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Improving Treatment Outcomes with a Clinical Pathway for Hysterectomy and Myomectomy

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OBJECTIVE: To determine if using a postoperative clinical pathway for women having hysterectomy or myomectomy would improve clinical care.

STUDY DESIGN: Data from the literature and patient focus groups guided development of a clinical pathway. Nurses, pharmacists and physicians participated in the development process. Implementation relied on accepted quality improvement methods. We used a case-control design to compare administrative and clinical data for patients managed with (n = 28) and without (n = 28) the aid of the clinical pathway between June 1997 and January 1998.

RESULTS: Case and control groups did not differ in age, race, payer status, severity of illness or procedure type. Clinical differences between pathway and nonpathway patients included a mean six-hour-shorter period of indwelling bladder catheters (P = .019), mean 11-hour more rapid return to regular diet (P = .014) and more pain assessments among pathway patients (mean, five vs. two; P < .001). There was no significant difference in length of stay between groups. Clinicians used the pathway for approximately one year, but with personnel changes the pathway gradually fell out of use.

Clinical pathways have the potential to improve quality of care for women having inpatient gynecologic surgery.

CONCLUSION: Clinical pathways can improve quality of care, even if they do not reduce length of stay. A team approach that focuses on patient concerns during pathway development may help ensure that quality improvement, rather than simply cost reduction, arises from the use of clinical pathways. (J Reprod Med 2002;47:999–1003)

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The principles of continuous quality improvement (CQI), or total quality management, are becoming increasingly familiar to physicians. Clinical pathways (sometimes called "critical pathways") are one common example of the increasingly widespread use of CQI techniques in health care.[1,2] Designed to limit variation while ensuring high quality of care, clinical pathways have been used most commonly to control the cost of high-volume procedures.[3] The basic elements of a clinical pathway include a list of tasks to accomplish and the expected dates or times of completion. In industry, the critical path method helps to prevent assembly-line bottlenecks by ensuring the timely completion of scheduled tasks. Health care organizations use pathways to reduce unwanted variation—ensuring, for example, that unneeded laboratory tests are not routinely performed—and to reduce cost.[4] We designed a clinical pathway for the postoperative care of women having hysterectomy or myomectomy with the goal of improving quality of care, not reducing cost. We evaluated the resulting changes in care using a retrospective medical record review.

Materials and Methods

A multidisciplinary group using accepted principles of CQI designed a clinical pathway to improve care and reduce resource use for women having hysterectomies or myomectomies.[5,6] Details of the pathway development process are reported elsewhere.[7] Briefly, direct observation of the gynecology service demonstrated wide variation in care from physician to physician. Discussions with administrators and faculty confirmed their interest in the development of a clinical pathway to address some of these issues. Coincident with this, our hospital sent a multidisciplinary team to a meeting designed to stimulate interest in, and use of, quality improvement techniques in health care. At that meeting, the team decided that care for women having hysterectomies would be a useful place to begin a pilot project using some of the techniques learned at the meeting. The quality improvement team initially comprised three obstetrician-gynecologists, an internist, the director of nursing services, a pharmacist, an administrator and two nurse-specialists. During the nine-month period while the pathway took shape, the team decreased in size to one obstetrician-gynecologist, the pharmacist, one nurse-specialist and the administrator. Changes in team composition substantially delayed the implementation of the project as responsibilities were shifted to the active members.

To develop the pathway, we searched the literature for high-quality, randomized trials related to the care of the postoperative patient. In the absence of randomized trials, we turned to large case series and cohort studies. The initial pathway orders differed from previous practice in three areas. First, a pain control regimen was introduced designed specifically to keep patient self-report of pain < 5 on a 0–10 scale with a minimum of physician intervention. To accomplish this, the frequency of nursing pain assessments was formally stated on the orders, parenteral ketorolac and patient-controlled analgesia (PCA) were used by default, and a rapid changeover from parenteral to oral pain medications was introduced. The pathway also eliminated the clear liquid diet as studies have demonstrated the lack of utility of this step after routine gynecologic surgery.[8,9] Third, early ambulation was encouraged in two ways: specific goals for increasing activity were stated, and urinary catheters were removed within 12 hours of surgery. The clinical pathway was discussed in several faculty forums, and copies were distributed to all physicians, nurses and pharmacists working in the gynecology division for comments. Several of the changes suggested at these forums were incorporated prior to the first use of the pathway.

Beginning in June 1997, selected patients were cared for using the hysterectomy/myomectomy clinical pathway. Patients were eligible for inclusion on the pathway if they had an abdominal hysterectomy or myomectomy after June 1997. We excluded patients who had radical pelvic surgery, bladder procedures or endoscopic procedures. If a patient was eligible for inclusion, the attending gynecologist made the final decision to include her on the pathway protocol.

We conducted a retrospective review of the medical records of patients managed with and without the pathway between its introduction, in June 1997, and January 1998. During this time 35 patients met the above inclusion criteria and were managed with the assistance of the clinical pathway. During this same period, an additional 48 patients had hysterectomy and myomectomy and were not managed with the pathway because they were ineligible (e.g., had radical surgery or concomitant procedures) or because the attending declined. Using an adminis-

trative database, we attempted to identify one matched control for each case patient. We first identified age-matched patients (age within two years of control) who had surgery within 18 months of the cases and had an identical ICD-9 code. We further restricted the list using a previously validated severity adjustment system (Medstat, Medstat Group, Ann Arbor, Michigan).[10] We identified matched controls for 28 of the cases. The seven unmatched patients were not included in the final analysis. We requested and obtained medical records for all case and control patients.

A trained abstractor carried out a structured review of the medical record using a computerized data collection form. The reviewer could not be blinded to the case/control status of the patient. The first author reviewed the first 15% of cases to ensure accurate data collection by the abstractor. Catheter removal times and meal times were abstracted first from nursing notes and, if not found there, from physician notes. Pain assessments were defined as a numerical recording of the patient's pain level using a 0–10 scale (the standard method on the gynecology nursing unit). Since a goal of the pathway was to increase numeric pain assessments, a notation that the patient had or did not have pain, even if descriptive terms were used (e.g., "minimal" or "severe"), was not counted as a "pain assessment." We measured length of stay by comparing the time the patient arrived on the ward (or left the recovery room) to the time of the nursing notation of discharge. We compared outcomes of cases and controls using paired *t* tests and Fisher's exact test. We used multiple regression analysis to model the effect of the various components of the pathway on outcomes. All reported *P* values are for two-sided comparisons. Statistical calculations were performed using SAS statistical software (SAS Institute, Cary, North Carolina). The human subjects protection committee approved the review of medical records.

Table I *Characteristics of Pathway and Control Patients*

Characteristic	Pathway	Control
Age (yr) (mean [range])	41.5 (30–54)	41.9 (30–54)
Mean severity of illness score	81	77
Procedure (%)		
Total abdominal hysterectomy	12	12
Myomectomy	12	12
Supracervical hysterectomy	4	4
Total	28	28

Table II *Postoperative Recovery in Pathway and Control Patients*

Recovery parameter	Pathway (n = 28)	Control (n = 28)	*P* value
Hours to ambulate (mean [SD])	37 (13.4)	32 (13.4)	.33
Hours to regular diet (mean [SD])	32 (15.8)	43 (15.1)	.014
Hours to removal of bladder catheter (mean [SD])	17 (8.9)	23 (10.6)	.019

Results

The success of the matching procedure can be seen in Table I. The mean patient age was 41.5 years in the pathway group and 41.9 in the controls. Mean severity of illness was similar in both groups. The distribution of procedures was the same between groups.

Pathway cases began to ambulate a mean of 37 hours after surgery and control patients at 32 hours ($P = .33$). Patients cared for with the clinical pathway had their urinary catheters removed a mean of six hours sooner than controls ($P = .019$) and tolerated regular diets a mean of 11 hours sooner than controls ($P = .014$) (Table II). Recovery-related complications (e.g., nausea and vomiting, urinary retention) did not differ significantly between the groups. Five of 28 patients (18%) in the control group needed their catheter reinserted as compared to 4 of 28 (14%) in the pathway group ($P = .13$). Four patients in each group (14%) had emesis following a regular diet.

All patients in both groups used PCA. Physicians ordered parenteral ketorolac in 23/28 (82%) pathway patients and 16/28 (57%) control patients ($P = .04$). Numerical assessment of postoperative pain level was significantly greater in the pathway group, with a mean of five numerical assessments in the first 12 hours after surgery, as compared to two in the control group (Table III).

The mean time to discharge was 2.4 days for pathway patients and 2.6 days for control patients ($P = .19$). Pathway treatment might be expected to

Table III *Pain Control in Pathway and Control Patients*

Control	Pathway	Control	*P* value
PCA use (n [%])	28 (100)	28 (100)	0
Ketorolac use (n [%])	23 (82)	16 (57)	.04
Pain assessments (n/12 h) (SD)	5 (3.0)	2 (1.9)	< .001

lead to earlier discharge but did not do so in this sample. To investigate whether certain individual pathway steps were associated with earlier discharge, we created a multiple regression model. To avoid errors due to correlation, we performed this analysis separately for pathway and control patients. In both groups, the speed at which patients began eating regular diets predicted earlier discharge. For each hour earlier a patient ate a regular diet, discharge was 0.56 hours earlier in the control and 0.47 hours earlier in the pathway group. Use of ketorolac was not associated with a statistically significant reduction in length of stay.

In a sensitivity analysis to determine the effects of secular trends in care, we limited the comparison to cases in which the controls had surgery after the introduction of the clinical pathway. A statistically significant difference remained between cases and controls with regard to time until regular diet and time until removal of the urinary catheter. In our regression model, date of surgery did not predict length of stay among either pathway or control patients.

Discussion

Using accepted quality improvement techniques for designing and implementing the pathway, we successfully decreased the time until patients tolerated regular diets, removed urinary catheters more rapidly and increased the number of pain assessments in the first 12 hours after surgery. We had hoped to decrease the pain score reported by patients after surgery, but we did not find pains scores to be recorded frequently enough for us to evaluate a change in this measure. The increase in the number of pain assessments is a necessary, but not sufficient, step toward improving pain control and represents a more-than-twofold increase in the number of pain assessments.

A lack of statistically significant reduction in length of stay (LOS) may not be surprising as the pathway design focused on clinical factors designed to improve care and reduce variation, not on early discharge. Our regression model demonstrated that clinical differences (particularly early refeeding) were predictive of shortened length of stay. With a sample size of 28 patients in each group, we had limited power (.32) to detect a difference in LOS of 0.24 days (5.8 hours) with $\alpha = .05$.

Flexibility in the design and modification of the pathway was crucial to its initial acceptance. We relied on input from patients (obtained in structured focus group discussions), nurses and physicians in the design of the pathway. During the testing phase, we recorded variances in care. Based on these variances and on discussions with faculty and nurses, we modified the pathway several times during the first months of use. We expected changes to occur and therefore routinely printed only enough pathway materials to last two to four weeks. This flexibility ensured that implementation took place "in deed" and not just in word. Finally, as Shortell has demonstrated, institutional support, both administrative and philosophical, was crucial in allowing the process to move forward.[11]

The primary limitations of this study are the lack of randomization and the small sample size. Pearson and others have pointed out the relative absence of randomized trials examining CQI techniques like clinical pathways.[12,13] Some have argued that randomized trials are most appropriate when "clinical equipoise" exists—when clinicians have no basis for believing one treatment to be superior to another—and the introduction of well-accepted interventions (use of PCA, early ambulation) may not require randomized trials.[14] Nonetheless, a randomized trial would have eliminated the potential for biased assignment to pathway or control group. We attempted to control for the most likely potential biases (e.g., inclusion of less ill patients in the pathway group, differences in age or procedure) by matching using a severity adjustment system.

The improvements we produced involved both nursing and physician care and resulted from a multidisciplinary, collaborative effort backed by an administrative quality improvement support system. We have found that effort must be continuously focused on educating resident staff to the use of quality improvement techniques, or pathway use declines as residents change services.

Clinical pathways have the potential to improve quality of care for women having inpatient gynecologic surgery. Pathway use should be encouraged even if it does not reduce length of stay.

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