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Original Research

Cost-Effectiveness Analysis of Primary Arthrodesis Versus Open Reduction Internal Fixation for Primarily Ligamentous Lisfranc Injuries

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ABSTRACT

The purpose of the present study was to determine whether surgical intervention with open reduction internal fixation (ORIF) or primary arthrodesis (PA) for Lisfranc injuries is more cost effective. We conducted a formal cost-effectiveness analysis using a Markov model and decision tree to explore the healthcare costs and health outcomes associated with a scenario of ORIF versus PA for 45 years postoperatively. The outcomes assessed included long-term costs, quality-adjusted life-years (QALYs), and incremental cost per QALY gained. The costs were evaluated from the healthcare system perspective and are expressed in U.S. dollars at a 2017 price base. ORIF was always associated with greater costs compared with PA and was less effective in the long term. When calculating the cost required to gain 1 additional QALY, the PA group cost $1429/QALY and the ORIF group cost $3958/QALY. The group undergoing PA overall spent, on average, $43,192 less than the ORIF group, and PA was overall a more effective technique. Strong dominance compared with ORIF was demonstrated in multiple scenarios, and the model's conclusions were unchanged in the sensitivity analysis even after varying the key assumptions. ORIF failed to show functional or financial benefits. In conclusion, from a healthcare system's standpoint, PA would clearly be the preferred treatment strategy for predominantly ligamentous Lisfranc injuries and dislocations.

Injuries to the Lisfranc or tarsometatarsal complex occur at a rate of 1 per 55,000 in the United States, accounting for nearly 0.2% of all fractures (1). Nearly 20% of these injuries will be either missed or misdiagnosed on the initial clinical and radiographic examination (2). Lisfranc injuries are associated with long-term disability from subsequent painful osteoarthritis and residual deformity (3). Although studies have reported a near-normal quality of life for patients after surgery, many patients still experience persistent midfoot pain. Cassinelli et al (4) found a mean visual analog scale pain score of 7 of 10, and many have reported persistent functional deficits. Ly and Coetzee (5) reported a mean American Orthopaedic Foot and Ankle Society midfoot scale score of 60 of 100 in their open reduction internal fixation (ORIF) group at 2 years. Perhaps what has been most troubling is that the outcomes after operative treatment of Lisfranc injuries have not been consistent. This might be, at least in part, explained by the wide practice variation among providers when addressing these injuries. During the past 10 years, a substantial increase has occurred in foot and ankle reports regarding the ideal treatment for these injuries. Perhaps the most well-known report is that by Ly and Coetzee (5), in which they directly compared their results

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obtained with ORIF and midfoot primary arthrodesis (PA) in a randomized controlled study design. They found clearly superior results with limited midfoot arthrodesis of the first, second, and, sometimes, third tarsometatarsal articulations compared with ORIF (5). Although these results were certainly encouraging, not all investigators have found the same level of success with midfoot arthrodesis. In another well-publicized randomized prospective study, Henning et al (3) found that although 11 of 14 ORIF patients required removal of hardware and 1 required secondary arthrodesis, 17% of their PA group (3 of 18) also required a secondary surgery for nonunion or hardware removal. In a recent meta-analysis comparing these 2 strategies, Smith et al (6) concluded that the incidence of hardware removal was nearly 5 times greater in patients undergoing ORIF compared with those undergoing arthrodesis (odds ratio 0.23; 95% confidence interval 0.11 to 0.45). They also found that the need for revision surgery (other than hardware removal) was likely less for patients undergoing PA (odds ratio 0.36, 95% confidence interval 0.08 to 1.59); however, this finding did not reach statistical significance (6). The investigators acknowledged that PA should not be considered a superior strategy because these patients will carry an inherently greater risk of nonunion and possibly symptomatic midfoot pseudoarthrosis. These often require return trips to the operating room and further increases the healthcare costs (6). The purpose of the present study was to conduct a formal cost-effectiveness analysis (CEA) to explore the short- and long-term costs and outcomes associated with these 2 competing strategies.

Materials and Methods

Design

The present study followed the National Institute for Health and Care Excellence guidelines for performing a CEA, with the exception of discounting rates, for which U.S. rates were used. We assumed the base case to be an otherwise healthy individual who had sustained a Lisfranc fracture or dislocation, with instability of the joint requiring operative treatment. A thorough published data search was completed to identify the studies available with the highest level of evidence and reporting postoperative outcomes after ORIF for Lisfranc injuries or PA for Lisfranc injuries. Please see Supplemental Table S1 for full disclosure of the published articles used to obtain probabilities. Both purely ligamentous injuries and those in which a fracture had been sustained were included. When PA was used, it was performed on all unstable Lisfranc joints, consisting of, at a maximum, the medial 3 rays only. The lateral rays (4 and 5) were fixated with Kirschner wires only when instability was present. Cases described in the published studies in which all 5 rays underwent fusion were excluded, because this type of procedure has been demonstrated to produce worse outcomes (5,7). All methods of fixation were considered, with most studies using screws or plates, or a combination of both. We sought to identify a difference in the effectiveness and costs of each procedure (ORIF versus PA), with less emphasis placed on the techniques and skill sets of the individual surgeons; therefore, fixation using minimally invasive methods (e.g., percutaneous techniques, fixation with TightRope [Arthrex, Naples, FL]) were excluded. The longest follow-up time for either technique identified in the published data was 24 years (8).

Decision Model

A Markov model using a cohort approach was built in TreeAge Pro Healthcare 2017 (TreeAge Software, Inc., Williamstown, MA). The model was used to conduct a CEA that compared the costs and overall effectiveness of operative intervention for Lisfranc injuries using ORIF versus PA. For each surgical scenario, the 2 strategies were compared in terms of 2 outcomes: the incremental healthcare costs and incremental quality-adjusted life-years (QALYs). The 2 outcomes were combined in the form of incremental cost-effectiveness ratios (ICERs). We calculated the long-term results as lifetime outcomes. We assumed hardware removed was performed on a routine basis if the incidence of removal was >50%, unless explicitly stated otherwise within the report. Hardware was not routinely removed in the PA group.

The costs were evaluated from the healthcare system perspective and are expressed in 2017 U.S. dollars. The costs were derived from the relevant data and use Medicare 2017 fee schedules. For the long-term analysis, future costs and QALYs were discounted at a 3% annual rate. In the base case, it was assumed that the initial cost of surgery for both strategies (ORIF and PA) were equal, allowing patients to enter the model with no previous cost deficit. The relevant costs included the cost of complications, outpatient follow-up visits, cost of radiographs postoperatively, cost of revision procedures, and prescription costs. Revision surgery was assumed to be on an outpatient basis. All patients with an end result of "arthrosis" were assumed to have incurred the costs associated with obtaining a supportive insole with both strategies. Health-related quality of life data were obtained from previous data that had used the EQ-5D, the preferred measure of health-related quality of life in adults according to the National Institute for Health and Care Excellence guidelines. If data were not available, the algorithm derived by Ara and Brazier (9) was used to convert Short-Form Health Survey 36-item (SF-36) questionnaire scores to health utility indexes (HUIs). For the cases in which SF-36 data were not available, the documented HUI of similar foot pathologies was used, and the final HUI was agreed upon by the authors, who are physicians treating the ailments in question on a consistent basis (3,9–15). The HUI assigned to the base case was 0.70 using the cited method. All patients were entered into the model at the same HUI.

Uncertainty

A variety of assumptions are made with an economic analysis that should be accounted for appropriately. A variety of sources are used to incorporate data into the model; therefore, multiple sensitivity and probabilistic analyses were performed to assess the effect of uncertainty on the results. One-way sensitivity analyses were performed to assess the effect of variations in the parameters of the model for a range of values based on the 95% confidence interval. Probabilistic analysis was performed to ensure our base case estimates were as close to the true values as possible.

Structure

The Markov model is presented in Fig. 1. Patients undergoing ORIF were assumed to be in 1 of several health states postoperatively:

1. Resolution
2. Arthrosis (midfoot)
3. Infection treated on an outpatient basis
4. Infection treated on an inpatient basis
5. Removal of hardware
6. Conversion to arthrodesis

Patients in the arthrodesis group were assumed to be in the health states identical to those for the ORIF arm, with the exception of "conversion to arthrodesis," which was substituted with "revision surgery." These health states were identified as common complications occurring after these types of surgery as found in the published data. Other complications (e.g., neuritis, complex regional pain syndrome) were not considered in the model, because they occur infrequently, and the rates of occurrence could only be found in uncontrolled trials and case reports. The model estimates were recalculated on a yearly basis, with the costs and effects calculated at the end of each year. Patients transitioned among the health states according to their characteristics and event probabilities reported in the published data, and the calculations were started again. A half-cycle correction was made in the model to allow for patients to transition into other health states before the end of the cycle to eliminate bias in the form of over- or undercorrection (16–18).

Results

The total lifetime cost for treatment with PA was $27,849, and the total effectiveness was 18.68 QALYs over the patient's lifetime postoperatively (Table). The total lifetime cost for treatment with ORIF was $127,294, with a total effectiveness of 17.66 QALYs. When calculating the cost required to gain 1 additional QALY, the PA group cost $1490/QALY, and the ORIF group cost $7208/QALY. The group undergoing PA overall spent, on average, $99,445 less than the ORIF group, and PA was overall a more effective technique. In terms of ICER, the ORIF group exhibited a negative ICER value, indicating that the ORIF group was strongly dominated by the PA group (Fig. 2).

Sensitivity Analysis

Multiple 1- and 2-way sensitivity analyses were performed to examine scenarios in which ORIF might be seen as the more competitive strategy. We believed 1 of the most likely causes of the lower effectiveness of ORIF could have been the high rate of second surgeries in the ORIF arm. For example, it was common in the reported studies for surgeons to routinely remove hardware from the ORIF group even