## ARTICLE IN PRESS

# Operative Versus Nonoperative Treatment of Anterior Cruciate Ligament Rupture in Patients Aged 40 Years or Older: An Expected-Value Decision Analysis

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**Purpose:** Our purpose was to determine the optimal treatment of anterior cruciate ligament (ACL) rupture in patients aged 40 years or older. Methods: Our method was expected-value decision analysis with sensitivity analysis, which is a systematic tool for quantitating clinical decisions. We evaluated 100 randomly selected individuals aged 40 years or older with regard to the following variables: age, gender, activity level (International Knee Documentation Committee form), and visual analog scale regarding potential outcome preferences. Patients with prior knee injury or surgery were excluded. A decision tree was constructed (operative v nonoperative potential outcomes). Literature review determined probabilities of outcomes. Statistical fold-back analysis calculated optimal treatment. Sensitivity analysis determined the effect of changing the outcome probabilities on the decision. Results: This study included 69 patients (31 with prior knee injury or surgery were excluded). The mean age was 53 years (range, 40 to 80 years), 48% were men, and the activity level was normally distributed (with a slight lower activity skew as anticipated for an older population). The expected value for operative treatment was 7.99 versus 1.86 for nonoperative treatment. Increasing the probability of surgical complications (sensitivity analysis) decreased the expected value of operative treatment but not below the expected value of nonoperative treatment. Conclusions: Decision analysis shows that surgery is the optimal treatment of ACL rupture in patients aged 40 years or older. A limitation is that, by convention, decision analysis does not investigate actual patients with the condition. Clinical Relevance: Individuals aged 40 years or older are extremely averse to accepting potential knee instability during pivoting and thus prefer ACL surgery despite the risk of surgical complications. Key Words: Knee—Anterior cruciate ligament—Age of 40 years or older—Operative—Nonoperative—Decision analysis.

The decision to perform operative versus nonoperative treatment of anterior cruciate ligament (ACL) rupture in patients aged 40 years or older is controversial. For members of the American Academy of Orthopaedic Surgeons who treat or refer ACL-

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insufficient patients, the question of whether to perform surgery on patients aged 40 years or older was one of a few decisions about ACL injury management where surgeons significantly disagreed. The question is specifically described as an area of "significant clinical uncertainty." This uncertainty is believed to result from a lack of "adequate clinical evidence in the literature to support clinical decision-making," and we are unaware of published data comparing operative versus nonoperative treatment of ACL rupture in patients aged 40 years or older or in similar age groups.

In the absence of adequate randomized trials or comparative studies to support clinical decision making, we turn to alternative evidence-based medicine tools to determine treatment strategies by integrating the best available "research evidence with clinical expertise and with patient values." Expected-value decision analysis is one such systematic method for quantitative analysis of clinical decision making. Using decision analysis, we may rely on available clinical evidence by combining this evi-

dence with quantitative determination of outcome utilities (patient's values with regard to how strongly a patient would prefer or not prefer a specific treatment outcome) and outcome probabilities (probabilities of various objectively standardized potential outcomes).

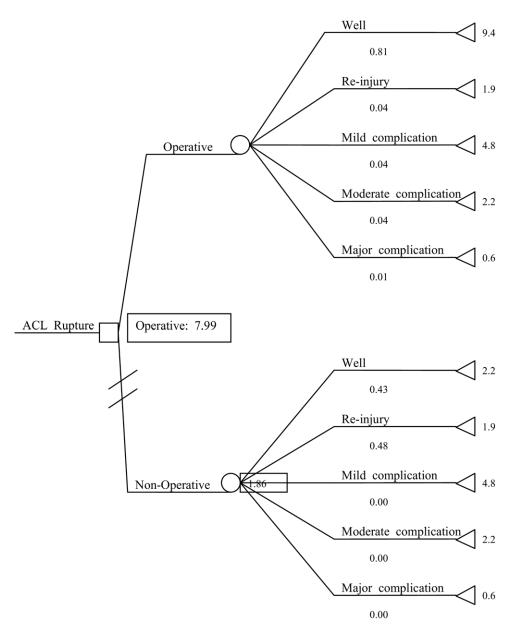


FIGURE 1. Decision tree structuring treatment options (first decision node: operative  $\nu$  nonoperative), potential outcomes (terminal outcome nodes: well, reinjury, mild complication, moderate complication, major complication), mean probabilities of the potential outcomes of operative and nonoperative treatment (outcome probabilities: values recorded beneath potential outcomes) plus outcome utilities (patients' values with regard to how strongly they would prefer or not prefer each potential outcome) for the problem of ACL rupture in patients aged 40 years or older, with values recorded to right of potential outcomes. The optimal treatment strategy is the treatment strategy with the higher expected value (recorded in rectangular boxes). As opposed to nonoperative treatment (indicated by double slashed line), operative treatment is the treatment decision.

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The purpose of this study was to determine the optimal treatment strategy for patients with ACL rupture in those aged 40 years or older by use of expected-value decision analysis. The null hypothesis was that there is no difference in the expected value of surgical versus nonsurgical treatment.

#### **METHODS**

Our methods followed the 5 steps of expected-value decision analysis as described in the orthopaedic literature by Kocher et al.<sup>2</sup>: (1) structuring the decision problem, (2) determining outcome probabilities, (3) determining outcome utilities, (4) performing foldback analysis, and (5) performing sensitivity analysis.

## **Structuring the Decision Problem**

First, a decision tree was created to give structure to our decision problem (Fig 1). Our problem was defined as ACL rupture in patients aged 40 years or older. The first decision (first decision node) was between operative and nonoperative treatment. Then, each decision was defined as having 5 different potential outcomes (terminal outcome nodes). These outcomes are (1) well (operative or nonoperative), (2) reinjury, (3) mild complication, (4) moderate complication, or (5) major complication. Potential outcomes are defined in Table 1.

## **Determining Outcome Probabilities**

A literature review was performed by use of the Medline database (1966-2006). Search terms included ACL, injury, tear, rupture, 40, age, middle, older, nonoperative, operative, natural history, and complications. We included articles relevant to patients aged 40 years or older or similar age groups that contained any data that could be used to determine the mean probabilities of the potential outcomes as defined in Table 1. We additionally searched the references cited in all of the included articles. Because our review revealed a relative absence of published, quantitative data with regard to probabilities of complications after operative treatment of ACL rupture (as discussed in the "Results" section), supplementary evidence regarding the probabilities of mild, moderate, and major postoperative complications was generated by performing a survey of 20 randomly selected members of the ACL Study Group.

## **Determining Outcome Utilities**

One hundred randomly selected individuals in Taos, New Mexico, who were predetermined to be aged 40 years or older were evaluated with regard to demographic variables: age, gender, International Knee Documentation Committee subjective level of activity<sup>3</sup> (Table 2), and prior knee injury or surgery. Patients with prior knee injury or surgery were excluded from the study.

Patient's values (outcome utilities) with regard to how strongly a patient would prefer or not prefer each specific potential treatment outcome (Table 1) were determined by use of a 10-cm visual analog scale (VAS), where 0 represented the worst possible medical outcome that he or she could imagine and 10 represented the best possible medical outcome.

## **Fold-Back Analysis**

Fold-back analysis was performed. In decision analysis, fold-back analysis was used to calculate the

**TABLE 1.** Potential Outcomes of Operative or Nonoperative Treatment of ACL Rupture in Patients Aged 40 Years or Older or in Similar Age Groups

Potential Outcome	Description
Well	
Operative	No complication, no instability, low chance of reinjury, full return to activity
Nonoperative	No complication, possible instability during pivoting or cutting, higher chance of reinjury, modified return to activity
Reinjury	Second knee injury with possible pain or swelling, possible meniscus injury, possible need for surgery (or repeat surgery)
Mild complication	Postoperative knee stiffness without need for repeat surgery, possible incision-site pain, possible wound problem without need for hospitalization
Moderate complication	Postoperative wound problem or infection with need for hospitalization but without need for repeat surgery, lost time from work
Major complication	Postoperative serious health risk of deep venous thrombosis with possible pulmonary embolism requiring hospitalization, possible severe knee infection or stiffness with need for repeat surgery, significant lost time from work and ability to return to activity

**TABLE 2.** International Knee Documentation Committee Subjective Levels of Activity<sup>3</sup>

IKDC Subjective Level of Activity	Type of Activity				
Very strenuous	Jumping or pivoting as in basketball or soccer				
Strenuous	Heavy physical work, skiing, or tennis				
Moderate	Moderate physical work, running, or jogging				
Light	Walking, housework, or yard work				
Unable	None of the previously mentioned activities because of knee pain				

optimal treatment strategy by combining the outcome probability data with the outcome utility data to compute the expected value of the various treatment options. The expected value was the product of the utility of an uncertain outcome (outcome utility) and the probability of the occurrence of that outcome (outcome probability). The optimal treatment strategy was the treatment strategy with the higher expected value.<sup>4</sup>

## **Sensitivity Analysis**

Sensitivity analysis was performed. In decision analysis, sensitivity analysis was performed to establish the effect of varying the outcome probability data or the outcome utility data to determine how such changes would affect the treatment strategy decision. Ultimately, sensitivity analysis allowed clinical scientists to ensure against sampling bias by allowing scrutiny of the data using quantitatively different outcome probabilities or outcome utilities. As an example, if the probability of a postoperative complication increased, the decision to pursue operative treatment would be expected to decrease. Sensitivity analysis required a series of calculations where either the outcome utility or the outcome probability was varied, and the range of expected values was calculated.<sup>4</sup>

## **Statistical Methods**

Methods for fold-back analysis and sensitivity analysis were described previously and were performed by use of Microsoft Office Excel 2003 (Microsoft, Redmond, WA). Mean outcome probabilities and mean outcome utilities were likewise determined with Microsoft Office Excel 2003.

#### **RESULTS**

This study included 69 patients; 31 patients were excluded because of a history of prior knee injury or surgery. The mean patient age was 53 years (range, 40 to 80 years). With regard to gender, 48% of included patients were men and 52% were women. With regard to International Knee Documentation Committee subjective level of activity, 20% participated in very strenuous activity on a regular basis, 29% participated in strenuous activity, 24% participated in moderate activity, 25% participated in light activity, and 2% were unable to participate in such activities.

## Literature Review and Survey

We identified 8 published articles reporting potential outcomes of operative treatment of ACL rupture in patients aged 40 years or older or in similar age groups<sup>5-12</sup> and 2 articles reporting potential outcomes of nonoperative treatment of ACL rupture in patients aged 40 years or older or in similar age groups. <sup>13,14</sup> From these articles, we extracted the outcome probabilities for operative treatment, as reported in Table 3, and we extracted the outcome probabilities for nonoperative treatment, as reported in Table 4. In addition, because there were few reports of the probability of postoperative complications for this age group, the results of the survey data (response rate, 70%) are included in Table 3.

#### **Outcome Probabilities**

From our literature review and survey data (Tables 3 and 4), we calculated the mean probabilities of the potential outcomes of operative and nonoperative treatment of ACL rupture as defined in Table 1. For operative treatment, the mean probabilities of the potential outcomes of operative and nonoperative treatment probabilities were as follows: well operative, 0.81; reinjury, 0.04; mild complication, 0.04; moderate complication, 0.04; and major complication, 0.01. For nonoperative treatment, the probabilities were as follows: well nonoperative, 0.43; reinjury, 0.48; mild complication, 0; moderate complication, 0; and major complication, 0 (values recorded beneath potential outcomes in Fig 1).

#### **Outcome Utilities**

Patients' values (where 0 represents the worst possible medical outcome and 10 represents the best possible medical outcome) with regard to how strongly they would prefer or not prefer each specific

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TABLE 3.	Probabi	ility of Pote	ntial Outcor	nes of Op	perative	Treatmen	t of ACL	Rupture
in Patients	Aged 40	Years or O	lder or in Si	milar Age	Groups	Based on	Literatur	e Review
			and Sui	rvey Data				

Source of Data	Well Operative	Reinjury	Mild Complication	Moderate Complication	Major Complication
Adams and Moore <sup>5</sup>	1	0	0.16		
Barber et al.6	0.67				
Brandsson et al.7	0.73		0.23	0.3	0
Deakon and Zarnett8	0.8			0.1	0.03
Heier et al.9	0.64	0.04		0.03	0
Javernick et al.10		0.02		0	0
Plancher et al.11	1	0.07	0.01	0.18	0
Stein et al.12	0.84	0.08	0	0	0
Survey data			0.05	0.01	0.01
·			0.01	0.01	0.05
			0.05	0.05	0.01
			0.01	0.01	0.01
			0.01	0.01	0.03
			0.005	0.01	0.01
			0.02	0.01	0.01
			0.03	0.005	0.001
			0.03	0	0.001
			0.03	0.01	0.005
			0.03	0.05	0.01
			0.05	0.01	0.005
			0.02	0.001	0.005
			0.03	0.001	0.01

potential treatment outcome (Table 1) were as follows: well operative, 9.4; well nonoperative, 2.2; reinjury, 1.9; mild complication, 4.8; moderate complication, 2.2; and major complication, 0.6 (values recorded to right of potential outcomes in Fig 1).

## **Decision Analysis**

Fold-back analysis revealed operative treatment as the optimal treatment strategy. The expected value or utility for operative treatment was 7.99, and that for nonoperative treatment was 1.86 (values recorded in rectangular boxes in Fig 1).

When analyzed by level of activity, individuals with lower levels of activity had lower expected values for operative treatment. However, operative treatment was preferred as the optimal treatment strategy by individuals of all levels of activity, and significant differences were not detected when utility of operative versus nonoperative treatment was analyzed by activity level.

## **Sensitivity Analysis**

To ensure against sampling bias, 1-way sensitivity analysis was performed to vary the probability of complications. With sensitivity analysis of mild complications selected as a representative example, these results are illustrated in Fig 2. As the probability of a complication increases, the expected value of operative treatment decreases. Yet, operative treatment remains the optimal treatment strategy.

Results for sensitivity analysis of moderate and major complications were similar. In addition,

Table 4. Probability of Potential Outcomes of Nonoperative Treatment of ACL Rupture in Patients Aged 40 Years or Older or in Similar Age Groups Based on Literature Review

Source of Data	Well Nonoperative	Reinjury	Mild Complication	Moderate Complication	Major Complication
Buss et al. <sup>13</sup>	0.42	0.33	N/A	N/A	N/A
Ciccotti et al.14	0.83	0.37	N/A	N/A	N/A

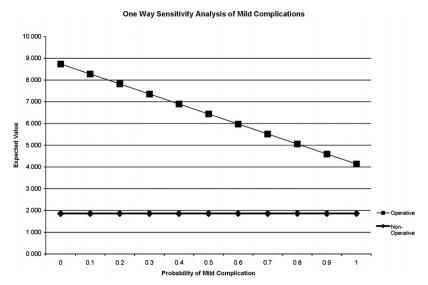


FIGURE 2. Sensitivity analysis. As the probability of a complication increases, the expected value of operative treatment decreases. Yet, operative treatment remains the optimal treatment strategy.

whereas the expected value of operative treatment decreases as the severity of a postoperative complication increases, operative treatment is still preferred.

#### DISCUSSION

In contrast to the null hypothesis, our results show that surgery (as opposed to nonsurgical treatment) is the optimal treatment strategy for ACL rupture in patients aged 40 years or older.

We identify that the factor driving this result is that the population investigated is so extremely averse to accepting a risk of possible instability during pivoting or cutting, a higher chance of reinjury, or a modified return to activity that the population investigated rates the outcome utility of "well nonoperative" (Table 1) as approaching a worst possible medical outcome (VAS score of 2.2).

This factor clarifies the sensitivity analysis (Fig 2), which reveals the following: (1) as would be predicted, the expected value of operative treatment decreases when the probability of a postoperative complication increases, and (2) as may not have been predicted, the expected value of operative treatment is greater than the expected value of nonoperative treatment even when the probability of a complication is 1.0 (100%). This is not to indicate that patients value postoperative complications as acceptable medical outcomes. The VAS score for a mild, moderate, or severe complication is 4.8, 2.2, and 0.6, respectively. Yet, patients value the outcome of a moderate postoperative complication as equal to a "well nonopera-

tive" result. Simply put, the population studied highly values a stable knee.

Although we are unaware of publications directly comparing operative and nonoperative treatment of ACL rupture in patients aged 40 years or older, our findings are supported by previous publications. Though lacking a nonoperative control group, excellent patient-reported satisfaction and validated objective outcomes have been reported after operative treatment of ACL rupture in similar age groups by Adams and Moore,5 Heier et al.,9 Javernick et al.,10 Plancher et al.,11 and Stein et al.12 Our finding is further supported by previous publications by Barber et al.,6 Brandsson et al.,7 and Deakon and Zarnett,8 who similarly reported excellent patient-reported satisfaction and validated objective outcomes after operative treatment of ACL rupture in similar age groups and also showed no difference in outcomes of ACL reconstruction in patients aged 40 years or older as compared with younger patients. Finally, Miller and Sullivan<sup>15</sup> present a case report of the oldest ACL reconstruction patient of which they are aware, 84 years old, and concisely summarize that the historically proposed 40-year-old upper age limit for ACL reconstruction is "arbitrary."

Our finding is, at first glance, not supported by previous publications regarding nonoperative treatment of ACL rupture in patients aged 40 years or older or in similar age groups because Buss et al.<sup>13</sup> and Ciccotti et al.<sup>14</sup> report satisfactory outcomes of nonoperative treatment. However, both groups qualify that these patients must be "willing to accept a modest amount of instability"<sup>13</sup> or that some patients who

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wished to resume "sports activity that required pivoting were dissatisfied." In addition, Jokl et al. 16 report that with regard to nonoperative treatment of patients with concomitant injuries to the medial collateral ligament and ACL, "the older . . . individuals had the poorest final results." Furthermore, Daniel et al. 17 and Fithian et al. 18 identify that rather than age, it is (1) hours of participation in jumping or cutting sports and (2) knee laxity measurements that determine the fate of the ACL-injured patient.

Our study has limitations. Our data are generalizable to a population of patients aged 40 years or older with diverse activity levels. Our level-of-activity results show a normal distribution with a slight skew toward lower activity level, as would generally be expected in a population (mean age, 53 years) that is tending to give up participation in very strenuous activities such as basketball or soccer. However, clinical experience dictates that treatment may differ for individual older patients facing the decision of operative versus nonoperative treatment for ACL tear based on more specific demographics of age, gender, and level of activity, as well as other potential unique variables such as regional location. For example, a 40-year-old female molybdenum miner who participates in basketball and resides in the town of Questa in Taos County, New Mexico, may have different preferences than an 80-yearold, sedentary man living on a ground-floor apartment in a major urban center. Future research could include a larger sample size as required to achieve adequately powered, prospective subgroup analysis, which would have greater clinical utility with regard to counseling individual patients based on specifics of a more narrow age range, male or female gender, specific activity level, and other demographic variables.

An additional limitation is that although outcome probabilities are based on the best evidence available, the included studies both had lower levels of evidence or were insufficient such that a survey was required to determine probabilities of surgical complications.

With regard to outcome utilities, we assessed subjects who potentially faced ACL injury rather than assessing actual ACL-injured patients. This is done, by convention, in decision analysis, because patients who have already had the clinical problem may have biased outcome utilities based on their prior decisions and experiences.<sup>2</sup> Nevertheless, a study limitation is that such subjects may have different values than actual ACL-injured patients. Future research is required to address this issue.

## **CONCLUSIONS**

Operative management is the optimal treatment strategy for ACL rupture in patients aged 40 years or older.

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