Quality of life during the wait for ruptured anterior cruciate ligament reconstruction: a randomized controlled trial

Gabriel Larose, MD, MSc
Jeff Leiter, PhD
Jason Peeler, PhD
Sheila McRae, PhD
Gregory Stranges, MD
Meaghan Rollins, MD
Mike Davidson, MD
Peter MacDonald, MD

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Correspondence to:
G. Larose
Pan Am Clinic
University of Manitoba
75 Poseidon Bay
Winnipeg MB R3M 3E4
laroseg@myumanitoba.ca

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Background: There is a lack of prospective evidence to guide surgeons when making recommendations about the appropriate timing of surgical intervention for ruptured anterior cruciate ligament (ACL), activity modifications to reduce the risk of secondary injury before surgery, and the short- and long-term risks associated with delayed ACL reconstruction. This study aimed to determine whether longer wait times are associated with a prolonged decrease in quality of life and an increased incidence of secondary joint injury after ACL rupture.

Methods: We recruited 53 patients who presented between 2013 and 2017 at a single sports medicine minor injury clinic with a suspected acute ACL rupture, based on clinical examination; ACL rupture was confirmed on magnetic resonance imaging. Patients were randomly allocated to undergo early reconstruction (< 12 wk after injury) or reconstruction after a regular wait time (≥ 12 wk). We compared scores on the ACL quality of life measure (ACL-QOL) and the incidence of secondary knee injury at baseline and at surgery between the 2 groups. Participants also completed the Tegner scale (level of activity) at the time of consent and within 7 days before surgery.

Results: Twenty-eight patients were randomly assigned to the early surgery group and 25 patients to the regular wait time group. There was no difference in mean age between the 2 groups. There were no between-group differences in mean ACL-QOL score at the time of injury (28.5 [standard deviation (SD) 12.5] v. 28.5 [SD 12.6]) or at surgery (34.9 [SD 17.5] v. 38.0 [SD 17.5]). The mean wait time was significantly longer in the regular wait time group than in the early surgery group (29.6 wk [SD 13.2 wk] v. 10.6 wk [SD 5.1 wk], $p = 0.001$). In both groups, Tegner scale scores were significantly lower after than before ACL rupture ($p < 0.001$) and remained low while patients waited for surgery. There were no between-group differences in the incidence of chondral or meniscal injury at surgery, although the study was not adequately powered to draw any statistical conclusions.

Conclusion: Wait time for ACL reconstruction may affect patients' quality of life, as it remained diminished for a longer period when surgery was delayed. A low activity level during the waiting period was observed in both groups; this low activity level may be one reason why no between-group differences in the incidence of secondary injury were observed. The findings suggest that patients with a limited activity level during the waiting period have a low risk of secondary injuries.

Contexte : On manque de données prospectives pour guider les recommandations aux chirurgiens concernant le bon moment d'opérer une rupture du ligament croisé antérieur (LCA), les changements aux activités pour réduire le risque de blessure secondaire avant l'intervention, et les risques à court et à long terme d'une reconstruction tardive du LCA. Cette étude visait à déterminer si les temps d'attente plus longs sont associés à une baisse prolongée de la qualité de vie et à une incidence accrue de blessure articulaire secondaire après une rupture du LCA.

Méthodes : Nous avons recruté 53 patients d'une même clinique de médecine du sport pour blessures mineures s'y étant présentés de 2013 à 2017 avec une rupture aiguë du LCA soupçonnée, selon l'évaluation clinique; la rupture a été confirmée par imagerie par résonance magnétique. Les patients ont été répartis au hasard entre 2 groupes : reconstruction rapide (< 12 sem. après l'incident) ou dans les délais habituels (≥ 12 sem.). Nous avons ensuite comparé les scores de qualité de vie liés au LCA (ACL-QOL) et l'incidence d'une blessure secondaire au genou au départ et au moment de l'opération. Les participants ont également rempli une échelle de Tegner (niveau d'activité) une première fois quand ils ont donné leur consentement, puis dans les 7 jours précédant l'intervention.

Résultats : Vingt-huit patients ont été placés au hasard dans le groupe d'intervention rapide, et 25 patients, dans le groupe des délais habituels. Il n'y avait pas de différence entre les groupes quant à l'âge moyen ni quant au score ACL-QOL moyen lors de l'incident (28,5 [écart-type (É.-T.) 12,5] c. 28,5 [É.-T. 12,6]) ou de l'intervention (34,9 [É.-T. 17,5] c. 38,0 [É.-T. 17,5]). Le temps d'attente moyen était significativement plus long chez le groupe des délais habituels que chez le groupe d'intervention rapide (29,6 sem. [É.-T. 13,2 sem.] c. 10,6 sem. [É.-T. 5,1 sem.]; p = 0,001). Dans les deux cas, les scores de l'échelle de Tegner étaient significativement inférieurs à ceux précédant la rupture (p < 0,001) et demeuraient faibles durant la période précédant l'opération. Il n'y avait pas de différence entre les groupes quant à l'incidence de lésions chondrales ou méniscales au moment de l'intervention; l'étude n'avait toutefois pas la puissance nécessaire pour tirer des conclusions statistiques.

Conclusion : Le temps d'attente pour une reconstruction du LCA peut affecter la qualité de vie des patients, qui est demeurée réduite sur une période prolongée dans le cas des interventions tardives. Le faible niveau d'activité durant l'attente, observé chez les 2 groupes, pourrait expliquer en partie l'absence de différences entre eux quant à l'incidence de blessures secondaires. Les résultats suggèrent que les patients qui limitent leur niveau d'activité en attendant d'être opérés ont un faible risque de blessures secondaires.

Anterior cruciate ligament (ACL) reconstruction is a common orthopedic operation, with more than 400 000 procedures completed each year in the United States[1] and close to 17 000 in Canada.[2] An ACL injury may be associated with damage to the menisci, other knee ligaments or articular cartilage.[3–5] These associated joint injuries can occur at the initial trauma or secondary to altered knee kinematics associated with the ACL-deficient knee.[3,6] This altered kinematics is believed to be highly susceptible to secondary joint injury, and long-term instability and degenerative changes.[7]

Retrospective research examining the relation between time from injury to ACL reconstruction and the incidence of secondary knee injury while waiting for surgery suggests that delay of ACL reconstruction of more than 12 weeks significantly increases the incidence and severity of injury to the meniscus and cartilage.[8,9] More recent observational studies have given conflicting results.[10–12] Gupta and colleagues[10] found that surgical delay was significantly associated with the occurrence of medial meniscal tears after 6 months. Hur and colleagues[11] failed to show a difference in the incidence of injury between their early reconstruction group (≤ 3 wk) and their delayed reconstruction group (> 3 mo), but significantly more patients in the former group had repairable meniscal tears. Ahlén and Lidén[12] did not find any differences in incidence or severity of knee joint injury between their early reconstruction group (≤ 5 mo) and delayed reconstruction group (> 24 mo). The methodologies used in each of these studies failed to quantify the presence, severity or location of secondary joint injury at the initial ACL injury. As such, the investigators were unable to determine whether the secondary joint injuries observed at the ACL reconstruction were associated with the initial joint trauma or occurred secondary to altered joint kinematics associated with ACL deficiency.[8–13]

Previous studies have shown that quality of life improves quickly after ACL reconstruction.[14,15] However, Barenius and colleagues[16] reported a lower quality of life 8 years after ACL reconstruction in patients with delayed surgery compared to those who had early surgery (< 5 mo). The evolution of quality of life during the period from injury to surgery has not been well studied. There is a lack of prospective evidence to guide surgeons when making recommendations about the appropriate timing of surgical intervention, activity modifications to reduce the risk of secondary injury before surgery, and the short- and long-term risks associated with delayed ACL reconstruction. Therefore, there is a need for well-designed prospective studies to examine the relation between the time from injury to surgery, quality of life and the incidence of secondary joint injury.

The primary purpose of this randomized controlled trial was to assess whether a relation exists between the time from ACL rupture to surgery and patient quality of life. The secondary aim was to report the incidence of secondary joint injuries after ACL rupture. Our hypothesis was that longer delay to surgery is associated with a prolonged decrease in quality of life. A secondary hypothesis was that, compared to patients with early surgery, patients with delayed surgery would have a higher incidence of secondary joint injuries.

Methods

Study design

We conducted a parallel randomized controlled trial, with patients allocated at a ratio of 1:1 to either an early surgery group (< 12 wk from the initial trauma) or a regular wait time group (≥ 12 wk from the initial trauma). Using a threshold of 12 weeks for early versus delayed reconstruction is controversial. A recent meta-analysis failed to show any difference in subjective or objective outcomes with 3 weeks as the threshold.[17] However, other retrospective studies showed a higher incidence of secondary knee injuries with a delay to reconstruction of more than 12 weeks.[9,13,18]

We obtained approval from the appropriate ethics and institutional review boards before initiating any study activities.

Participants

Patients aged 18–45 years who presented between 2013 and 2017 at a single sports medicine minor injury clinic with a suspected acute ACL rupture, based on clinical examination, were considered for this study. Exclusion criteria included previous history of knee joint disease, trauma and an inability to communicate in English. Patients requiring urgent surgery consultation (e.g., those with a displaced meniscal tear or multiligament injuries, with severe instability) were also excluded from the study, as it was not medically appropriate for them to be randomly allocated to a surgery group. All patients had magnetic resonance imaging (MRI) within 14 days of their knee injury to confirm ACL rupture.

Once ACL rupture was confirmed, a research assistant obtained participants' informed consent and then randomly assigned them to the early surgery or the regular wait time group. We generated randomization numbers using a computer-based program, and allocations were held in a series of opaque envelopes. The research assistant opened the randomization envelope only after consent had been obtained.

Outcome measures

The primary outcome was the patient's quality of life during the waiting time for the surgery, measured with the ACL quality of life measure (ACL-QOL).[19] The ACL-QOL measure is a validated, reliable, disease-specific questionnaire containing 31 questions addressing symptoms, function and general impacts. All patients completed the ACL-QOL at the time of consent and within 7 days before surgery.

Secondary outcomes included the incidence of secondary knee injuries (meniscal tear, chondral injury) at the time of injury and at surgery, although this study was not adequately powered to determine a statistically significant difference. We determined the presence of secondary joint injuries at the injury based on MRI performed within 14 days of the initial trauma. A standardized protocol was used for image acquisition and interpretation. All MRI examinations were performed on a 1.5 T magnet[20] with previously described methodologies.[21] All MRI scans were reviewed by a fellowship-trained radiologist based on a standardized list of elements. The radiologist determined whether there was a complete, acute tear of the ACL, and recorded the incidence and location of secondary injuries. The radiologist was blinded to the findings of the clinical examination and group allocation.

The presence of secondary joint injuries was also evaluated intraoperatively. All surgical procedures were completed arthroscopically with a semitendinosus-gracilis graft by 1 of 2 fellowship-trained orthopedic surgeons (G.S., P.M.). The surgeon conducted a thorough and standardized diagnostic scope of all structures and documented all injuries identified. Because of the low prevalence of secondary injuries in this study, injuries to the femur or the tibia in the same compartment were counted as 1 injury. This was not a validated measure, but it allowed reporting of the prevalence of injury in the 2 groups.

We included the Tegner scale[22] score as a secondary measure. The measure is an 11-point scale ranging from 0 (sick leave or disability) to 10 (competitive sports: soccer, football, rugby [national elite]) indicating level of activity. We also included the International Knee Documentation Committee (IKDC)[23] Subjective Knee Form to standardize the clinical assessment, including range of motion, anterior drawer and pivot shift, along with other components. Participants completed the Tegner scale and the IKDC Subjective Knee Form at the time of consent and within 7 days before surgery, indicating their preinjury and current level of activity.

We calculated the sample size based on an estimated minimally clinically important difference in ACL-QOL score of 10% and a standard deviation (SD) of 17. These values were based on pilot data collected from all ACL reconstruction procedures performed at our institution in 2007 (about 150 patients). These values approximate the minimal clinically important difference found in a more recent study by Lafave and colleagues.[24] Based on these data, together with $\alpha = 0.05$ (2-tailed) and $\beta = 0.20$, the estimated sample size for the study was 50 patients.

Statistical analysis

We generated descriptive statistics to describe demographic characteristics for the 2 study groups at baseline. We used 2 independent group *t* tests to compare the ACL-QOL score between the 2 groups. We analyzed scores on the Tegner scale and IKDC Subjective Knee Form using the Mann–Whitney *U* test. We analyzed the incidence and location of secondary joint injury associated with the initial ACL injury (i.e., baseline MRI) and at the ACL reconstructive surgery using the Fisher exact test. Significance was set at $p < 0.05$.

Results

Between 2013 and 2017, 118 patients were screened for the study, of whom 71 met the inclusion criteria, gave consent and were randomly allocated to 1 of the study groups (Figure 1). Eighteen of these patients were later excluded, leaving data for 53 patients for analysis: 28 (17 men and 11 women) in the early surgery group and 25 (18 men and 7 women) in the regular wait time group. There was no difference in mean age between the 2 groups (28.9 [SD

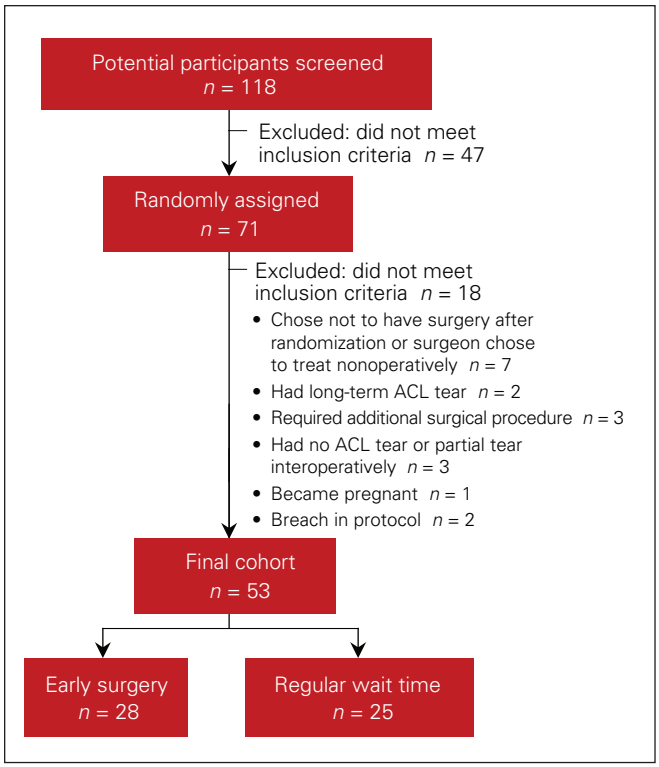

Fig 1. Flow diagram showing patient selection. ACL = anterior cruciate ligament.

Table 1. Mean scores on subjective measures in patients with an acute anterior cruciate ligament rupture

Measure; time point	Group; mean score ± SD		
	Early surgery *n* = 28	Regular waiting time *n* = 25	*p* value
ACL-QOL			
After injury	28.5 ± 12.5	28.5 ± 2.6	0.8
≤ 7 d before surgery	34.9 ± 17.5	38.0 ± 17.5	0.6
Tegner scale			
Before injury	8.1 ± 1.6	7.8 ± 1.4	0.5
After injury	1.9 ± 1.2	2.4 ± 1.4	0.2
≤ 7 d before surgery	3.3 ± 1.0	2.7 ± 1.0	0.1

ACL-QOL = anterior cruciate ligament quality of life measure; SD = standard deviation.

7.1] yr and 28.7 [SD 7.3] yr, respectively). There was no difference between groups in preinjury activity level. The mean waiting time was significantly longer in the regular wait time group than in the early surgery group (29.6 [SD 13.2] wk v. 10.6 [SD 5.1] wk, $p = 0.001$).

The mean scores on the ACL-QOL and Tegner scale at each time point are presented in Table 1. In both groups, mean baseline ACL-QOL scores were low (early surgery group 28.5 [SD 12.5], regular wait time group 28.5 [SD 2.6], $p = 0.8$) and remained low during the waiting period (34.9 [SD 17.5] and 38.0 [SD 17.5], respectively, $p = 0.6$). Participant activity levels were significantly decreased after ACL injury compared to the

Table 2. Incidence of secondary knee injuries identified at the time of injury and at surgery

Injury; time point	Group; no. (%) of patients		
	Early surgery	Regular waiting time	*p* value
Chondral injury			
Medial compartment			
Injury	1 (4)	1 (4)	0.7
Surgery	3 (11)	3 (12)	0.6
Meniscal tear			
Lateral compartment			
Injury	0 (0)	0 (0)	—
Surgery	1 (4)	3 (12)	0.6
Patellofemoral compartment			
Injury	0 (0)	0 (0)	—
Surgery	2 (7)	2 (8)	0.6
Medial compartment			
Injury	5 (18)	8 (32)	0.6
Surgery	5 (18)	8 (32)	0.6
Lateral compartment			
Injury	8 (29)	13 (52)	0.1
Surgery	10 (36)	13 (52)	0.2

preinjury level ($p < 0.001$) in both groups and remained low while patients waited for surgery. Mean Tegner scale scores before the injury approximated level 8 (involvement in competitive sports). After the injury, activity approximated level 2 (light work duties, no sporting activity).

There were no differences in the location or incidence of chondral injuries or meniscal tears at the initial injury or at surgery between the 2 groups (Table 2).

There was no between-group difference in the incidence of abnormal or severely abnormal findings on the IKDC Subjective Knee Form immediately after the injury (19 [68%] in the early surgery group and 17 [68%] in the regular wait time group) or just before surgery (25 [89%] and 23 [92%], respectively).

Discussion

We observed a decrease in quality of life both in patients who underwent early ACL reconstruction (< 12 wk wait period) and in those with a regular wait period (≥ 12 wk). Those who waited longer for their surgery spent a longer period with a diminished quality of life, which supported our hypothesis. The early surgery group spent on average 11 weeks awaiting their ACL reconstruction, and the regular wait time group spent an average of 30 weeks awaiting surgery. This period of diminished quality of life is in addition to the postoperative period, over which quality of life returns. One report suggested that it takes about 6 months after ACL reconstruction for quality of life to return to preinjury levels.[14] The ramifications of an extended period of diminished quality of life have not

been fully explored, but it is plausible that additional wait time may lead to decreased activity, deconditioning and the impact of prolonged periods of lifestyle modifications (e.g., changes in activity habits and sport involvement, occupational changes).

We found no differences in the incidence of secondary joint injury (meniscal tear or chondral injury) between the 2 groups, although the study was not adequately powered to draw statistical conclusions. The timing of surgery remains unresolved in the literature, with several studies showing an increase in the incidence of secondary injury if the ACL is not reconstructed within 6 months.[10,13,25] Two of the 3 studies were retrospective and assessed the incidence of secondary injuries without examining the incidence at the time of the initial ACL injury. As a result, it is difficult to conclude that waiting time was the cause of the increased incidence.

The Tegner scale scores in the present study showed that a decrease in activity levels occurred after ACL injury. Activity levels remained low throughout the waiting period regardless of group assignment, with mean Tegner scores approximating level 2 (light work duty and no recreational sporting activity). A previous study suggested that a higher activity level may influence the incidence of secondary injury while awaiting ACL reconstruction.[13] In the current study, patients likely reduced their activity levels while awaiting surgery, thereby possibly reducing the risk of exacerbating the extent of injury in their ACL-deficient knee. This suggests that there may be merit in patients' decreasing their level or type of activity, or performing guided prehabilitation while awaiting ACL reconstruction surgery. However, since it is generally accepted that a decrease in activity level affects general health, they would need to be guided on safe alternative activities to reduce the risk of secondary injury.

Limitations

The design of this study is not without limitations. The inclusion of a second MRI examination immediately before surgery would have enabled a direct comparison of baseline and follow-up imaging between the 2 groups. However, the cost associated with performing 2 MRI examinations in such a short period could not be justified for the early surgery group. Diagnostic arthroscopy for all participants at the time of injury was also not feasible. Although some secondary injuries (e.g., intrasubstance meniscal tears, subchondral edema from cartilage injury) may have gone undetected because they are more difficult to detect intraoperatively than on MRI, this measurement error would have been the same for the 2 groups. Moreover, because of the small number of meniscal tears, different tear patterns (e.g., ramp lesion, root tears) were not specified, and all were reported as meniscal tears; therefore, no analysis was done on this aspect.

Wait times for participants in the regular wait time group were significantly shorter than has been previously observed within our clinic.[26] A possible explanation may be unintentional fast tracking to MRI and surgery. Although the wait times for the majority of participants in the regular wait time group were still longer than 6 months (the time point at which a previous prospective study showed a difference in the incidence of secondary injuries between early and delayed surgical reconstruction[10]), it is possible that the shorter than expected time from injury to surgery may have skewed the results for this group.

Another limitation is that participants had a low level of activity while waiting for surgery. This decrease in activity may have influenced the incidence of secondary joint injuries in both groups.

Finally, the study was conducted between 2013 and 2017. No changes have since been made in the health care system to alter the waiting period in the region in which this study was performed. Therefore, the findings remain applicable to the current state of affairs and may also be applicable to other institutions dealing with wait times for diagnosis and for surgery consultation and scheduling.

Conclusion

In this prospective randomized controlled trial, patients waiting for ACL reconstructive surgery had a lower quality of life while waiting for surgery, and these low levels were maintained throughout the waiting period. Those with a longer wait for surgery experienced diminished quality of life for a longer period. The study failed to show a relation between time from injury to surgery and the incidence of secondary joint injuries. It is possible that the lower levels of physical activity during the waiting period reduced the overall risk of a secondary injury. Further research looking at the timing, type and intensity of physical activity is needed to fully understand the impact and risk of secondary injury during the wait for ACL reconstruction.

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Affiliations: From the Department of Surgery, University of Manitoba, Winnipeg, Man. (Larose, Stranges, MacDonald, Rollins, Leiter, McRae); the Department of Radiology, University of Manitoba, Winnipeg, Man. (Davidson); the Department of Anatomy, University of Manitoba, Winnipeg, Man. (Peeler); the Pan Am Clinic Foundation, Winnipeg, Man. (Leiter, McRae); and the Pan Am Clinic, Winnipeg, Man. (Stranges, Davidson, MacDonald).

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S. McRae and G. Larose analyzed. G. Larose wrote the manuscript, which J. Leiter, J. Peeler, M. Davidson, M. Rollins, G. Stranges, P. MacDonald and S. McRae critically revised. All authors gave final approval of the article to be published.

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