of the average salary per month about 15 nurses in 2011

Step 2

Ward nurses average salary per day=Ward nurses total salary per month/20

Step 3

Ward nurses average salary per patients per day=Ward nurses average salary per day/42

Step 4

Ward nurses salary inputs in every patients=Ward nurses average salary per patients per day\*hospital stays

According to the stipulation of wage in this hospital, , the number of nurses in ward were 15, and the work days were 20 days, so the total salary about nurse are

94646 RMB, because the ward nurse work days are 20 days per month, so the ward nurses average salary per day are 4732.8 RMB, and the average inpatients are 42 per day in this ward, so the Ward nurses average salary per patients per day are 112.68 RMB, so according to 112.68 times the hospital days ,this study get the ward nurses salary inputs in every patients. More details in table 2

Steps	formulas	results
1. Ward nurses total	sum of the 15 nurses salary	94656
Salary per month		
2. Ward nurses average	$94656/20$	4732.8
Salary per day		
3. Ward nurses average	$4732.8/42$	112.68
Salary per patients per day		

Step 4 Ward nurses salary inputs in every patients=Ward nurses average salary per patients per day\*hospital stays

**Table 21 salary cost in ward nurses**

Patients code	Hospital stays		salary cost	
	Laparoscope	open surgery	Laparoscope	open surgery
001	8	13	922.4	1498.9
002	38	14	4282.1	1614.2
003	9	11	1037.7	1268.3
004	10	14	1153	1577.6
005	17	14	1915.7	1614.2
006	10	14	1126.9	1577.6
007	16	15	1844.8	1729.5
008	13	15	1498.9	1690.3
009	13	17	1498.9	1960.1
010	11	21	1268.3	2421.3
011	16	15	1803.0	1690.3



012	14	18	1614.2	2028.3
013	22	19	2479.1	2141.0
014	14	12	1614.2	1383.6
015	15	17	1690.3	1960.1
016	39	13	4394.7	1498.9
017	19	20	2141.0	2253.7
018	16	15	1844.8	1690.3
019	10	11	1126.9	1239.5
020	10	12	1126.9	1383.5
021	11	15	1268.3	1690.2
022	15	13	1690.3	1464.8
023	16	15	1844.8	1729.4
024	13	14	1464.9	1577.5
025	14	17	1577.6	1960
026	15	10	1690.3	1126.8
027	9	12	1014.2	1383.5
028	14	16	1614.2	1844.7
029	18	14	2075.4	1577.5
030	16	14	1803.0	1614.1
Total cost			52426.5	50223.9
Total cost			52426.5	50223.9

About doctors salary, According to the management of the physician service of this hospital, the doctors provide inpatient service for 12 days per month, outpatient for 6 days, operation for 12 days. So this study will use the direct allocation to allocate the salary of the physician by the allocation index about the working times. And there are 7 doctors in this department. More details in table 5.15

**Table 22 Total salary of doctors' allocation**

Total salary of doctors'	Percentage day allocation		
	inpatient	outpatient	operation
Per month	40%	20%	40%
37265	14906	7453	14906

Because the doctors support treatment in operation room and ward room, so the salary of the doctor will use the direct allocation method, the criteria is the percentage time usage in every cost centers, and according to the

Disease this study analysis, the cost just include in inpatient and operation, so the inpatient salary for doctors in ward are 14906 RMB.

When finish the doctor allocation, the calculation are same like nurse salary in ward, and the formulas are same like the steps introduced before.

**Table 23 Total salary cost of doctors in ward time**

Steps	formulas	results
1. Ward doctors total salary per month	allocation from the total salary	14906
2. Ward doctors average salary per day	$14906/12$	1242.2
3. Ward doctors average salary per patients per day	$1242.2/42$	29.6

Step 4 Ward doctors salary inputs in every patients=Ward doctors average salary per patients per day\*hospital stays

**Table 24 salary cost in ward doctors**

Patients code	Hospital stays		salary cost	
	Laparoscope	open surgery	Laparoscope	open surgery
001	8	13	242.1	393.4
002	38	14	1123.9	423.7
003	9	11	272.4	332.9
004	10	14	302.6	414.1
005	17	14	502.8	423.7
006	10	14	295.8	414.1
007	16	15	484.2	454.0
008	13	15	393.4	443.6

009	13	17	393.4	514.4
010	11	21	332.9	635.5
011	16	15	473.2	443.6
012	14	18	423.7	532.4
013	22	19	650.7	561.9
014	14	12	423.7	363.1
015	15	17	443.6	514.4
016	39	13	1153.4	393.4
017	19	20	561.9	591.5
018	16	15	484.2	443.6
019	10	11	295.8	325.3
020	10	12	295.8	363.1
021	11	15	332.9	443.6
022	15	13	443.6	393.3
023	16	15	484.2	453.8
024	13	14	384.5	414.0
025	14	17	414.1	514.3
026	15	10	443.6	295.7
027	9	12	266.2	363.1
028	14	16	423.7	484.1
029	18	14	544.7	414.0
030	16	14	473.2	423.6
Total cost			13759.8	13181.1
<b>Total cost</b>			<b>13759.8</b>	<b>13181.1</b>

Table 25 Summary of the total salary cost in ward

Cost	lap	ope
Doctors	13759.8	13181.1
Nurses	52426.5	50224
<b>Total cost</b>	<b>66186.3</b>	<b>63405.1</b>

Thirdly, Equipment and building cost. About the equipment and building cost in ward, there are several methods of calculating the capital cost in the research of economic evaluation, the best way is to use annuity of the initial equipment and building over the useful life. This method have many advantages which has been reported before. Because about the capital cost, the important index are opportunity cost and depreciation, so this method take into account both of them. (Michael 2008)

According to the database, the equipment and building was bought in 2005, so this study use present value formula to convert the cost which from 2005 to 2010 and 2011. The discount rate was used by the annual interest rate which formulate by Central Bank of China. (3.6%)

$$C_{2010/2011} = C_t * (1+r)^{2010-t}$$

Where  $C_{2010/2011}$  = present cost of capital in year 2010/2011

$C_t$  = purchase cost of capital in year t (2005)

r = discount rate

t = the year of capital was bought

After conversion from the original value (2005) to the year of patients used (2010-2011), this study used the expected years of useful life of the equipment and building based on estimate useful lives. According to the hospital assets book, the useful life for equipment is 5 years, building is 20 years. Because this study use the annuity to calculate the depreciation, so and annuity formula and capital cost formula is below:

$$A = [1 - (1+r)^{-n}] / r$$

Where A = annuity

r = discount rate (0.036)

n = useful life or life time of capital for depreciation

$$E = C_{2010/2011} / A$$

Where A = annuity

E=equivalent annual cost

Taking the diagnosis beds as examples:

$$C_{2011}=900*(1+0.036)^6=1112.8 \text{ RMB}$$

$$\text{Annuity in 2011}=[1-(1+0.036)^{-5}]/0.036=4.5$$

$$\text{Equivalent annual cost}=1112.8/4.5=247.2$$

This results stand for the diagnosis beds depreciation are 247.2 in 2011.

After calculate the total capital cost of the ward from the 2005 to 2011 and 2010, which are total 5 and 6 years, next step is to allocate the cost to the patients in ward, like the assumption which salary cost calculation part wrote, this part this study also has an assumption, which is the depreciation cost of each patient daily consumption is the same, no matter renal cell carcinoma patients or other patients, so this study will use the total capital cost to calculate the average capital cost per patient per day, and times the hospital days, get the capital cost consumption for every patients, the formulas has written below:

Step 1

$$\text{Average capital cost per day}=\text{total cost}/365=1002.3\text{RMB}$$

Step 2

$$\text{Average capital cost per day per patient}=\text{average capital cost per day}/\text{average numbers of patients}=1002.3 \text{ RMB}/42=23.9 \text{ RMB}$$

Step 3

$$\text{Capital cost consumption for every patients}=\text{Average capital cost per day per patient}*\text{hospital stays}$$

**Table 26 capital cost in ward**

	LAP	OPE	data source
2010	3800	4629.7	patients' documents
2011	7064	5666.7	
Total cost	10864	10296 .4	

So after the ward cost calculation, sum of the disposable material cost, drug cost, salary cost and building cost, the total cost in ward which in two treatments are 264087.9 RMB and 196911.2 RMB.

**Table 27 summary of the cost in ward**

Step	cost type	LAP	OPE
1	disposable materials	87607.7	26487.9
2	pharmacy	101705.3	96721.8
3	salary	66186.3	63405.1
4	building and equipment	10864	10296 .4
5	total ward cost	264087.9	196911.2

### 5.2.2: operation cost

**Table 28 cost types in operation room**

Step	cost type	LAP	OPE
1	disposable materials	√	√
2	salary	√	√
3	building and equipment	√	√
4	total operation cost	sum of 1, 2, 3,	

Firstly, disposable materials cost calculation, this part of cost calculation will use the price charge ratio according to the patients' records.

**Table 29 Disposable materials cost in two treatments**

	LAP	OPE	data source
Total cost	86635.6	18577	patients documents
Unit cost	2887.9	619.2	

Secondly, salary cost in operation room is divided into 3 types of medical staff, operation room nurse, doctors and anesthetists, the operation room nurses are managed by the operation room, the doctors are managed by the ward, but they also input their labor force in operation room, and the anesthetists are managed by operation, too. And according to the different professional qualifications, every rank of the medical staff can support services to patients, so this study will take the total salary every year in nurses, physicians and anesthetists. And in operation room, hospital not send the salary to trainee, so this study not consider the trainee cost.

When calculate the salary cost for the nurses, physicians and anesthetists in operation room, same like the ward salary calculation there are a assumption, about the operation service, nurses, physicians and anesthetists input the same value of labor to every patients, no matter renal cell carcinoma patients or other diseases patients. In another word, salary in every patients are the same, the difference are the operation hours. And according to the renal cell carcinoma operation procedure which formulate by Ministry of Health in China to calculate the operation salary cost.

code	treatment	Content	Human recourse	hours
HRB7 7301	Open surgery	1, Disinfection first. 2, electrosurgical generator cut step by step. 3, separation of kidney without the adipose capsule.4, dispose the renal arteries. 5,ligature And dividing the ureteral and genital vein, remove adipose capsule, kidney, adrenal gland. 6, lymph node dissection. 7, drainage and Close the incision	4 doctors 2 nurses 1 anesthetist	4
HRB7 7501	Laparoscopy c surgery	1, Disinfection first. 2, Selection of puncture part, insert the puncture outfit. 3, expansion retroperitoneal clearance first with balloon if via retroperitoneal cavity. 4, establish pneumoperitoneum, insert in sight glass, 5, put into operation channel casing and operating equipment. 6, Using ultrasonic knife separation, titanium clamp, pipe clip wall of bloodvessels .7, separation of kidney without the adipose capsule. 8, dispose the renal arteries. 9, ligature and dividing the ureteral and genital vein, remove adipose capsule, kidney, adrenal gland. 10, lymph node dissection.11, 11,drainage and Close the incision	3 doctors 2 nurses 1 anesthetist	4



Firstly is operation nurses salary. The operation room has 15 nurses, the work days are 30 days, according to the operation procedure of the two kind of operation, two treatments both use 2 nurses can finish one operation, so this study calculate the average salary of the nurse, and times 2, get the operation nurses salary input of two treatments. The work days are 8 hours. So this study will take the formulas.

**Table 31 operation nurse salary calculation**

Steps	formulas	results
1. operation nurses average	sum of the 15 nurses salary/	3500
Salary per mouth	15	
2. operation nurses average	3500/30	116.7
salary per day		
3.operation nurses average	116.7/8	14.6
salary per patients per hour		
4.operation nurses salary	14.6*4*2	116.7
Input in two treatments		

Secondly is doctors salary, this study has been finish the doctor's salary allocation in above according to the doctors work time, which are inpatients, outpatients and operation, this part use the allocated salary in operation time, which are 14906 RMB, same like the nurses, the doctors salary also need to calculate the average salary by numbers of doctors, and according to the operation procedure, laparoscopic surgery need 3 doctors, open surgery need 4 doctors, and the average operation hours are 4 hours, So this study will take the formulas.

Table 32 operation doctors' salary calculation

Steps	formulas	results
1.operation doctors average salary per mouth	$14906/7$	2129.4
2.operation doctors average salary per day	$2129.4/30$	71
3.operation doctors average salary per patients per hour	$71/8$	8.9
4.operation doctors salary Input in two treatments	$8.9*4*3(\text{lap})$ $8.9*4*4(\text{opec})$	106.5 142

Thirdly is anesthetists cost, the cost is also calculate based on the operation procedure, The anesthesia department has 30 anesthetists, the work days are 30 days, according to the operation procedure of the two kind of operation, two treatments both need 1 anesthetist can finish one operation, so this study calculate the average salary of the anesthetist, get the operation anesthetist salary input of two treatments. The work days are 8 hours. So this study will take the formulas.

Table 33 anesthetist salary calculation

Steps	formulas	results
1.anesthetist average Salary per mouth	sum of the 30 nurses salary/ 30	5400
2.anesthetist average salary per day	$5400/30$	180
3.anesthetist average salary per patients per hour	$180/8$	22.5
4.anesthetist salary	$22.5*4$	90

Input in two treatments

**Table 34 Summary of the total salary cost in operation**

Cost	lap	ope
Doctors	106.5	142
Nurses	116.7	116.7
Anesthetist	90	90
Total cost	313.2	348.7

Because the patients are select from 2010 and 2011, so after the adjustment of the monetary value by inflation rate, the total cost of the salary in operation are laparoscope is 9497.7, open surgery are 10598.5.

Thirdly, equipment and building cost in operation room. As the calculation of capital cost in ward, this study used the annuity formula get the depreciation. The difference is because in this hospital, there are 24 operation rooms, one operation just use one room, and one room has one set of equipment, and the equipment was bought in the same year, which is 2005. So this study assume that the every patients in one hour consume the same depreciation, so this study take one set of the equipment in one operation room, calculate the depreciation per patients by operation hours. More details appendix.

After calculate the total capital cost of one set of equipment in operation room, this study allocate the total cost into the patients by the operation hours, as we present before, the average operation hours are 4 hours for both of the treatments, and more details in steps and table 5.28

Step 1

Average capital cost per hour=total capital cost/(365\*8)

Step 2

Average capital cost for every patients=Average capital cost per hour\*4

**Table 35 operation room capital cost in open surgery**

Steps	formulas	results
1. Average capital cost per hour	$374341.8 / (365*8)$	128.2
Average capital cost for every patients	$128.2*4$	512.8(2010)
3. Average capital cost per hour	$387818/(365*8)$	132.8
Average capital cost for every patients	$132.8*4$	531.3(2011)

**Table 36 operation room capital cost in laparoscopic surgery**

Steps	formulas	results
1. Average capital cost per hour	$479840.7 / (365*8)$	164.3
Average capital cost for every patients	$164.3*4$	657.3(2010)
3. Average capital cost per hour	$497114.9 / (365*8)$	170.2
4. Average capital cost for every patients	$170.2*4$	681(2011)

According to the patients' year information, this study get the total capital cost in two treatments, which are 63703.4 RMB and 64592.6 RMB.

**Table 37 summary of the operation room cost**

Step	cost type	LAP	OPE
1	disposable materials	86635.6	18577
2	salary	9497.7	10598.5
3	building and equipment	20078	15607
4	total operation cost	116211.3	39742

**Table 38 summary of the costing calculation in two treatments**

Step	cost center	LAP	OPN
1	ward room	264087.9	196911.2
2	operation room	116211.3	39742
3	total cost	380299.2	236653.2

### 5.2.3. Estimated cost calculation

As the study analysis before, according to the decision tree and cost, this study get the expected cost for each treatment, this study calculate the expected cost by patients unit, because the medical resource consumed by the complication were included in the every patients medical records, so this study use the patients unit to calculate the estimated cost.

Estimated cost of laparoscopic surgery in renal cell carcinoma=cost of subcutaneous emphysema patients\*0.17 + cost of renal nest bleeding patients\*0.17 + cost of operating operation patients\*0.33 + cost of anesthesia accident patients\*0.33 + no complication patients\*0.8=256964.8RMB=\$39,785.2

Estimated cost of open surgery in renal cell carcinoma=cost of pleural burst patients\*0.13+no complications patients cost \* 0.87=178379.6 RMB=\$27,618

1 dollar=6.4588 RMB (2011)

### 5.3. Effectiveness

This study will use the numbers of patients not have the complications undergo the two treatments as the short-term effectiveness, according to the decision tree, the effectiveness patients of laparoscope are 24. So rate of not have complications are  $24/30=80\%$  and the effectiveness patients of open surgery are  $26/30=86\%$ .

**Table 39 summary of the complications in two groups of patients**

Name	type	LAP (n)	OPN (n)
Subcutaneous emphysema	intraoperative	1	—
Renal nest bleeding	postoperative	1	—
Operating accident	intraoperative	2	—
Anesthesia accident	intraoperative	2	—
Pleural burst	intraoperative	—	4

About the medium effectiveness, this study will use the 2-year disease free period situation, which the survival years that without recurrence, death and metastasis because of renal cell carcinoma. According to the patients history record, there is only one patient had lung metastasis after the laparoscopic surgery 6 months ago. So the 2-year disease free rate in laparoscopic is 96.7%, and the open surgery is 100%.

However, results were short term, and it is necessary to follow up the long-term result, because the cancer maybe recurrence in 5 or 10 years, so compare long-term survival and disease-free rates with those of open surgery is important. (ABBOU 1999)

And because of the limitation of database, there are just 2-year follow up, so the results is just one patients underwent laparoscopic surgery lung metastasis, so this database is not so convincing on 2-year follow up, so this study will add the system analysis and Meta-analysis to find more effectiveness in long term, and get the more convincing results.

#### 5.4 Cost-Effectiveness analysis

On the basis of this study definition of cost-effectiveness analysis, this evaluation is aim at to calculate the average cost of each complications avoided, and average cost of each 2-year disease free survival. This study get the results:

Unit cost of LAP=  $39,785.2/30=\$1326.2$

Unit cost of OPE=  $27,618/30=\$920.6$

Short-term CEA

CEA=cost/effectiveness

CEA<sub>lap</sub>= $1326.2/24=\$55.25$

CEA<sub>ope</sub>= $27,618/30=\$35.4$

Therefore, in laparoscopic surgery, the average cost of each complications avoided is \$55.25. In open surgery, the average cost of each complications avoided is \$35.4.

So according to the the less ratio, the more cost effectiveness treatment, so this study get the results which are the open surgery is the more cost effectiveness than laparoscopic surgery.

Because this study is cost-effectiveness, when we calculate this ratio, we need to ensure the cost and effectiveness follow up at the same time, so we need to change the cost according to the follow up year of effectiveness, which means calculate the medium period time (2-year) cost and match the effectiveness. This study used the present value to convert to the future value, with the formula :

$$FC_{\text{cost in 2013}} = PC_{\text{cost in 2011}} * (1+i)^2$$

**Table 40 future value calculation**

Steps	formulas	results
1. Laparoscope	$256964.8*(1+0.036)^2$	275799.3
Future cost in 2013		
2. Open surgery	$178379.6*(1+0.036)^2$	191454.1
Future cost in 2013		

275799.3 RMB=\$44,532.6

191454.1 RMB=\$30,913.6

1 dollar=6.1932 RMB (2013)

Unit cost of LAP=  $44,532.6/30=\$1484.4$

Unit cost of OPE=  $30,913.6/30=\$1030.5$

Medium-term CEA

CEA=cost/effectiveness

CEA<sub>lap</sub>= $1484.4/29=\$51.2$

CEA<sub>ope</sub>= $1030.5/30=\$34.3$

Therefore, in laparoscopic surgery, the average cost of each 2-year disease free survival is \$51.2. In open surgery, the average cost of each complications avoided is \$34.3.

According to the less ratio, the more cost effectiveness treatment, so this study get the results which are the open surgery is the more cost effectiveness than laparoscope. Although the result is be similar with the short-term result, but follow up 2 year is not enough for cancer treatment, so the medium outcome reliability is low.

## 5.5. System review

### 5.5.1 Review purpose

For one research objective maybe has many different analysis research aspect related to some specific problems, for the situation about thesis sample size are small, research scope is limited, it is difficult to get a clearly and general conclusion, Integration of the conclusions of system review, get the comprehensive results, which are more convincing than any other single results doubtless.

This study include in totally 60 samples, and just collect the one hospital data, the research scope is very limited, so it is difficult to get the convinced conclusion from



the single result, it is useful to do the system review and Meta-analysis. This study collect the information about the effectiveness, because in the clinical research, the effectiveness has many index to measure, not just about the complications and disease free period, and this study uses system review techniques to compare laparoscopic and open surgery for renal cell carcinoma with regard to operative outcomes, intraoperative complications, postoperative complications and disease free period, in addition, this study also consult other clinical outcome, and to descriptive them.

### 5.5.2 Review strategy

Analysis question:

What are clinical outcomes that renal cell carcinoma patients undergoing laparoscopic surgery and open surgery? What kind of complications are they occurred? How about the situation in 2-year disease free period.

Retrieval strategy:

This review will use one databases which is Science Direct, retrieval strategy are “renal cell carcinoma” AND “laparoscopic” AND “open surgery”. Paper types include journals from countries, books, professional web site, etc. And because of the developed of the clinical technology, so this study limited the review year, limited year is from 1990 to 2014.

Inclusion criteria

To enter the analysis, studies has to (1) comparative research from renal cell carcinoma underwent laparoscopic surgery and open surgery. (2) Report on at least one of the outcome measures mentioned below or other outcome, and (3) clearly document treatment as either an “radical nephrectomy” or “renal cell carcinoma resection”. (4) This study is retrospective research, but this study is also cooperate the clinical trial on the part of the clinical outcome, in this study is effectiveness, so this system review included the literature which are retrospective study and prospective study.

Exclusion criteria

Patients must be matching with this study database, means the patients are matching the eligible criteria of patients which included age, basic complications, staging. If the review analysis's samples not match the criteria, these study exclude in this analysis.

#### Statistical analysis

Using the Review Manager 5.2 to do the statistical analysis, draw the forest figure and funnel plots, do the heterogeneous test and test for overall effect, get the range of the number of the not have complications and 5-year disease free survival rate.

#### 5.5.3 Review results

There are totally 932 literatures be searched for this fields, after the process of inclusion and exclusion, for complications, there are totally 10 papers included in this study. More details in table 41.

**Table 41 systematic review literature information**

Author	Year	Design	LAP	OPE	Matching
YOSHINARI	2001	retro	103	46	1, 3, 4
DAVID	2001	retro	67	54	1,2,3,4
TAKASHI	2003	retro	195	68	1, 3, 4
MASATOSHI	2000	retro	6	12	1, 2, 3
Ondina	2008	persp	38	33	1, 2, 4
INDERBIR	2000	retro	34	34	1,2,3,4
C. C. ABBOU	1999	retro	29	29	1,2,3,4
Jose R	2008	retro	63	53	1,2,3,4
Matthew D	2004	retro	41	15	1,2,3,4
ANDREW P	2004	retro	65	34	1, 3, 4
B Makhoul	2004	retro	39	26	1,2,3,4
Hattori R	2009	retro	52	79	1,2,3,4

[Matching: 1, age 2, tumor diameter 3, retroerspective 4 pure laparoscopic (not by hand)]

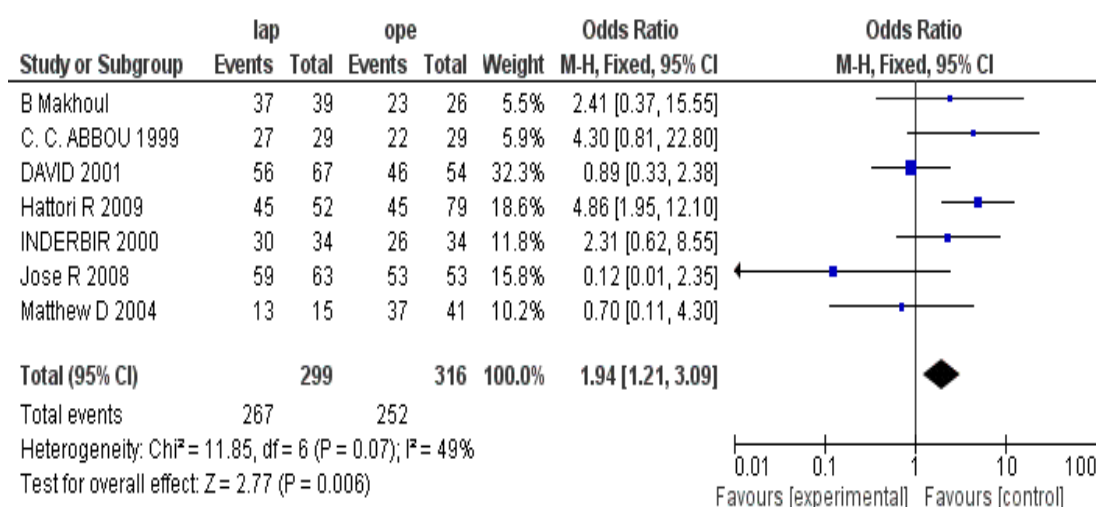
From the table, only 3 studies match the age, tumor diameter, retroerspective and pure laparoscopic, some studies not match the tumor size, because some papers analysis the renal cell carcinoma stage is T3N0M0, and some have transfer, so this situation maybe lead to the different outcome; Ondina(2008) not match the retroerspective, because the prospective analysis is quite different with retroerspective, in term of the data bias. And MASATOSHI(2010) not match the criteria because they use the laparoscopic with hand-assist, so it is also different with the study database, the rate of complications avoided in systematic review are described in table 42.

**Table 42 Study effectiveness (rate of not have complications) for system review**

Author	Year	LAP	OPE
DAVID	2001	84%	85%
INDERBIR	2000	87%	76%
C. C. ABBOU	1999	92%	76%
Jose R	2008	93%	100%
Matthew D	2004	88%	90%
B Makhoul	2004	95%	88%
Hattori R	2009	87%	57%

According to the study property, this study use the Review Manager 5.2 to get the statistical results which from the system review, and statistical analysis for effectiveness was performed by using the odds ratio (OR) as the statistical index. This ratio represents the odds of a thing occurring in the LAP compared with the OPE.(Omer 2006), The Mantel-Haenszel method is used to combine the ORs for the effectiveness of interest by using a fixed-effects model technique. And according to the Chi square value get the heterogeneous test as well.

Table 43 Statistical analysis for systematic review



$H_0$ : Two groups of papers not have the heterogeneity.

$H_1$ : Two groups of papers have the heterogeneity.

According to the  $\text{Chi}^2$  test and  $I^2$  test, we got the result,  $\text{Chi}^2=11.85$ ,

$\text{df}=9$ ( $p=0.07$ );  $I^2=49\%$ ,  $I^2$  value not bigger than 50%, so two groups of papers not have heterogeneity. And  $p=0.07$ . P value bigger than 0.05, accept  $H_0$ , reject  $H_1$ , which means the two groups of papers not have heterogeneity, therefore, the 10 papers not have the heterogeneity. And the method of combined analysis use the fixed effect model.

Consolidation effect value test

This study use the OR value to calculate consolidation effect value, because the OR value more aim at the retro perspective analysis, and use the M-H method and fixed effect model to get the effect value, from the forest plots, there are several effect lines though the inefficient line, some outcomes in accordance with inefficient line, but the consolidation effect value is in the right of the inefficient line. This statistical test use the Z value which equal to 2.77( $p=0.006$ ), which means the combined value have the significant.

## 5.6 Sensitivity analysis

This study use the effectiveness to do sensitivity analysis, because this study's effectiveness not have big difference, so according to the system review can get

more information about the effectiveness to analysis the change of the results. And on the basis of system review, because 10 papers not have the heterogeneity, and combined value have the significant, so this study put the range of the original effectiveness. And get the range of the effectiveness, LAP=[84%-95%], (84% means the rate of complication survival in paper DAVID published in 2001, 95% means the rate of complication survival in paper B Makhoul published in 2004). OPE=[57%-100%], (57% means the rate of complication survival in paper Hattori R published in 2009, 100% means the rate of complication survival in paper Jose R published in 2008). Based on my database cost, this study assumed that use the unit cost to calculate.

And because of the different complication situation, so the sensitivity analysis not used the estimated cost but total cost. And consider of the unification in currency, this study use the unified database year 2011 overall. And because every papers have different total patients, so the sensitivity used the rate of complication survival.

1 dollar=6.4588 RMB (2011)

Total cost LAP=380299.2RMB=\$58,880.8

Total cost OPE=236653.2RMB=\$36,640.4

Lowest value:

CEALAP=58,880.8/84%=70096

CEAOPE=36,640.4/57%=64281.5

Highest value:

CEALAP=58,880.8/95%=61979.77

CEAOPE=36,640.4/100%=36,640.4

According to the sensitivity analysis of the two range of the effectiveness, there are no difference between the results of the original database. The open surgery is the better way to treat the renal cell carcinoma.

## CHAPTER VI

## CONCLUSION

Table 44 Conclusion of the comparative between the two treatments

	Lap	Ope	Commands
No. of patients	30	30	
Imitated cost	\$39785.2	\$27618.1	
Unit cost	\$1326.2	\$920.6	
Imitated outcome	24	26	complication avoided
CEA ratio	\$55.3	\$35.4	
Medium Cost	\$44,532.6	\$30,913.6	
Unit cost	\$1484.4	\$1030.5	
Medium outcome	29	30	disease free survival
CEA ratio	\$51.2	\$34.3	

According to table 44, compared the two cost-effectiveness results which are short-term (complication avoided) and medium-term (disease free survival), this study got the conclusion, which is the open surgery is the more cost-effectiveness treatment for cure renal cell carcinoma, but based on the limited database, this study just analysis the short-term and medium-term, not have long-term outcome (5-year disease free survival, 10-year disease free survival). And the cost just included the direct cost, therefore, this study has limitation, maybe the results have bias.

## CHAPTER VI

### DISCUSSION

#### 7.1 Discussion

1. There were a lot of papers to do the laparoscopic surgery versus open surgery in renal cell carcinoma. The difference is some from the view of clinical outcome, some from the cost, compared with the previously study, some outcomes is similar with other papers, but some not.

The similar aspect is the cost, most of the research hold the views that the laparoscopic is more expensive in short term. But with the advantages of short hospital stays, in medium term maybe not too expensive.

This study analysis that no matter in short term or in medium term, the laparoscopic surgery is more expensive than open surgery, and observes the hospitals in database, also not have the big difference between two treatment.

The different aspect is the effectiveness, for more than 80% reference, the result is the laparoscopic surgery is more effect than open surgery, which reflects in the aspects of hospital stays, wound situation, recovery time. With the development of the economics and the popularization of health insurance, the demand of the patients in terms of high quality treatment increasing recently, according to the demand and supply theory. It is also effect the hospital choose to provide laparoscopic surgery. Therefore, there are a lot of other determinants need to consider.

This study use the number of complications avoided and 2-year disease free survival, firstly, out of the consideration of the cost-effectiveness analysis calculation. The hospital stays, wound situation, recovery time are not the applicable index, the complication avoided is related index of the effectiveness. But the results reflection also has limitation. The 2-year disease free survival is also not meet the request of the follow up time. So the 2-year disease free survival result is lack of persuasion.

2. Salary cost in ward cost center, About the salary cost calculation, this study not use use the number of patients as the index get the result but use the hospital stays

and operation hours. The assumption is the doctors and nurses have the same salary inputs, but in fact, they not provide the same services.

3. From other effectiveness, this study just take account into one aspect of effectiveness, complication and recurrence situation, but according to the papers that compare with the patients, they also think about the other effectiveness, and also have many aspects to influence the results, like because of the advantages of the recovery time and the cost small, with the economic development in recently years, patients want more comfortable treatment, so this index maybe effect the effectiveness.

#### **7.2 Limitation of the study:**

1. Because of the limitation of the database, this study just include 60 samples from 1 hospital, so the patients samples size is very small, so this study just include the direct cost, not include the indirect cost, like overhead cost, laboratory costs, not the correctly definition of hospital cost, so the results of the cost analysis maybe have much offsets.
2. This study analysis the long term effectiveness is 2-year disease free survival rate, but the disease free survival is significant in 5 and 10 years, because of the cancer research, maybe recurrence period in 5 or 10 years.



## CHAPTER VII

## SUGGESTIONS

This study may have some possible benefits: firstly, it can provide more effective, safe, economic treatment which from the cost perspective and effectiveness perspective; this study got the open surgery for hospital no doubt is the more cost effectiveness treatment to cure the renal cell carcinoma. Secondly, for hospital, it can make policy recommendations, the two treatments do some reform or improvement, provide reasons and evidence on establish disease charge criteria and achieve rational allocation of health resources, improve the utilization.

In conclusion, cost-effectiveness of a treatment takes account into not only the contributed benefit expended from the clinical effectiveness which from short term to medium term, but also think of the monetary perspective. Thus, this study is good for both patients and hospitals. So we can suggest the hospital and patients to choose the better treatment, which is open surgery.

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