Complete Summary

GUIDELINE TITLE

National Institutes of Health consensus statement on total knee replacement.

BIBLIOGRAPHIC SOURCE(S)

National Institutes of Health. National Institutes of Health consensus statement on total knee replacement December 8-10, 2003. Final statement. Rockville (MD): U.S. Department of Health and Human Services (DHHS); 2004 Feb 17. 18 p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Knee joint failure caused by osteoarthritis (OA); rheumatoid arthritis (RA), juvenile rheumatoid arthritis, osteonecrosis, and other types of inflammatory arthritis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Rehabilitation
Treatment

CLINICAL SPECIALTY

Geriatrics
Nursing
Orthopedic Surgery

Physical Medicine and Rehabilitation
Rheumatology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To explore and assess the current scientific knowledge regarding total knee replacement (TKR) and to address the following questions:

- What are the current indications for and outcomes from primary TKR?
- How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors affect the short- and long-term outcomes of primary TKR?
- Are there important perioperative interventions that influence outcomes?
- What are the indications, approaches, and outcomes for revision TKR?
- What factors explain disparities in the utilization of TKR in different populations?
- What are the directions for future research?

TARGET POPULATION

Patients with knee joint failure who do not respond to nonsurgical therapies

INTERVENTIONS AND PRACTICES CONSIDERED

1. Total knee replacement (TKR)
2. Standardized instruments to measure patient´s pain, physical function, and quality of life (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC], the New Zealand Priority Criteria for Major Joint Replacement, the Knee Society Score [KSS], or the Hospital for Special Surgery [HSS])
3. Perioperative interventions and management
    - Antibiotic and operating room procedures (antibiotic impregnated bone cement, ultraclean-air operating rooms, and whole-body exhaust-ventilated suits)
    - Deep venous thrombosis prophylaxis (oral anticoagulants, low-molecular-weight heparin, adjusted-dose heparin, intermittent pneumatic compression/elastic stockings plus low-dose unfractionated heparin or low-molecular-weight heparin)
    - Rehabilitation services
    - Prevention and/or treatment of postoperative anemia (autologous blood transfusion and erythropoietin)
    - Postoperative analgesia (epidural analgesia versus intravenous narcotics, the use of cyclooxygenase-2 selective inhibitors)
    - Cardiac risk assessment and optimized cardiopulmonary function
    - Smoking cessation
    - Assessment of mental status (Mini Mental Status Exam [MMSE])
    - Patient education including use of pain medications and reduced anxiety

4. Revision surgery performed in high-quality hospitals by skilled health care teams
5. Radiographic monitoring

MAJOR OUTCOMES CONSIDERED

- Pain relief
- Functional status
- Quality of life
- Adverse events
- Prosthesis failure rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To address the first key question about the indications and outcomes of total knee arthroplasty (TKAs), the National Library of Medicine staff conducted a systematic literature review from 1995 to April 2003. The titles and abstracts of the resulting 3,519 references were then screened, using predefined inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; baseline data and post-op outcomes data provided; experimental or quasi-experimental study design, English language, tricompartment).

In addressing key question 4, heavy emphasis was placed on the meta-analysis recently completed by one of the principals, which covered the period from 1966 through 2000. To update this meta-analysis, a literature search was undertaken to assess the status of the literature relating to revision TKA after (and including) the year 2000. The literature search was done via PubMed® using a strategy based on the search described in the previously published meta-analysis; 14 new studies were uncovered.

To answer key question 5, about the evidence for access differences (disparities in utilization) related to race and gender, a literature search was conducted via PubMed from 1995 to 2003. This search resulted in 176 references. Titles and abstracts of the references were reviewed, and 23 met preliminary inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; gender/racial data provided; experimental or quasi-experimental design). Of these, three met inclusion criteria for analysis. Additionally, reference lists from the above articles and from articles recommended by colleagues were searched. Three additional articles were found and included in the analysis.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

All articles that appeared to meet the screening criteria were abstracted by trained abstractors. Of the original results, 611 references either met the inclusion criteria or needed further screening of the full article to determine if they met inclusion. Of these, 62 studies reported pre- and post-total knee arthroplasty (TKA) functional data using at least one of four established measures (Knee Society score, Hospital for Special Surgery score, Western Ontario and McMaster Universities [WOMAC], or SF-36).

To address key question 2 regarding prosthesis material/design or surgical factors, studies that fell within the original search parameters were analyzed and classified as primarily addressing either the use of a specific type of prosthesis or testing a specific surgical procedure or technique.

The evidence to assess important perioperative interventions that influence outcomes (key question 3) were limited to studies published since 1994. All were randomized controlled studies with the exception of one large cohort study. Interventions were categorized as prophylaxis for postoperative deep venous thrombosis/pulmonary embolism or infection.

A meta-analysis was conducted on the functional outcomes data. Because the data at baseline and follow-up was not consistent, a model with random effects was selected to simplify the interpretation. Because precise information from all studies was not available, each pre and post pair was treated as if they were separate data sets.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A consensus conference was convened to explore and assess the current scientific knowledge regarding total knee replacement (TKR). During the first one and a half

days of the conference, experts presented the latest TKR research findings to an independent panel. After each set of presentations, a discussion period was held to allow conference attendees to ask questions of the speakers and make comments. The panel then met in executive session to weigh all of the scientific evidence and prepare its consensus statement answering the above questions. On the final day of the conference, the panel chairperson read the draft statement to the conference audience and invited comments and questions.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The panel´s draft consensus statement was posted to the National Institutes of Health (NIH) Consensus Development Program´s Web site after the close of the conference proceedings. The final statement was posted 3 to 4 weeks later.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Primary total knee replacement (TKR) is most commonly performed for knee joint failure caused by osteoarthritis (OA); other indications include rheumatoid arthritis (RA), juvenile rheumatoid arthritis, osteonecrosis, and other types of inflammatory arthritis. The aims of TKR are relief of pain and improvement in function. Candidates for elective TKR should have radiographic evidence of joint damage, moderate-to-severe persistent pain not adequately relieved by an extended course of nonsurgical management, and clinically significant functional limitation resulting in diminished quality of life.

The success of primary TKR in most patients is strongly supported by more than 20 years of follow-up data. There appears to be rapid and substantial improvement in the patient´s pain, functional status, and overall health-related quality of life in about 90 percent of patients; about 85 percent of patients are satisfied with the results of surgery.

Short-term outcomes, as documented by functional outcome scales, are generally substantially improved after TKR. Functional outcome is improved after TKR for people across the spectrum of disability status. In general, prostheses are durable, but failure does occur.

Age younger than 55 at the time of TKR, male gender, diagnosis of osteoarthritis, obesity, and presence of comorbid conditions are risk factors for revision.

Factors related to a surgeon´s case volume, technique, and choice of prosthesis may have important influences on surgical outcomes. One of the clearest associations with better outcomes appears to be the procedure volume of the individual surgeon and the hospital.

Technical factors in performing surgery may influence both the short- and long-term success rate. Proper alignment of the prosthesis appears to be critical. Many design features, such as use of mobile bearings or designs sparing cruciate ligaments, have theoretical advantages, but durability and success rates appear roughly similar with most commonly used designs.

There is consensus regarding the following perioperative interventions that improve TKR outcomes: systemic antibiotic prophylaxis, aggressive postoperative pain management, perioperative risk assessment and management of medical conditions, and preoperative education.

The effectiveness of anticoagulation for the prevention of pulmonary emboli is unclear. There are insufficient data to support specific perioperative rehabilitation strategies, methods to reduce postoperative anemia, postoperative physical activity recommendations, and the site of post-acute care.

Revision TKR is done to alleviate pain and improve function. Fracture or dislocation of the patella, instability of the components or aseptic loosening, infection, and periprosthetic fractures are common reasons for total knee revision. A painful knee without an identifiable cause is a controversial indication. Contraindications for revision TKR include persistent infection, poor bone quality, highly limited quadriceps or extensor function, poor skin coverage, and poor vascular status. Results are not as good as with primary TKR; outcomes are better for aseptic loosening than for infections. When infection is involved, successful results occur with a two-stage revision. Failed revisions require a salvage procedure (resection of arthroplasty, arthrodesis, or amputation), with inferior results compared with revision TKR.

There is clear evidence of racial/ethnic and gender disparities in the provision of TKR in the United States. Racial or ethnic differences in the provision of care are not limited to joint replacements. The limited role of economic and other access factors in these racial or ethnic disparities can be demonstrated by significant differences in the rate of procedures in the Veterans Administration (VA) system, where cost and access are assumed equivalent across race or ethnic groups.

Patients´ acceptance of physician recommendations varies greatly. Among persons with a potential need for TKR, only 12.7 percent of women and 8.8 percent of men were "definitely willing" to have the procedure. The interaction between the patient and physician affects the final recommendations and the patient´s acceptance of those recommendations. Physicians´ beliefs about their patients, the limited familiarity with these procedures in minority communities, patients´ mistrust of the health care system, and personal beliefs about the most effective treatment of joint problems may all have a role in these racial or ethnic disparities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved understanding of the current indications and outcomes for primary total knee replacement (TKR)
- Increased understanding of how the specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short- and long-term outcomes of primary TKR
- Familiarity with important perioperative interventions that influence outcomes
- Increased knowledge of the indications, approaches, and outcomes for revision TKR
- Understanding of the factors that explain disparities in the utilization of TKR in different populations
- Knowledge of the directions for future research

POTENTIAL HARMS

Complications following total knee replacement (TKR) include wound-healing problems; wound and deep-tissue infection; deep-vein thrombosis and pulmonary embolism; pneumonia; myocardial infarction; patellar fracture and/or extensor mechanism disruption; joint instability, stiffness, and/or malalignment; and nerve and vascular injuries.

CONTRAINDICATIONS

CONTRAINDICATIONS

There are few absolute contraindications for total knee replacement (TKR) other than active local or systemic infection and other medical conditions that substantially increase the risk of serious perioperative complications or death. Obesity is not a contraindication to TKR; however, there may be an increased risk of delayed wound healing and perioperative infection in obese patients. Severe peripheral vascular disease and some neurologic impairments are both relative contraindications to TKR.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.
- The statement reflects the panel´s assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institutes of Health. National Institutes of Health consensus statement on total knee replacement December 8-10, 2003. Final statement. Rockville (MD): U.S. Department of Health and Human Services (DHHS); 2004 Feb 17. 18 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Feb 17

GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) Consensus Development Panel on Total Knee Replacement - Independent Expert Panel

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

National Institutes of Health (NIH) Consensus Development Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: E. Anthony Rankin, MD (Chair), Chief of Orthopaedic Surgery, Providence Hospital, Clinical Professor of Orthopaedic Surgery, Howard University, Washington, District of Columbia; Graciela S. Alarcón, MD, MPH, Jane Knight Lowe Chair of Medicine in Rheumatology, Division of Clinical Immunology and Rheumatology, University of Alabama School of Medicine, Birmingham, Alabama; Rowland W. Chang, MD, MPH, Professor, Departments of Preventive Medicine, Medicine, and Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine, Chicago, Illinois; Leo M. Cooney, Jr., MD, Professor of Medicine, Division of Geriatrics, Department of Internal Medicine, Yale University School of Medicine, Yale-New Haven Hospital, New Haven, Connecticut; Linda S. Costley, Covington, Georgia; Anthony Delitto, PhD, PT, FAPTA, Associate Professor and Chair, Department of Physical Therapy, University of Pittsburgh, Pittsburgh, Pennsylvania; Richard A. Deyo, MD, MPH, Professor, Departments of Medicine and Health Services, University of Washington School of Medicine, Seattle, Washington; Sue Karen Donaldson, PhD, RN, FAAN, Professor of Physiology, School of Medicine, Professor of Nursing, School of Nursing, Johns Hopkins University, Baltimore, Maryland; Marc C. Hochberg, MD, MPH, Professor of Medicine, Head, Division of Rheumatology and Clinical Immunology, Department of Medicine, University of Maryland School of Medicine, Baltimore, Maryland; Catherine H. MacLean, MD, PhD, Assistant Professor, Division of Rheumatology, Geffen School of Medicine, University of California, Los Angeles, Natural Scientist, RAND Health, Los Angeles, California; Edward H. Yelin, PhD, Professor of Medicine and Health Policy, Division of Rheumatology, Department of Medicine, University of California, San Francisco, San Francisco, California

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panelists may not have real or apparent conflicts of interest. If they do have conflicts, they are eliminated from consideration. Panelists sign a statement attesting to the absence of real or apparent conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Kane RL, Saleh KJ, Wilt TJ, Bershadsky B, Cross WW III, MacDonald RM, Rutks I. Total Knee Replacement. Evidence Report/Technology Assessment No. 86 (Prepared by Minnesota Evidence-based Practice Center, Minneapolis, Minnesota). AHRQ Publication No. 04-E006-1. Rockville, MD: Agency for Healthcare Research and Quality. November 2003. Available from the AHRQ Web site.
- Program and abstract book. 2003 Dec. Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 15, 2004.

COPYRIGHT STATEMENT

No copyright restrictions apply.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/15/2004

FIRSTGOV