

Quality Indicators for the Management of Osteoarthritis in Vulnerable Elders

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Osteoarthritis is the most common chronic condition affecting older persons. This condition is probably not a single disease but rather “a group of overlapping distinct diseases, which may have different etiologies but with similar biologic, morphologic, and clinical outcomes” (1). A common final result of these diseases, however, is the degeneration of articular cartilage with loss of the joint surface (1). Depending on the method of evaluation and the diagnostic criteria used, estimates of symptomatic disease prevalence range from 50% to 80% in the elderly population (2, 3).

Half of all disability among older persons has been attributed to arthritis (3, 4). Osteoarthritis is associated with pain, functional disability (5, 6), and being homebound (3). Although effective therapies exist to treat this disease, many are associated with substantial toxicities. Several studies have demonstrated regional and subspecialty variations in the use of pharmacologic, non-pharmacologic, and surgical treatments (7–9). Indirect evidence suggests that these differences result in variations in outcomes and in quality of care. On the basis of a comprehensive literature review, a set of process indicators to assess the quality of health care for vulnerable elders with osteoarthritis was developed. This paper summarizes the methods used to develop these indicators and reviews the evidence on which they are based.

METHODS

The methods for developing these quality indicators, including literature review and expert panel consideration, are detailed in a preceding paper (10). For osteoarthritis, the structured literature review identified 6201 titles from which abstracts and articles relevant to this report were identified. Finally, the supporting evidence was supplemented with the author’s own extensive files from previous related work and with the recommendations of an external expert reviewer. On the basis of the literature and the author’s expertise, 18 potential quality indicators were proposed. The search

terms and results of the literature review can be accessed at www.acponline.org/sci-policy/.

RESULTS

Of the 18 potential quality indicators, 11 were judged valid by the expert panel process (see the quality indicators on pp 653–667) and 7 were not accepted (www.acponline.org/sci-policy/). The literature summaries that support each of the indicators judged to be valid by the expert panel process are described below.

Quality Indicator 1

Assessment of Pain and Functional Status

IF a vulnerable elder is diagnosed with symptomatic osteoarthritis, THEN his or her functional status and the degree of pain should be assessed annually BECAUSE this information is necessary to direct therapeutic decisions.

Supporting Evidence. The literature review identified no studies that demonstrate a direct association between the assessment of pain or function and therapeutic decision making. However, given that principal goals of treatment for osteoarthritis are to reduce pain and maximize function, such assessments are necessary to meet these treatment goals.

Assessment of pain and function are implicitly recommended by the American College of Rheumatology in its guidelines for the treatment of osteoarthritis (11–13). The American Board of Family Practice specifically recommends assessing both pain and functional status during the evaluation of patients with arthritis (14).

Quality Indicator 2

Aspiration of Hot Joints

IF a vulnerable elder has monoarticular joint pain associated with redness, warmth, or swelling AND the patient also has an oral temperature greater than 38.0 °C and does not have a previously established diagnosis of pseudogout or gout, THEN a diagnostic aspiration of

the painfully swollen red joint should be performed that day BECAUSE this sign–symptom complex is common with joint infection, and it requires treatment that is different than that for osteoarthritis.

Supporting Evidence. No studies directly describe the relationship between the aspiration of painful, swollen, red joints in the presence of fever and establishment of a diagnosis of a septic joint. This sign–symptom complex is uncommon in uncomplicated osteoarthritis, however, and its presence raises the possibility that the affected joint may be septic. Given that an untreated septic joint can rapidly lead to joint destruction and that joint aspiration is necessary to make the diagnosis of a septic joint, it would seem prudent to aspirate in the described scenario.

The American College of Rheumatology, guideline statements, and numerous textbooks of medicine recommend aspiration in this clinical setting (11–13, 15, 16).

Quality Indicators 3 and 4

Exercise Therapy for Patients with Newly Diagnosed Disease

IF an ambulatory vulnerable elder is newly diagnosed with osteoarthritis of the knee, has no contraindication to exercise, and is physically and mentally able to exercise, THEN a directed or supervised strengthening or aerobic exercise program should be prescribed within 3 months of diagnosis BECAUSE such programs improve functional status and reduce pain.

Exercise Therapy for Patients with Prevalent Disease

IF an ambulatory vulnerable elder has had a diagnosis of symptomatic osteoarthritis of the knee for longer than 12 months, has no contraindication to exercise, and is physically and mentally able to exercise, THEN there should be evidence that a directed or supervised strengthening or aerobic exercise program was prescribed at least once since the time of diagnosis BECAUSE such programs improve functional status and reduce pain.

Supporting Evidence. The literature review identified one relevant systematic review and an additional randomized, controlled trial that was published after the systematic review. In the systematic review, van Baar and colleagues (17) evaluated the effectiveness of exercise therapy for osteoarthritis of the knee or hip. Among

the randomized clinical trials on exercise therapy for osteoarthritis that were generated from a computerized search, the authors identified 11 trials that reported the effect of aerobic or strengthening exercise programs on pain, self-reported disability, observed disability in walking, or patient-rated global assessment (18–27). Most patients enrolled in these studies were older than 60 years of age. Effect sizes for these outcomes could be calculated, and were reported, for 9 of these studies (18–24, 26, 27). The effect size is calculated by dividing the observed result by the standard deviation for that result, producing a unitless outcome that is useful for comparing studies that report outcomes in the same domain (that is, pain) but use different instruments. Among the 6 studies that evaluated the effect of exercise on pain, 4 demonstrated statistically significant (small to medium) effect sizes (18, 19, 21, 22). Four of the 5 studies that recorded self-reported disability reported statistically significant positive effects associated with exercise (18, 19, 22, 26). Four studies reported the effect of exercise on observed disability in walking. In 3 of these studies (18, 19, 22), the effect size was positive, with small or large effect sizes; in 1 study (7), it was negative. All results were statistically significant. The effect of exercise on patient global assessment was evaluated in 2 studies; the effect sizes were medium and large (both statistically significant) (18, 21).

One additional trial that evaluated the effect of exercise among patients with osteoarthritis was published after the systematic review (28). In this study, 83 patients with knee osteoarthritis were randomly assigned to a 4-week physical therapy regimen or to a control group. The physical therapy regimen included manual therapy of the knee by a trained physical therapist and a standardized knee exercise program in the clinic and at home. The control group received subtherapeutic knee ultrasonography and no exercise. At 8 weeks, 6-minute walk times and functional status, measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), were clinically and statistically significantly better in the treatment group than in the control group.

The American College of Rheumatology (11, 12), the American Board of Family Practice (14), and the American Academy of Orthopaedic Surgeons (29) recommend exercise for the treatment of osteoarthritis of the knee and hip.

Quality Indicators 5 and 6*Patient Education for Incident Disease*

IF an ambulatory vulnerable elder is diagnosed with symptomatic osteoarthritis THEN education regarding the natural history, treatment, and self-management of the disease should be offered at least once within 6 months of diagnosis BECAUSE such education produces improvements in physical functioning and pain.

Patient Education for Prevalent Disease

IF a patient COX has had a diagnosis of symptomatic osteoarthritis for 12 months or longer THEN there should be evidence that the patient was offered education regarding the natural history, treatment, and self-management of the disease at least once since the time of diagnosis BECAUSE such education produces improvements in physical functioning and pain.

Supporting Evidence. The literature search identified two meta-analyses (30, 31) and seven reviews (32–38) that addressed the effect of patient education on outcomes among patients with rheumatoid or osteoarthritis. Because these meta-analyses and reviews reported data from more than 60 different reports and came to similar conclusions, only the results from the most recent meta-analysis and the studies included in that report are discussed here.

The most recent meta-analysis, published in 1996, differentiated between trials that were performed in patients with osteoarthritis, those performed among patients with rheumatoid arthritis, and those performed among patients with combined arthritis (30). Nineteen studies were included in the meta-analysis. In 10 of those studies, the study sample exclusively or primarily included patients with osteoarthritis.

The study calculated and reported effect sizes for the effect of patient education on pain and disability. Effect size was calculated as change in the intervention group minus change in the control group divided by the pooled pretreatment standard deviation. Therefore, positive effect sizes indicate that the intervention group had greater improvement in the outcome of interest than the control group; negative effect sizes indicate that the control group had greater improvement than the intervention group. All effect sizes were weighted for sample size. Table 1 summarizes the results of these calculations. No statistically significant differences were seen between the groups.

Table 1. Effect of Patient Education on Pain and Disability among Patients with Arthritis*

Study Type	Pooled Effect Size (95% CI)†	
	Pain	Functional Disability
All studies	0.17 (−0.22 to 0.56)	0.00 (−0.38 to 0.38)
Osteoarthritis studies	0.15 (−0.43 to 0.73)	−0.02 (−0.51 to 0.47)
Rheumatoid arthritis studies	0.18 (−0.28 to 0.64)	0.18 (−0.18 to 0.54)

* Based on reference 30.

† Effect size weighted for sample size. Based on effect sizes calculated separately for each treatment group.

The individual studies reported in this meta-analysis were also reviewed. In each of them, the mean age was older than 60 years. Among the 10 studies pertaining to osteoarthritis (39–48), a total of 20 treatment groups included an education intervention. Pain improved in 13 of these groups and worsened in 7. Disability improved in 11 of these groups, worsened in 7, and was unchanged in 2. In 2 of the studies, the effect of education was confounded by co-interventions, thus making it impossible to definitively attribute the outcome to either intervention (41, 44).

The guidelines for the treatment of osteoarthritis published by the American College of Rheumatology (11, 12) and by the American Board of Family Practice (14) cite education as a nonpharmacologic treatment option, but they do not specifically advocate its use in all patients.

Quality Indicators 7, 8, and 9*First-Line Pharmacologic Therapy*

IF oral pharmacologic therapy is initiated to treat osteoarthritis in a vulnerable elder, THEN acetaminophen should be the first drug used, unless there is a documented contraindication to use, BECAUSE this agent is as effective in treating osteoarthritis as other oral agents, and it is less toxic.

Treatment Failure for First-Line Pharmacologic Therapy

IF oral pharmacologic therapy for osteoarthritis in a vulnerable elder is changed from acetaminophen to a different oral agent, THEN there should be evidence that the patient has had a trial of maximum-dose acetaminophen (suitable for age and comorbid conditions) BECAUSE acetaminophen, in adequate doses, is as effective in treating osteoarthritis as other oral agents, and it is less toxic.

Informing Patients about the Risks of Nonsteroidal Anti-Inflammatory Drugs

IF a patient is treated with a COX nonselective nonsteroidal anti-inflammatory drug (NSAID), THEN there should be evidence that the patient was advised of the risk for gastrointestinal bleeding associated with these drugs BECAUSE this risk is substantial.

Supporting Evidence. Oral agents available to treat osteoarthritis include acetaminophen, NSAIDs, the newly approved COX-2 selective NSAIDs, and opioid analgesics.

Three trials, including one that was published after the panel meeting (49), have compared the efficacy of acetaminophen with nonselective NSAIDs. In one double-blind study (50), 184 patients with osteoarthritis of the knee were randomly assigned to receive acetaminophen, 4000 mg/d; ibuprofen, 1200 mg/d; or ibuprofen, 2400 mg/d. After 4 weeks, Health Assessment Questionnaire (HAQ) pain scores improved by 10% to 12% in all groups ($P < 0.05$). Walking and rest pain improved by 10% to 15% in the ibuprofen groups ($P < 0.05$). Small improvements in the 50-foot walk time and HAQ disability score were observed in the acetaminophen group. However, comparisons of the three treatment groups showed no statistically significant differences in any of the outcome variables except for rest pain; patients treated with ibuprofen, 1200 mg/d, had greater improvement in rest pain than patients taking acetaminophen.

Similar results were reported in a double-blind, randomized, controlled trial that compared the efficacy of naproxen, 375 mg twice daily, with acetaminophen, 650 mg four times daily, among patients with osteoarthritis (51). After 4 weeks of treatment, rest pain had improved 35% in the naproxen group ($P = 0.001$) but had not improved in the acetaminophen group ($P = 0.008$ for between-group comparison). Although improvements in pain on motion, 50-foot walk time, and physician assessment were also reported for the naproxen and acetaminophen groups, no differences between groups were found.

The most recent study (49), a randomized, double-blind, crossover trial, compared the efficacy of the combination of diclofenac and misoprostol, 75 mg and 200 μ g twice daily, and acetaminophen, 1000 mg four times daily, among 218 patients with osteoarthritis. Improvements in pain (measured by WOMAC) and in

function (measured by the modified HAQ) were similar among patients with mild osteoarthritis, but the diclofenac–misoprostol combination was favored for patients with moderate or severe osteoarthritis ($P < 0.001$). No studies that compared the efficacy of acetaminophen and COX-2 selective NSAIDs were found.

Two meta-analyses have addressed the relative efficacy of different nonselective NSAIDs in treating osteoarthritis. One of these meta-analyses focused on studies pertaining to osteoarthritis of the hip (52), and the other focused on studies pertaining to osteoarthritis of the knee (53). Neither meta-analysis could demonstrate differences in efficacy among different traditional NSAIDs.

One study was identified that compared the efficacy of celecoxib, a COX-2 selective NSAID, with that of naproxen in osteoarthritis (54). In this 12-week multicenter trial, 1003 patients with symptomatic knee osteoarthritis were randomly assigned to receive celecoxib (50, 100, or 200 mg twice daily), naproxen (500 mg twice daily), or placebo. Outcomes reported at 12 weeks included pain measured on a visual analogue scale; patient and physician global assessment; the Osteoarthritis Severity Index, which measures pain, walking distance, and activities of daily living; and the WOMAC Osteoarthritis Index, which is composed of items pertaining to pain, stiffness, and physical function. Pain and physical function measures improved significantly in patients treated with celecoxib or naproxen compared with placebo. The celecoxib group and the naproxen group did not differ for any of the outcomes assessed in this study.

No studies were identified that compared the efficacy of opioid analgesics with that of nonselective or COX-2–selective NSAIDs or selective COX inhibitors. However, one randomized, controlled trial was identified that compared opioid analgesics with acetaminophen (55). This study compared the effect of paracetamol with that of paracetamol plus codeine on pain and patient-related global assessment in patients with osteoarthritis of the hip. No statistically significant differences were seen for either variable.

Data on the relative toxicities of traditional NSAIDs come from a large literature. Serious NSAID toxicities, primarily related to gastrointestinal perforations, ulcerations, and bleeding episodes, have been studied in numerous clinical trials, case-control studies, and large population-based cohort studies. Several meta-analyses have evaluated the relationship between NSAIDs and

gastrointestinal perforations, ulcers, and bleeding episodes and have reported similar findings. Among these meta-analyses, one pooled data from 7 cohort and 27 case-control studies and reported that the overall risk ratio for “NSAID-related gastrointestinal tract disease” was 3.5 (95% CI, 2.8 to 4.5) (56). Another meta-analysis reviewed 16 cohort and case-controls studies and reported that the overall pooled odds ratio was 2.74 (CI, 2.54 to 2.97) for serious gastrointestinal complications; among patients 60 years of age and older, the odds ratio was 5.52 (CI, 4.63 to 6.60) (57).

Several studies have evaluated the gastrointestinal toxicities of nonselective NSAIDs specifically in elderly populations. In a nested case-control study of patients at least 65 years of age, Griffin and associates (58) reported that the relative risk for the development of peptic ulcer disease was 4.1 (CI, 3.5 to 4.7) among current users of NSAIDs compared with nonusers. A randomized, controlled trial of the effect of misoprostol on NSAID-related gastrointestinal toxicities also reported data on the risk for NSAID-induced gastrointestinal toxicities among elders (59). This study reported that among patients 75 years of age and older, the odds ratio for the development of serious gastrointestinal events was 2.48 (CI, 1.48 to 4.14) relative to younger patients.

Data from three studies on symptomatic gastrointestinal toxicities of COX-2 selective NSAIDs were reported to the expert panel. Since the panel meeting, two additional studies (60, 61) have been published and are also described here. The first study was a prespecified analysis of eight randomized, double-blind trials that compared rofecoxib with placebo, nonselective NSAIDs (including ibuprofen, diclofenac, and nabumetone), or both for the treatment of osteoarthritis (62). The 3690 patients (67.9%) who completed the primary trials were included in the analysis. In this analysis, the cumulative 12-month incidence of confirmed gastrointestinal perforations, symptomatic ulcers, and upper gastrointestinal bleeding was 1.3% for rofecoxib over 1428 patient-years and 1.8% for nonselective NSAIDs over 615 patient-years ($P = 0.046$) (27% reduction in incidence for rofecoxib compared with naproxen). The rate per 100 patient-years was 1.33 for rofecoxib and 2.60 for the nonselective NSAIDs (relative risk, 0.51 [CI, 0.26 to 1.00]). The drugs differed in cumulative incidence of dyspeptic symptoms at 6 months (23.5% vs. 25.5% [$P = 0.02$] among patients treated with rofecoxib and

those treated with nonselective NSAIDs, respectively) but not at 12 months.

The second study that reported clinical gastrointestinal outcomes for COX-2 selective NSAIDs compared the efficacy of celecoxib, naproxen, and placebo among patients with knee osteoarthritis (54). In this study, the reported incidence of gastrointestinal adverse events was 22%, 24% to 28%, and 32% for patients treated with placebo, celecoxib at various doses, and naproxen, respectively (statistical significance was not reported).

Likewise, the third study was primarily an efficacy study but also reported clinical safety data. In this double-blind, multicenter study, patients with rheumatoid arthritis were randomly assigned to receive celecoxib (100, 200, or 400 mg twice daily), naproxen (500 mg twice daily), or placebo (63). The combined incidence of the most frequently reported gastrointestinal adverse events (dyspepsia, diarrhea, abdominal pain, nausea, and flatulence) was 19%, 25% to 28%, and 31% for placebo, celecoxib, and naproxen, respectively (statistical significance was not reported).

More recently, two large multicenter studies have been reported that were specifically designed to compare the upper gastrointestinal toxicities of COX-2 selective and nonselective NSAIDs. In the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, a multicenter, double-blind trial, 8076 patients with rheumatoid arthritis were randomly assigned to receive rofecoxib (50 mg/d) or naproxen (500 mg twice daily) (60). Aspirin use, including aspirin for cardiovascular prophylaxis, was not permitted. Efficacy and overall mortality were similar for the two agents, but adverse events differed. Higher rates of serious upper gastrointestinal events were seen in the naproxen group, and higher rates of myocardial infarction were seen in the rofecoxib group. During a median follow-up of 9 months, the incidence of serious upper gastrointestinal events (perforations, obstructions, severe bleeding) was 0.6 per 100 patient-years for rofecoxib and 1.4 per 100 patient-years for naproxen (relative risk, 0.4 [CI, 0.2 to 0.8]). The incidence of myocardial infarction was 0.1% in the naproxen group and 0.4% in the rofecoxib group (relative risk, 0.2 [CI, 0.1 to 0.7]).

The Celecoxib Long-Term Arthritis Safety Study (CLASS), a multicenter, double-blind, randomized, controlled trial, evaluated the incidence of symptomatic gastrointestinal ulcers and ulcer complications among

7968 patients with rheumatoid arthritis or osteoarthritis (61). Patients were treated with celecoxib, 400 mg twice daily; ibuprofen, 800 mg three times daily; or diclofenac, 75 mg twice daily for 6 months or longer. Aspirin use for cardiovascular protection was allowed in this study. Among 2244 patients not taking aspirin, the annualized incidence of upper gastrointestinal ulcer complications for celecoxib and the other NSAIDs was 0.44% and 1.27%, respectively ($P = 0.04$); annual incidence of upper gastrointestinal ulcer complications combined with symptomatic ulcers was 1.4% for celecoxib and 2.91% for the other NSAIDs ($P = 0.02$). Among 581 patients who were taking aspirin, those taking celecoxib and those taking other NSAIDs did not differ in annual incidence of upper gastrointestinal ulcer complications alone or combined with symptomatic ulcers.

Neither acetaminophen nor narcotic analgesics are associated with gastrointestinal ulcerations or bleeding episodes. Narcotic analgesics are, however, associated with constipation, sedation, and cognitive impairment.

The American College of Rheumatology guidelines for the medical management of osteoarthritis of the hip and knee state that acetaminophen should be considered the first-line pharmacologic therapy for symptomatic patients (11, 12). The American Board of Family Practice also advocates acetaminophen as the first-line pharmacologic agent for treating osteoarthritis (14).

Quality Indicator 10

Gastrointestinal Prophylaxis with Use of Nonsteroidal Anti-Inflammatory Drugs

IF a vulnerable elder is older than 75 years of age, is treated with warfarin, or has a history of peptic ulcer disease or gastrointestinal bleeding, AND is being treated with a COX nonselective NSAID, THEN he or she should be offered concomitant treatment with either misoprostol or a proton-pump inhibitor BECAUSE this will substantially reduce the risk for NSAID-induced gastrointestinal bleeding.

Supporting Evidence. The literature search identified one trial that assessed the effect of any agent on preventing clinically detectable upper gastrointestinal toxicities from NSAIDs. This large, multicenter, randomized, double-blind, placebo-controlled trial evaluated the occurrence of serious gastrointestinal side effects among nonselective NSAID users who were randomly assigned

Table 2. Effects of Misoprostol and H₂-Receptor Antagonists on the Development of Endoscopic Lesions among Patients Treated with Nonsteroidal Anti-Inflammatory Drugs*

Outcome	Pooled Rate Difference (95% CI), %†	
	Misoprostol	H ₂ -Receptor Antagonists
Duodenal ulcers at 4 weeks	-3 (-0.2 to -5)	-2 (-0.2 to -5)
Gastric ulcers at 4 weeks	-8 (-1 to -18)	-0.9 (-0.4 to 2.2)

* Based on reference 64.

† Compared with placebo.

to receive misoprostol or placebo in addition to their usual nonselective NSAID (59). The 8843 participants (mean age, 68 years) were monitored for gastrointestinal complications. During the 2 years of the study, 25 serious gastrointestinal events were reported among the 4404 patients in the misoprostol group and 42 serious gastrointestinal events were reported among the 4439 patients in the placebo group ($P < 0.05$ for between-group comparisons). Using multiple logistic regression modeling, the study authors evaluated the effects of several patient factors, as well as the effect of treatment, on the risk for serious gastrointestinal events. They identified the following risk factors for gastrointestinal bleeding: 1) age at least 75 years (odds ratio, 2.48 [CI, 1.48 to 4.14]), 2) history of peptic ulcer (odds ratio, 2.29 [CI, 1.28 to 4.12]), 3) history of gastrointestinal bleeding (odds ratio, 2.56 [CI, 1.30 to 5.03]), and 4) history of heart disease (odds ratio, 1.84 [CI, 1.07 to 3.15]). Treatment with misoprostol reduced the risk for serious gastrointestinal events by 40% (odds ratio, 0.60 [CI, 0.36 to 0.98]).

The literature review did not identify any studies that assessed the effect of H₂-receptor antagonists or proton-pump inhibitors on clinically evident gastrointestinal side effects. However, several studies that assessed the effect of these agents on endoscopic outcomes were identified. A meta-analysis, which included 24 clinical trials, assessed the effect of misoprostol and H₂-receptor antagonists on the development of endoscopic lesions among patients treated with nonselective NSAIDs (64). This study demonstrated benefit for misoprostol compared with placebo for the development of endoscopically detected gastric ulcers and duodenal ulcers and benefit for H₂-receptor antagonists compared with placebo for the development of endoscopically detected duodenal ulcers (Table 2).

Table 3. Effects of Omeprazole, Ranitidine, and Misoprostol on Prevalent Gastric and Duodenal Ulcers among Patients Continuously Treated with Nonsteroidal Anti-Inflammatory Drugs: Summary of the Healing Phase Results from ASTRONAUT and the OMNIUM Study*

Variable	ASTRONAUT			OMNIUM Study		
	Omeprazole, 20 mg/d	Omeprazole, 40 mg/d	Ranitidine, 150 mg Twice Daily	Omeprazole, 20 mg/d	Omeprazole, 40 mg/d	Misoprostol, 200 mg Four Times Daily
Success rate, %†	80‡	79‡	63	76	75	71
Gastric ulcer healing rate, %	84‡	87‡	64	87§	80	73
Duodenal ulcer healing rate, %	92¶	88	81	93**	89**	77
Difference between mean dyspepsia rates at 0 and 8 weeks, percentage points	NR	NR	NR	34‡‡	39§§	24

* Based on references 65 and 66. ASTRONAUT = Acid Suppression Trial: Ranitidine versus Omeprazole for NSAID-Associated Ulcer Treatment; NR = not reported; NSAID = nonsteroidal anti-inflammatory drug; OMNIUM = Omeprazole versus Misoprostol for NSAID-Induced Ulcer Management.

† Success = disappearance of ulcers and the presence of fewer than five erosions in the stomach, fewer than five erosions in the duodenum, and not more than mild dyspeptic symptoms.

‡ $P < 0.001$ for comparisons with ranitidine.

§ $P = 0.004$ for comparison with misoprostol.

|| $P = 0.14$ for comparison with misoprostol.

¶ $P = 0.03$ for comparison with ranitidine.

** $P < 0.001$ for comparison with misoprostol.

‡‡ $P = 0.08$ for comparison with misoprostol.

§§ $P = 0.004$ for comparison with misoprostol.

Two randomized, controlled trials with similar designs, the Acid Suppression Trial: Ranitidine versus Omeprazole for NSAID-Associated Ulcer Treatment (ASTRONAUT) (65) and the Omeprazole versus Misoprostol for NSAID-Induced Ulcer Management (OMNIUM) (66) study, described the effect of proton-pump inhibitors on endoscopic ulcers. Each of these studies enrolled patients who required continuous non-selective NSAID therapy and had endoscopic ulcers or more than 10 erosions in the stomach or the duodenum. These studies assessed the effects of omeprazole and ranitidine (65) and omeprazole and misoprostol (66) on the healing of endoscopic ulcers and erosions. In addition, each study assessed whether continued treatment with these agents after successful healing could prevent subsequent endoscopic lesions. In both studies, healing of gastric and duodenal ulcers was demonstrated in more than two thirds of the patients in each study group, although the percentage of patients with healing of gastric or duodenal ulcers was higher for omeprazole than for ranitidine or misoprostol (Table 3). Among patients with healed gastric or duodenal lesions, 50% or more of those treated with omeprazole, ranitidine, or misoprostol remained in remission after 6 months. A significantly greater percentage of patients who received omeprazole remained in remission compared with those who received misoprostol. Patients treated with omeprazole and those treated with ranitidine did not differ

(Table 4). The literature review identified no studies that directly evaluated the relationship between endoscopic lesions and clinical outcomes.

The American College of Gastroenterology recommends the use of misoprostol in patients treated with NSAIDs who are at high risk for hemorrhage or perforation, states that proton-pump inhibitors are an acceptable alternative, and specifically notes that H₂-receptor antagonists cannot be recommended for prophylaxis (67). The American College of Rheumatology guidelines for the medical management of osteoarthritis of the hip and knee note that misoprostol is the only drug approved by the U.S. Food and Drug Administration for prophylaxis against NSAID-induced upper gastrointestinal complications (68). The guidelines also state that there is insufficient evidence to recommend the use of famotidine, nizatidine, or omeprazole as prophylactic agents (69). Of note, however, the ASTRONAUT and OMNIUM trials were published after these guidelines.

Quality Indicator 11

Joint Replacement

IF a vulnerable elder with severe symptomatic osteoarthritis of the knee or hip has failed to respond to nonpharmacologic and pharmacologic therapy and has no contraindication to surgery, THEN the patient should be referred to an orthopedic surgeon to be eval-

Table 4. Effects of Omeprazole, Ranitidine, and Misoprostol on the Recurrence of Gastric and Duodenal Ulcers among Patients Continuously Treated with Nonsteroidal Anti-Inflammatory Drugs: Summary of the Maintenance Phase Results from ASTRONAUT and the OMNIUM Study*

Variable	ASTRONAUT		OMNIUM Study		
	Omeprazole, 20 mg/d	Ranitidine, 150 mg Twice Daily	Omeprazole, 20 mg/d	Misoprostol, 200 mg Twice Daily	Placebo
	← % →				
Remission at 6 months	72	59	61†	48	27‡
Gastric ulcer recurrence	5.2	16.3	13	10	32
Duodenal ulcer recurrence	0.5	4.2	3	10	12

* Based on references 65 and 66. ASTRONAUT = Acid Suppression Trial: Ranitidine versus Omeprazole for NSAID-Associated Ulcer Treatment; NSAID = nonsteroidal anti-inflammatory drug; OMNIUM = Omeprazole versus Misoprostol for NSAID-Induced Ulcer Management.

† $P = 0.001$ for comparison with misoprostol.

‡ $P < 0.001$ for comparisons with omeprazole and misoprostol.

uated for total joint replacement within 6 months unless a contraindication to surgery is documented BECAUSE hip and knee replacements markedly improve function and quality of life by reducing pain and/or improving range of motion.

Supporting Evidence. Numerous studies have demonstrated that total hip and total knee replacements reduce pain and improve function and quality of life. In a meta-analysis of 130 primarily observational studies that reported patient outcomes after tricompartmental total knee replacement, Callahan and coworkers (70) reported significant improvements in global rating scores. The 9879 patients included in this analysis had, on average, a 100% improvement in global rating after the total knee replacement. Depending on the type of prosthesis used, between 86% and 92% of patients reported a good or excellent outcome. The mean complication rate was 18.1%, and the mean mortality rate per year of follow-up was 1.5%.

The literature review identified one study that compared outcomes of total knee replacement among very elderly persons with those among young elders (71). In this study, 50 consecutive patients 80 years of age or older who were undergoing total knee replacement were compared with 50 patients 65 to 69 years of age who had the same diagnosis and who were undergoing the same type of surgery. Hospital for Special Surgery scores, a composite measure of pain, range of motion, and activity, were compared before surgery and at intervals up to 2 years after surgery. Scores did not differ between these age groups at baseline or at any point after surgery.

Another report used a computerized search strategy to identify 20 articles that evaluated health-related quality of life after total hip replacement (72). The authors reported that each of the 20 studies demonstrated beneficial and often dramatic improvement in health-related quality of life after elective total hip replacement. Other studies have reported mortality rates between 0.34% (73) and 0.4% (74) after total hip replacement. The infection rate after primary total hip replacement has been reported to be less than 0.25% (75, 76).

Both the American College of Rheumatology (11, 12) and the American Board of Family Practice (14) recommend referral to an orthopedic surgeon for further evaluation and possible joint replacement if response to medical therapy for osteoarthritis of the knee or hip is inadequate. The National Institutes of Health consensus statement on total hip replacement states that “hip replacement is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment” (77). The orthopedic clinical policies of the American Academy of Orthopaedic Surgeons list pain and functional disability and non-response to medical treatment as indications for knee and hip replacement surgery (29, 78).

DISCUSSION

Osteoarthritis primarily affects older persons and imposes a significant burden on this population. Older patients with osteoarthritis frequently experience substantial variations in processes and outcomes of care (7–9). Improvements in processes of care for this high-risk

population may lead to substantial reductions in disease burden and improvements in patient outcomes. This project investigated the relationship between processes and outcomes of care and aimed to develop explicit criteria to evaluate the quality of care of elderly persons with osteoarthritis. Eleven indicators were judged sufficiently valid for use as measures of quality of osteoarthritis care for vulnerable elders. These indicators can potentially serve as a basis to compare the care provided by different health care delivery systems and to compare the change in care over time.

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