Conservative Versus Tailored Surgical Treatment in Patients With First Time Lateral Patella Dislocation: a Randomized-controlled Trial

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Abstract

Background

Patellar instability has a high incidence and occurs particularly in young and female patients. If the patella dislocates for the first time, treatment is usually conservative. However, this cautious approach carries the risk of recurrence and of secondary pathologies such as osteochondral fractures. An initial surgical treatment could possibly avoid these consequences of recurrent patella dislocation.

Methods

A prospective, randomized-controlled trial design is applied. Patients with unilateral first-time patella dislocation will be considered for participation. Study participants will be randomized to either conservative treatment or to a tailored patella stabilizing treatment. In the conservative group patients will use a knee brace and will be prescribed outpatient physical therapy. The surgical treatment will be performed in a tailored manner, addressing the pathologic anatomy that predisposes to patella dislocation.

The Banff Patellofemoral Instability-Instrument 2.0, recurrence rate, apprehension test, joint degeneration and the Patella Instability Severity Score will serve as outcome parameters. The main analysis will focus on the difference in change of the scores between the two groups within a two-year follow-up.

Statistical analysis will use linear mixed models. Power analysis was done for the comparison of the two study arms at 2-year follow-up with regard to the BPII score. A sample size of N=64 per study arm (128 overall) provides 80% power (alpha=0.05, two-tailed) to detect a difference of 0.5 standard deviations in a t-test for independent samples.

Discussion

Although several studies have already dealt with this issue, there is still no consensus on the ideal treatment concept for primary patellar dislocation. Moreover, most of these studies show a unified surgical group, which means that all patients were treated with the same surgical procedure. This is regarded as a major limitation as surgical treatment of patella dislocation should depend on the patient's anatomic pathologies leading to patellar instability. To our knowledge, this is the first study investigating whether patients with primary patella dislocation are better treated conservatively or operatively with tailored surgery to stabilize the patella.

Trial registration

The study will be prospectively registered in the publicly accessible database *www.clinicaltrials.gov.*

Background

Instability of the patella has a high incidence, particularly in the young and female population. Because the vast majority of unstable patella are unstable towards *lateral* and because instability is objective when the patella is fully *dislocated* the term “lateral patella dislocation (LPD)” is used throughout this study protocol.

First time or *primary* LPD is often treated conservatively. Although this is a cautious approach it bears risks of recurrence and secondary pathologies like osteochondral fractures. Therefore, it might well be speculated whether primary LPD should better be treated surgically. With this regard, several researchers already dealt with that issue (Only studies with Level of Evidence 1 or 2 were taken into account) (Table 1).

Apostolovic et al. performed a prospective, non-randomized controlled trial comparing 23 conservatively treated patients with 14 surgically treated patients in the context of primary LPD (1). The criterion to treat surgically was the presence of (osteo)chondral lesions. Besides loose body removal/refixation the patients received medial capsular repair and lateral retinacular release. The authors reported no differences between groups regarding recurrence rate or Cincinnati Knee Scores. Bitar et al. conducted a randomized-controlled trial on primary LPD (2). 39 patients were randomized to either non-operative treatment (immobilisation and physical therapy) or reconstruction of the medial patellofemoral ligament (MPFL). At 2 years follow-up the MPFL group was superior in terms of Kujala scores and recurrence rates. Camanho et al. also investigated patients with primary LPD (3). 33 patients were randomly assigned to either conservative treatment (immobilization and physiotherapy) or MPFL repair. The authors reported superior results in the surgical group. Christiansen et al. randomized 80 patients with primary LPD to either conservative therapy or MPFL repair (4). Patients were followed 2 years and demonstrated no significant differences between groups with regard to recurrence rate, KOOS score and Kujala Score. Two studies very similar to each other were published by Sillanpää et al. in 2008 and 2009 (5, 6). The older study investigated primary LPD in 61 military recruits. Conservative patients were compared to patients with MPFL repair, but were not randomized. The authors determined recurrence rates, Kujala Scores and “return to sports – rate” seven years postoperatively. While the surgical group was superior in terms of “return-to-sports” there were no significant differences in the other outcome parameters (5). The design of the other study from Sillanpää et al. was randomized-controlled. Again, the outcome parameters recurrence rates, Kujala Scores and “return to sports – rate” were determined in patients with conservative treatment and in those with surgery (medial repair or Roux-Goldthwait). Sillanpää et al stated that the patients treated surgically were superior in terms of recurrence rate but not in the other parameters (6). A randomized-controlled trial was also published by Petri et al. (7). In a multi-centric approach, patients with primary LPD were randomized to either conservative treatment or MPFL repair. Unfortunately, the trial was discontinued after 20 patients and did therefore not reach sufficient power.

In synopsis of the above-mentioned studies, there is no consensus on whether patients with first time LPD should be treated conservatively or surgically (Table 1). Besides, in most of those studies the surgically group was uniform, meaning that all patients were treated with the same surgical procedure. This is regarded as a major limitation as surgical treatment of LPD should be done in a tailored manner,

depending on the patient's anatomic pathologies which lead to LPD. Moreover, it is striking that most above-mentioned studies applied MPFL repair. Only Bitar et al. performed MPFL-reconstruction.

Table 1. Current evidence on conservative vs. surgical treatment on patients with first-time lateral patella dislocation. Only studies with Level of Evidence 1 or 2 were taken into account.

Author	Year	Random	Evidence Level	Surgical Procedure	Outcome Parameters	n	mean FU time	Findings	Misc
Camanho	2009	y	2	MPFL repair	recurrence, Kujala	33	3y	Surgery: better in all parameters	only 'statistical trends'
Bitar	2012	y	1	MPFL recon	recurrence, Kujala	41	44mo	Surgery: signif. better in all parameters	
Apostolovic	2011	n	2	loose body removal/refixation, medial capsular repair, lateral retinacular release.	Cincinatti Score, Recurrence	37	6y	no diff	
Christiansen	2008	y	1	MPFL repair	recurrence, Kujala, KOOS	80	2y	no diff	
Petri	2013	y	1	MPFL repair	recurrence, Kujala, satisfaction	20	2y	no diff	Power 25%
Sillanpää	2008	n	2	MPFL repair	recurrence, return to sports, Kujala	61	7y	Surg better return to sports, rest: no diff	
Sillanpää	2009	y	1	medial repair or Roux-Goldthwait	recurrence, return to sports, Kujala	40	7y	Surgery better: recurrence, other parameters: no diff	

Aims of the study

Due to the above-mentioned lack of consistent evidence it is the aim of the study to investigate whether patients with primary LPD are better treated conservatively or operatively (tailored surgery to stabilize the patella).

Hypotheses

It is hypothesized that patients with primary LPD when treated either conservatively or surgically (tailored stabilizing procedure) will show significant differences *after two years* in terms of the Banff Patellofemoral Instability-Instrument (BPII) 2.0 (Hypothesis 1). We also assume that the above-mentioned groups also differ significantly in terms of recurrent patella dislocations (Hypothesis 2).

Methods

Study design and participants

A prospective, randomized-controlled trial design is applied. Before commencement of the study approval of the ethical committee (EC) was obtained (No. 1062/2020). Patients with objective, unilateral first time LPD will be considered for participation. After written informed consent the patients are included in the study. Excluded are a) patients with osteochondral lesions requiring removal/refixation, b) patients with recurrent LPD, c) pregnant patients, d) patients > 45 years of age and patients with physical maturity Kramer stage 1 to stage 3a (8, 9).

Clinical workup includes thorough history, physical evaluation, plain radiographs and magnetic resonance imaging in all patients. When the physical examination reveals suspicion of maltorsion syndrome, MRI (or CT scan) is done of the hip, knee and ankle to quantify femoral and tibial torsion. When the physical examination reveals suspicion of a relevant genu valgum or varum a whole leg radiograph is performed.

Patients successfully included in the study are then randomized to either conservative treatment or to a tailored patella stabilizing treatment. Block-Randomization is performed in advance with SPSS to guarantee equal group sizes. Syntax and seed for the random number generator are kept for reproducibility of the processes.

Interventions

In both groups in case of relevant hemarthrosis a joint aspiration if performed.

Conservative group

In the conservative group patients use a knee brace that a) protects the patella from lateralisation and b) limits knee range of motion. The range of motion limitation is set to 0-20-40 degrees for week 1 and 2, 0-10-60 degrees for week 3–4 and to 0-0-90 degrees for week 5–8. Partial weight-bearing is applied for week 1 and 2. Patients are prescribed outpatient physical therapy following a protocol suggested earlier by the “Patellofemoral Committee of the German-Speaking Arthroscopy Society (AGA)”:

Phase 1 (week 1 + 2):

Range of motion 0-20-40°, partial weight-bearing
Phase 2 (week 3 + 4):

Range of motion 0-10-60°, progression to full weight bearing, emphasis on quadriceps recruitment (especially vastus medialis).
Phase 3 (week 5–8):

Range of motion 0-0-90°, re-acquiring activities of daily living, core stability, sensorimotor training (leg axes stabilisation), strength training
Phase 4:

Return to sports, dependent on the type and previous level of sports activity, gradual increase of training volume and intensity

Surgical group

The surgical treatment is performed in a tailored manner, addressing the respecting pathologic anatomy that predisposes to LPD. MPFL reconstruction is performed in every patient. Other surgical techniques listed below will be applied in individual combinations, dependent on patient's needs.

MPFL reconstruction

Reconstruction of the medial patellofemoral ligament (MPFL) is a proven technique for LPD and today's established standard treatment. However, some authors have reported a considerable complication rate (10). Many failures were reported due to inappropriate indications. The latter means performing isolated MPFL in patients with coexisting severe osseous pathologies like high-grade trochlear dysplasia or a pathologic tuberositas-tibiae-trochlea-groove distance (TT-TG distance) (11, 12). Isolated MPFL reconstruction is regarded as inappropriate in patients with: 1) TT-TG distance > 20mm, 2) femoral anteversion ≥ 40° (n. Waidelich/Strecker), 3) high grade trochlea dysplasia, 4) severe patella alta, 5) tibiofemoral valgus > 5°. With accurate indications and surgical technique isolated MPFL reconstruction provides good outcome in patients with LPD (13, 14). MPFL reconstruction is applied in all patients of the surgical group. MPFL reconstruction was reported with a high variety of surgical techniques (graft type, single vs. double bundle, type of fixation etc). The specific surgical technique is carried out on surgeon's preference at the respective center of the multicentric study.

Trochleoplasty

When the trochlea is flat or convex (dysplasia Dejour type B, C or D) a "deepening trochleoplasty" should be considered. The aim of the trochleoplasty is to A) reduce the too prominent anterior bone stock and B) create better conformity with the patella (concave groove) and a lateral trochlea facet as restraint against the lateralizing quadriceps pull. Many authors have reported that trochleoplasty leads to good clinical outcome in patients' LPD due to a dysplastic femoral trochlea (15–22).

Deepening trochleoplasty will be carried out in those patients of the surgical group who suffer from high-grade trochlea dysplasia.

Tibial Tuberosity Transfer

The most popular type of osteotomy in the setting of LPD is certainly the osteotomy and transfer of the tibial tuberosity (TTT). Many articles reported good clinical success for medialising TTT in patients with LPD and high TT-TG values (23–27). Similarly, good results were found for distalizing TTT in patients with LPD and patella alta (28, 29). TTT can be tailored to the pathology of the patient by performing combined medialization and distalization.

Medializing TTT will be applied to those patients with TT-TG distances ≥ 18mm in the MRI. Distalizing TTT will be applied in patients with Caton-Deschamps Index > 1,2 (30).

Derotational Osteotomy

Derotational osteotomies of the femur (externally rotating) provide good results in patients with LPD and associated torsional deformities (31–33). However, the literature is incongruent on whether rotational osteotomies of the femur should be performed at the proximal or distal aspect (34–37). In the authors hand's derotational osteotomy is carried out at the distal femur.

In those patients with femoral antetorsion ≥ 40° (n. Waidelich/Strecker) a distal femoral derotational osteotomy is carried out. The precise surgical technique for that procedure is given over to the surgeon of the respective center.

Varus osteotomy

In patients with valgus clinical appearance a weight-bearing whole leg radiograph should be performed to precisely assess the degree of the deformity in the frontal plane (mechanical femorotibial angle).

In cases with a mechanical femorotibial angle > 5 degrees a varus osteotomy is performed at the location of the deformity.

Applying a "pragmatic" surgical approach, *not each* single pathology in the patient's anatomy is addressed. Instead, a maximum of 3 surgical techniques (including the MPFL reconstruction) are performed in one patient.

Outcome parameters

Patient-reported outcome

The Banff Patellofemoral Instability-Instrument (BPII) 2.0 was reported as valid, reliable and responsive patient-reported outcome tool in the field of patellofemoral instability (38, 39) and is used in the validated German version (40). The BPII 2.0 serves as one of two major outcome instruments (Hypothesis 1).

For exploratory reasons the following further patient-reported parameters will be assessed in both groups: As second disease specific score patients accomplish the Kujala Score (41) which was quoted as reliable, valid and responsive tool for patellofemoral disorders (42, 43). In addition, the Short-Form 12 is used (version 2, German; SF-12v2) (44) to determine the general health outcome and the Marx activity scale to rate a patient's physical activity (45). The Marx score asks for the highest activity in the last year. For postoperative monitoring of a patient's activity a "modified version of the Marx score" will be used that refers to the last 2 months.

All above-mentioned outcome scores are self-administered and will be assessed preoperatively, 6, 12 months postoperatively and then yearly. Those scores are collected during routine visits at the hospital.

Other outcome parameters

Recurrence rate is assessed as second major outcome parameter (Hypothesis 2). To keep proper medical records on recurrent patella dislocations the patients are interviewed by telephone on a monthly basis (in

addition to the above-mentioned visits at the hospital).

The apprehension test is assessed by an experienced observer during the above-mentioned routine clinical visits (Grade 0: no evasion, Grade 1: slight evasion/avoidance, Grade 2: gross evasion/avoidance, Grade 3: patient too anxious to allow the test).

Joint degeneration is assessed preoperatively and every three years postoperatively by means of MRI (PD-FSE with Fat-sat high-resolution in all three planes / T1-TSE, sagittal / T2 weighted, isotrope 3D sequence sagittal reformatted in all three planes). The semi-quantitative MRI Osteoarthritis Knee Score (MOAKS scoring) is applied to rate the degenerative changes determined by MRI (46). The MOAKS scoring is determined by always the same experienced musculoskeletal radiologist.

In addition, the Patella Instability Severity Score is assessed for exploratory reasons (47).

Statistics

Patient characteristics will be presented as means, standard deviations, and percentages. The main analysis will use linear mixed models that allow data modelling with a varying number of assessments per patient and time-varying covariates. Such a model will be used to compare the differences in changes over time between the two study groups. The following terms will be included in the model: a random baseline, a first-order autocorrelation covariance matrix, a fixed-effect patient group, a fixed effect time point, and the group-by-time interaction (reflecting the intervention effect). The BPII 2.0 will serve as the primary outcome parameters. The main analysis is “intention to treat” and will focus on the group difference in the change of BPII 2.0 scores between pre-op and 2-year follow-up. The above-mentioned secondary outcome parameters will be analysed with the same model.

Power / sample size analysis was done for the comparison of the two study arms at 2-year follow-up with regard to the BPII score. As there are no specific minimal important difference (MID) for the BPII available from the literature, we defined the MID to be 0.5 standard deviations following general recommendations from the literature (48). A sample size of N = 64 per study arm (128 overall) provides 80% power (alpha = 0.05, two-tailed) to detect a difference of 0.5 standard deviations in a t-test for independent samples. To account for 20% attrition during the study period we plan to recruit 80 patients per study group (160 overall) at baseline.

List Of Abbreviations

3D	three-dimensional
AGA	Gesellschaft für Arthroskopie und Gelenkchirurgie
BPII	Banff Patellofemoral Instability-Instrument
CT	computer tomography
EC	ethics committee
ICF	informed consent form
LPD	lateral patella dislocation
MID	minimal important difference
mm	millimeters
MOAK	MRI Osteoarthritis Knee Score
MPFL	medial patellofemoral ligament
MRI	magnetic resonance imaging
N	sample size
PD-FSE	proton density-fast spin echo
SF-12v2	Short-Form 12 version 2
TSE	turbo spin echo
TTT	transfer of the tibial tuberosity
TT-TG distance	tuberositas-tibiae-trochlea-groove distance

Declarations

Ethics approval and consent to participate

Prior to study start, the study protocol and/or other appropriate documents were submitted to the ethics committee for approval. The study protocol was approved by the local ethics committee of the Medical University of Innsbruck (No. 1062/2020).

Every patient has to give his/her written consent before the participation in the clinical trial.

The content of the consent information is documented on the patient information/ informed consent form (ICF). The patient will be notified, if essential findings appear during the study.

Consent for publication

For any individual person's data in any form (including any individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors were involved in the drafting of the study protocol.

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