Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

arthroscopic lateral patella retinaculum releasing through/outside synovial membrane for the treatment of lateral patellar compression syndrome

Protocol summary

Study aim

the goal of this study was to investigate the method and overcome of arthroscopic LPRR either OSM or TSM for the treatment of LPCS.

Design

This study was a prospective study. The authors performed arthroscopic LPRR OSM or TSM combined with joint debridement in 125 patients of LPCS from September 2014 to December 2017 . The method of simple random sampling was used to randomly divide the cases into the arthroscopic LPRR OSM group (OSM group) and TSM group (TSM group).

Settings and conduct

Data collectors were blinded to the treatment assignment when collecting any of the outcomes. The patient did not know exactly which arthroscopy procedure was used.

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: 1 The symptoms of anterior knee pain in the unilateral knee joint were not significantly relieved after 3-6 months of standardized non-surgical treatment; 2 Preoperative examination showed that the LPR was tightened; 3 Imaging examination prompted the patella tilt to the outside and Q angle was normal. Exclusion criteria were as follows: 1 Patients had the history of dislocation or subluxation of patella or excessive Q angle (>20°); 2 Severe patellofemoral arthritis was not suitable for LPRR alone; 3 Other diseases were not suitable for surgery treatment.

Intervention groups

The method of simple random sampling was used to randomly divide the cases into the arthroscopic LPRR OSM group (OSM group) and TSM group (TSM group).

Main outcome variables

Each patient was followed up by telephone or outpatient visit every month after surgery and every 3 months after 3 months after surgery. Lyshohn score (excellent: greater than 90 points, good: 80-90 points, better: 70-79 points, poor: less than 70 points), medial shift of patella, Kujala score, VAS, and surgical complications were used and evaluated for efficacy evaluation.

General information

Reason for update

Acronym

LPRR, LPCS

IRCT registration information

IRCT registration number: **IRCT20200205046378N1**
Registration date: **2020-02-11, 1398/11/22**
Registration timing: **prospective**

Last update: **2020-02-11, 1398/11/22**
Update count: **0**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Te Li

Name of organization / entity

General Hospital of Central Theater Command

Country

China

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2635-11-22, 2014/09/01

Expected recruitment end date

2639-03-21, 2018/01/01

Actual recruitment start date

2635-11-26, 2014/09/05

Actual recruitment end date

2639-03-19, 2017/12/28

Trial completion date

2641-03-21, 2020/01/01

Scientific title

arthroscopic lateral patella retinaculum releasing through/outside synovial membrane for the treatment of lateral patellar compression syndrome

Public title

arthroscopic lateral patella retinaculum releasing through/outside synovial membrane for the treatment of lateral patellar compression syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The symptoms of anterior knee pain in the unilateral knee joint were not significantly relieved after 3-6 months of standardized non-surgical treatment; Preoperative examination showed that the LPR was tightened; Imaging examination prompted the patella tilt to the outside and Q angle was normal.

Exclusion criteria:

Patients had the history of dislocation or subluxation of patella or excessive Q angle (>20°); Severe patellofemoral arthritis was not suitable for LPRR alone; Other diseases were not suitable for surgery treatment.

Age

From **16 years** old to **66 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **125**

Actual sample size reached: **125**

More than 1 sample in each individual

Actual sample size in each individual: **62**

Sixty six cases (23 males and 43 females) were included in the TSM group, aged 16-65 years with an average age of 48.3 years. Thirty-two cases were in the left knees and 34 cases in the right knees. The medical history was 6-29 months, with an average of 18.5 months. Thirty cases had traumatic history. Arthroscopic articular cartilage injury was assessed according to outerbridge classification . Grade I-II was in 51 cases, grade III in 10 cases, and grade IV in 5 cases. Twenty one cases had meniscus injury, 10 cases synovial fold hyperplasia and 8 cases free body. Fifty-nine cases were included in the OSM group, including 18 males and 41 females. The age ranged from 17 to 66 years, with an average age of 49.2 years. Twenty-eight cases were in the left knees and 31 cases in the right knees. The medical history was 7-29 months, with an average of 19.1 months. Twenty-seven cases had traumatic history. Outbridge classifications were as follows: Grade I-II was in 45 knee, III 8 knee, and IV 6 knee. Twenty cases had meniscus injury, 8 cases synovial fold hyperplasia and 8 cases free body .

Randomization (investigator's opinion)

Randomized

Randomization description

The method of simple random sampling was used to randomly divide the cases into the arthroscopic LPRR OSM group (OSM group) and TSM group (TSM group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Data collectors were blinded to the treatment assignment when collecting any of the outcomes. The patient did not know exactly which arthroscopy procedure was used.

Placebo

Not used

Assignment

Parallel

Other design features

This study was a prospective study. The authors performed arthroscopic LPRR OSM or TSM combined with joint debridement in 125 patients of LPCS from September 2014 to December 2017 .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

the institutional review boards/Ethics Committees of Wuhan Hanyang Hospital (WHH20140715)□ CR & WISC

Street address

68 huangpu road, jiangan district

City

Wuhan

Postal code

430000

Approval date

2635-10-07, 2014/07/15

Ethics committee reference number

WHH20140715

2

Ethics committee

Name of ethics committee

the institutional review boards/Ethics Committees of CR & WISCO General Hospital

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209 yejin road,qingshan district

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Approval date

2635-10-18, 2014/07/26

Ethics committee reference number

CWGH20140726

3

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Name of ethics committee

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Approval date

2635-11-14, 2014/08/23

Ethics committee reference number

WHH20140823

Health conditions studied

1

Description of health condition studied

Lateral patellar compression syndrome (LPCS) is a disease of musculoskeletal disorder with pathological manifestations of the increased lateral patellofemoral joint pressure, which is caused by the long-term lateral tilt of patella, the adaptive tightening of lateral patella retinaculum (LPR), and the long-term stress imbalance of medial and lateral articular surfaces. The main clinical manifestations are patellofemoral joint pain, abnormal patella trajectory and articular cartilage injury . LPCS has become one of the main causes of anterior knee pain . At present, the prevalence of anterior knee pain in the whole population is as high as 8.5%-17.0%, but women are obviously higher than men. Many studies have confirmed the effectiveness of lateral patella retinaculum releasing (LPRR), extension of LPR, and lateral patelloplasty . However, the gold standard of correction surgery for LPCS currently has not been determined. In 1974, Merchant et al proposed the LPRR for the treatment of LPCS. Nowadays, LPRR was the most widely used in clinical practice. The methods of the release include open incision, arthroscopic assisted incision and arthroscopic closure [8-10]. Among them, the most widely used method is arthroscopic closing release. Arthroscopic closure release includes arthroscopic LPRR either outside synovial membrane (OSM) or through synovial membrane (TSM). At present, there is no research to compare the clinical efficacy of the above two methods. So, the goal of this study was to investigate the method and efficacy of arthroscopic LPRR either OSM or TSM for the treatment of LPCS and compared the overcomes between arthroscopic LPRR OSM and TSM to find out which of the two methods is superior. Before and after surgery, Lysholm score, patella medial shift, Kujala score, VAS score and surgical complications were collected for evaluating clinical overcomes.

ICD-10 code

Lateral pa

ICD-10 code description

Lateral patellar compression syndrome

Primary outcomes

1

Description

Timepoint

Method of measurement

2

Description

Sixty six cases (23 males and 43 females) were included in the TSM group, aged 16-65 years with an average age of 48.3 years. Thirty-two cases were in the left knees and 34 cases in the right knees. The medical history was 6-29 months, with an average of 18.5 months. Thirty cases had traumatic history. Arthroscopic articular cartilage injury was assessed according to outerbridge classification [11]. Grade I-II was in 51 cases, grade III in 10 cases, and grade IV in 5 cases. Twenty one cases had meniscus injury, 10 cases synovial fold hyperplasia and 8 cases free body (Table 1).Fifty-nine cases were included in the OSM group, including 18 males and 41 females. The age ranged from 17 to 66 years, with an average age of 49.2 years. Twenty-eight cases were in the left knees and 31 cases in the right knees. The medical history was 7-29 months, with an average of 19.1 months. Twenty-seven cases had traumatic history. Outbridge classifications were as follows: Grade I-II was in 45 knee, III 8 knee, and IV 6 knee. Twenty cases had meniscus injury, 8 cases synovial fold hyperplasia and 8 cases free body (Table 1).

Timepoint

before surgery

Method of measurement

gender age, the left or right side of knee ,The medical history, cases of traumatic history. Arthroscopic articular cartilage injury assessed according to outerbridge classification [11]. cases of meniscus injury, synovial fold hyperplasia and free body (Table 1).

3

Description

In the TSM group, all patients were followed up for 1.5-5 years, with an average of 3.4 years. Sixty-six patients had pain when going up and down stairs and squatting down before surgery. Anterior knee pain was significantly reduced or disappeared in all patients 1 month after surgery. In 1 year after surgery, 55 (83.3%) of the patients were able to go up and down the stairs normally and 11 cases had pain when going up and down stairs and the function was slightly limited. 51 cases of anterior knee pain were basically disappeared at 1 year after surgery, and 15 cases had occasional pain. Lysholm

scores were as follows: 44 cases were excellent, 12 cases good, 7 cases better, and 3 cases poor. The effect of LPRR alone in 3 cases of severely damaged articular cartilage was poor, but the pain was relieved to some degree. The excellent rate was 84.8%. Five patients had haemarthrosis in the postoperative period, and the symptomatic treatment such as puncture and drainage was improved. Three cases of joint adhesion were relieved after manual loosening. Infection, deep vein thrombosis and other complications were not observed. The Lysholm scores were 77.4±2.7 before surgery and 94.3±3.4 at the last follow-up, and the difference was statistically significant (P<0.05). The medial pushing distances of patella were 0.76±0.21 cm before operation and 1.25±0.27 cm at the last follow-up (P<0.001). The Kujala scores were 60.4±8.6 before surgery and 84.5±9.2 points at the last follow-up (P<0.00l). The VAS were 7.5 ± 2.5 before operation and 2.3 ± 1.3 at the final follow-up (P < 0.001) (Table 2).All cases in the OSM group were followed up for 1.5-5 years with an average of 3.5 years (Figure 2). Fifty-nine patients had pain when going up and down stairs and squatting down before surgery. Anterior knee pain was significantly reduced or disappeared in all patients 1 month after surgery. In the first year after surgery, 50 (84.7%) cases were able to go up and down stairs normally, and 9 cases had pain when going up and down stairs and its function was slightly limited. Fifty cases of anterior knee pain were basically disappeared at 1 year after surgery, and 9 cases had occasional pain. Lysholm scores had excellent in 43 cases, good in 8 cases, better in 6 cases, and poor in 2 cases. The effect of LPRR alone in 2 cases of severely damaged articular cartilage was poor, but the pain was lower than before. The excellent rate was 86.4%. Postoperative complications such as infection, joint adhesion, joint hematoma, and deep vein thrombosis were not reported. The Lysholm scores were 76.7±2.8 before surgery and 95.4±3.5 at the last follow-up, and its difference was statistically significant (P<0.05). The medial pushing distances of patella were 0.78±0.23 cm before operation and 1.28±0.19 cm at the last follow-up (P<0.001). The Kujala scores were 60.7±8.7 at preoperation and 84.2±8.9 at the final follow-up (P<0.001). The VAS scores were 7.4±2.4 before surgery and 2.1±1.2 points at the final follow-up (P < 0.001) (Table 2).There were no significant differences of Lysholm rating and scoring, medial pushing distance of patella, Kujala score, and VAS before surgery and at the last follow-up between the OSM group and TSM group (P>0.05, respectively). However, the number of occurrences of joint hematoma and adhesion was significantly higher in the TSM group than the OSM group (P=0.024, Table 2).

Timepoint

before surgery and at the last follow-up

Method of measurement

Each patient was followed up by telephone or outpatient visit every month after surgery and every 3 months after 3 months after surgery. Lyshohn score (excellent: greater than 90 points, good: 80-90 points, better: 70-79 points, poor: less than 70 points), medial shift of patella, Kujala score, VAS, and surgical complications were used and evaluated for efficacy evaluation[6, 12-15].

Secondary outcomes

1

Description

Five patients had haemarthrosis in the postoperative period, and the symptomatic treatment such as puncture and drainage was improved. Three cases of joint adhesion were relieved after manual loosening. Infection, deep vein thrombosis and other complications were not observed.

Timepoint

after surgery

Method of measurement

Follow up the intraoperative and postoperative complications closely.

Intervention groups

1

Description

Control group: rthroscopic LPRR either outside synovial membrane (OSM)

Category

Treatment - Surgery

2

Description

Category

empty

3

Description

Category

empty

4

Description

Intervention group: arthroscopic LPRR outside synovial membrane (OSM)

Category

Treatment - Surgery

5

Description

Category

empty

6

Description

Control group: arthroscopic LPRR through synovial membrane (TSM)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Grant name
National Natural Science Foundation of China
Grant code / Reference number
31671235
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Natural Science Foundation of China
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Efficacy and experience of arthroscopic lateral patella retinaculum releasing through/outside synovial membrane for the treatment of lateral patellar compression syndrome
When the data will become available and for how long
starting in September 2014 and starting 24 months for publication
To whom data/document is available
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
Under which criteria data/document could be used
All statistical analyses were performed using SPSS 13.0 statistical software (SPSS, Chicago, IL, USA). Measurement data were expressed as mean ± standard deviation, and t test and paired z test were used for statistical analysis. The frequency of complications was analyzed using Chi Square with Yates Correction and the Fisher's Exact test. G*Power 3.1.9.2 software (http://www.gpower.hhu.de/) was used for statistical power analysis. $P \leq 0.05$ was considered statistically significant. The statistical requirements are met and the data are ready for use.
From where data/document is obtainable
* Address correspondence and reprint requests to: Te Li, Department of Orthopedic Surgery, General Hospital of Central Theater Command, 68 huangpu road, jiangan district, Wuhan, China. Tel: 86-027-50660142; Fax: 86-027-50660142, E-mail: xypambition@foxmail.com
What processes are involved for a request to access data/document
Tell the purpose of obtaining this information. If it is only for scientific research needs, we can give them this data.
Comments