Prospective Cost Analysis of Moxalactam versus Clindamycin plus Gentamicin for Endomyometritis after Cesarean Section

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The direct and indirect costs associated with either moxalactam or clindamycin plus gentamicin as treatment for endomyometritis after emergent cesarean section were compared in an open, randomized prospective trial of 114 patients. A total of 58 patients were assigned to receive moxalactam, 2 g intravenously (i.v.) every 8 h for 5 doses, followed by 2 g every 12 h and prophylactic vitamin K (10 mg) intramuscularly, and 56 patients were assigned to receive clindamycin (600 mg) i.v. every 6 h plus gentamicin (1.5 mg/kg) i.v. every 8 h. Prothrombin times were measured in moxalactam-treated patients, and patients treated with clindamycin plus gentamicin had urinalyses and blood urea nitrogen and serum creatinine determinations performed before and after treatment. Also, gentamicin levels in serum were determined as clinically indicated. A satisfactory treatment response was defined as the resolution of signs and symptoms of endomyometritis within 3 days of the start of antibiotic therapy. Satisfactory responses were demonstrated in 78% of the moxalactam-treated patients and 84% of patients treated with clindamycin plus gentamicin. Mean hospital costs for laboratory tests ($30.30 versus $4.53) and mean patient charges for laboratory tests ($76.39 versus $27.81) and medications ($559.45 versus $421.82) were significantly higher in patients treated with clindamycin plus gentamicin (P < 0.05), while mean medication costs to the hospital were greater in the moxalactam group ($255.47 versus $195.68; P < 0.05). However, total patient charges and total hospital drug-associated costs were not significantly different for the two groups. In this study, moxalactam was similar in efficacy and, despite its higher acquisition cost, was comparable in total hospital costs and patient charges to clindamycin plus gentamicin in treating endomyometritis.

Selection of antibiotic therapy is based on several considerations, including variations in bacterial susceptibility, clinical efficacy, toxicity, and cost. With the advent of cost containment programs, such as prospective reimbursement, use of the most cost-effective therapeutic drug regimens is becoming increasingly important to health care providers who must evaluate not only drug costs but also the total institutional cost of treating patients.

The availability of certain high-cost agents, such as broad-spectrum cephalosporins and extended-spectrum penicillins, has been restricted in many institutions because of their high acquisition costs relative to those of other antibiotics and antibiotic combinations (2). However, for drug regimens of comparable efficacies, objective comparisons that take into account only net acquisition cost and not the indirect costs associated with preparation, administration, monitoring, and treatment of drug toxicity can be misleading as a measure of the cost of therapy (4, 15, 17–19; M. Dudley, S. L. Barriere, and J. Mills, Letter, N. Engl. J. Med. 307:689, 1982; P. R. Murray and A. O’Byrne, Letter, N. Engl. J. Med. 306:226, 1983). It has been shown that drug administration costs alone can have a substantial impact on hospital operating expenses (7).

Moxalactam and the combination of clindamycin plus gentamicin have demonstrated efficacy in the treatment of mixed aerobic-anaerobic pelvic infections (1, 3, 5, 6, 9–11, 13, 16; Dudley et al., Letter). This study was undertaken to evaluate prospectively the comparative direct and indirect costs of these antibiotics in patients with postcesarean endomyometritis.

MATERIALS AND METHODS

The study was performed at a 540-bed university teaching hospital from January to December, 1984. Informed consent was obtained prior to participation in the study.

The criteria for participation of patients was clinical evidence of post-cesarean section endomyometritis, based on an oral temperature greater than 38°C and uterine tenderness, often with foul lochia. Patients allergic to penicillin or any of the study antibiotics were ineligible, as were patients experiencing only a single temperature elevation. Prophylactic administration of antibiotics prior to cesarean section did not preclude enrollment of any patient into the study.

Eligible patients were examined, and both peripheral venous blood cultures and uterine cultures (via transcervical catheter) were obtained. According to a randomization schedule, patients were assigned to treatment with either moxalactam (2 g, intermittent intravenous [i.v.] infusion every 8 h) for five doses, followed by 2 g every 12 h, or clindamycin (600 mg, intermittent i.v. infusion every 6 h) plus gentamicin (1.5 mg/kg, intermittent i.v. infusion every 8 h). In view of potential bleeding disorders associated with moxalactam, patients assigned to this regimen were given vitamin K (10 mg) intramuscularly prior to starting therapy. By usual hospital policy, the assigned medications were reconstituted by a nurse at the bedside of the patient. All medications were administered through an in-line volume control set (Buretrol system); the volume control and i.v. administration sets were changed daily. i.v. catheters were changed every 48 to 72 h or earlier, as needed.

Baseline laboratory values included a complete blood
count for all patients. Prothrombin times were determined in moxalactam-treated patients before and after therapy. Laboratory tests performed before and after treatment for patients assigned clindamycin plus gentamicin were a urinalysis and determinations of blood urea nitrogen and serum creatinine. Routine monitoring of gentamicin concentrations in serum was not performed for all patients receiving the aminoglycoside in this study. Aminoglycoside-level monitoring was indicated during the study, however, if the patient: (i) was >30% above ideal body weight, (ii) had a baseline serum creatinine of >1.2 mg/dl, (iii) had a poor clinical response, (iv) was on aminoglycoside therapy for more than 8 days, or (v) had bacteremia or was in septic shock. In monitored patients, peak gentamicin concentrations in serum of 5 to 10 μg/ml and trough concentrations of less than 2 μg/ml were goals of therapy.

Patient responses were judged as either satisfactory, clinical failure, or adverse effect failure. A satisfactory response was defined as the resolution of symptoms and a decline in fever and leukocyte count within 3 days of starting antibiotics. If a satisfactory response occurred, the same regimen was continued for a total of at least 5 days. Both clinical and adverse effect failures were unsatisfactory responses. The patient response was judged to be a clinical failure if there was an inadequate response or if additional antibiotics were required to effect a cure. Patients experiencing untoward reactions that resulted in a change in the initial antibiotics were judged to be adverse effect failures.

Patients having an unsatisfactory response were re-cultured prior to a change of therapy. Patients initially treated with moxalactam were empirically changed to a combination of clindamycin, gentamicin, and penicillin G (5 × 10^6 U i.v. every 6 h) if they had an unsatisfactory response. For the group of patients that failed clindamycin-plus-gentamicin treatment, penicillin G (as above) was added to the regimen. One month after hospital discharge, all patient records were screened to determine patient readmission to the hospital. Since study patients were predominantly indigent and the study hospital was the only hospital for indigent patients in the city, it was assumed that most patients would return to the institution if delayed complications of therapy occurred.

Analysis of the various cost parameters was performed and included the cost of laboratory monitoring, the cost of medication, and the cost of the i.v. solutions and supplies. A summary of both costs to the hospital and charge to the patient per item is presented in Table 1. All costs to the hospital were based on actual contract costs to the institution. Patient charges were based on actual charges at the time of the study; specifically, Blue Cross reimbursement fees were used to calculate medication charges.

Nursing time involved in preparation and administration of the medications was calculated based on a prestudy time-and-motion evaluation. Values of $1.05 per dose of moxalactam, $0.42 per dose of vitamin K, $0.49 per dose of gentamicin, $0.46 per dose of clindamycin, $0.98 per dose of penicillin, and $1.54 per angiocatheter insertion were used to calculate nursing labor cost. Pharmacy labor cost was included as part of the medication charge to the patient, since the pharmacy was not directly involved in preparing the medication. A hospital bed charge of $131.00/day was assessed during the postoperative period.

Total hospital cost was calculated by adding the cost for laboratory tests, medications, and supplies and nursing labor cost for antibiotic preparation and administration. The total patient charge was calculated by adding the patient charges for laboratory tests, medications, supplies, and hospital stay. Statistical analysis of continuous data was performed using an unpaired two-tailed Student’s t test, and discrete data were analyzed by the chi-square test with correction for continuity (alpha = 0.05).

**RESULTS**

Of the 114 patients enrolled in this study, 58 patients were initially assigned to moxalactam therapy and 56 patients were initially assigned to treatment with clindamycin plus gentamicin. The mean age (± standard deviation) of the moxalactam group (23.8 ± 5.3 years) did not differ from that of the clindamycin-plus-gentamicin group (23.8 ± 5.8 years). Patients in the moxalactam group had a mean weight of 76.6 (± 21.8) kg; this was not statistically different from that of the clindamycin-plus-gentamicin group of patients (72.2 ± 15.8 kg). Similar percentages of patients in each group received prophylactic antibiotics (33% in the moxalactam group versus 38% in the clindamycin-plus-gentamicin group). Of the 40 patients receiving prophylaxis, the majority received either a cephalosporin (n = 22) or ampicillin (n = 16).

No significant difference in organisms isolated from endometrial cultures was noted for the two groups. The most common isolates in uterine cultures were *Bacteroides bivius* (44%), enterococci (29%), *Escherichia coli* (18%), *Klebsiella pneumoniae* (17%), group B streptococci (14%), and anaerobic streptococci (14%).

Bacteremia was detected in five patients (9%) in the moxalactam group (group B streptococci, two patients; *Staphylococcus aureus*, one patient; enterococcus, one patient; and *Streptococcus viridans*, one patient) and in four patients (7%) in the clindamycin-plus-gentamicin group (*E. coli*, two patients; group B streptococci, one patient; and *Clostridium sp.*, one patient). Clinical outcomes were not significantly different for the two regimens (Table 2), and the mean hospital stay was the same for both groups (6.6 days).

Of the 12 clinical failures in the moxalactam group, 4 were due to wound infections and 3 were associated with enter-
cocc. In five cases, no specific cause was evident. In the seven clindamycin-plus-gentamicin clinical failures, one was due to wound infection, two were associated with enterococci, and in four, no cause was evident. In all cases of initial treatment failure, change in antibiotic therapy or wound drainage as indicated produced clinical cures.

Adverse reaction failures occurred in three patients overall. In the moxalactam group, a rash in one patient resulted in discontinuation of initial therapy. The two adverse reaction failures that occurred in the clindamycin-plus-gentamicin group were due to pruritis. The three cases of apparent allergic reactions (rash and pruritis) were mild and self-limited. No significant prolongation of the prothrombin time or bleeding complications occurred in the moxalactam group. Evaluation of patient records 1 month following hospital discharge indicated no delayed complications in any study patient.

Mean hospital costs per patient are summarized in Table 3. The mean medication acquisition cost was significantly greater for the moxalactam group, while the mean laboratory costs were significantly greater for the clindamycin-plus-gentamicin group. The latter reflects the monitoring necessary for surveillance of aminoglycoside efficacy and toxicity. Only 10 gentamicin concentrations in serum were determined for patients originally assigned to the clindamycin-plus-gentamicin group; 7 of these were determined for patients who had satisfactory responses. Two aminoglycoside concentrations were determined for patients treated with gentamicin after they initially failed moxalactam therapy.

The mean hospital costs for supplies and nursing labor were not significantly different between the two groups. The supply costs were similar, because the in-line burettes and administration sets were changed daily and the mean hospital stays were the same for both groups. Although more time was required to prepare moxalactam than the other antibiotics, similar nursing labor costs were seen between the two groups. This occurred because the difference in moxalactam preparation time was offset by preparation of a total of seven antibiotic doses per day in the clindamycin-plus-gentamicin group compared with only three doses per day in the moxalactam group. The mean total hospital costs were not significantly different between the two groups, indicating that the greater medication cost in the moxalactam group was offset by the additional laboratory tests necessary to monitor aminoglycoside toxicity in the clindamycin-plus-gentamicin group.

Charges to the patient are summarized in Table 4. Mean laboratory charges and medication charges were significantly higher for the clindamycin-plus-gentamicin group (P < 0.05). The higher medication charge reflects a hospital charge of approximately $10.00 above acquisition cost per antibiotic dose for each antibiotic in this group. Personnel time required for interpretation and adjustment of aminoglycoside levels in serum was not included in the laboratory charge to the patient. If this cost was included, the laboratory charges would be even greater for patients in the clindamycin-plus-gentamicin group.

**DISCUSSION**

In a time of increasing emphasis on cost containment, the need for clinical, pharmacokinetic, toxicologic, and comprehensive cost data in making therapeutic decisions is evident. This is particularly true for antibiotics, which account for up to 30% of total hospital drug costs (21). In recent years, the number of extended-spectrum penicillins and cephalosporins marketed in the United States has increased significantly. On a net acquisition cost basis, these antibiotics are generally more expensive to use than older agents. Many hospitals continue to place significant emphasis on the acquisition cost when making decisions regarding inclusion of antibiotics with similar spectra of activity and efficacies in the institutional formulary. Little consideration is given to the indirect costs associated with preparation, administration, and monitoring, which are also important components of the total cost of therapy.

Numerous investigators acknowledge that cost is an important consideration when selecting appropriate antibiotic therapy (4, 15, 17-19; Dudley et al., Letter; Murray and O'Byrne, Letter). However, few studies have specifically evaluated both direct and indirect costs of therapies, including personnel costs, supply costs, and differential laboratory and pharmacokinetic monitoring. Particularly lacking are data collected prospectively in a relatively homogeneous environment.

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**TABLE 2. Clinical outcome for patients with endometritis treated with either moxalactam or clindamycin plus gentamicin**

| Clinical outcome                      | No. (%) of patients |
|--------------------------------------|---------------------|
|                                      | Moxalactam | Clindamycin + gentamicin |
| Satisfactory response                | 45 (78)     | 47 (84)                 |
| Unsatisfactory response              |             |                        |
| Clinical failure                     | 12 (21)     | 7 (13)                  |
| Adverse reaction failure              | 1 (2)       | 2 (3)                   |

* Mean hospital stay for moxalactam group, 6.6 ± 2.2 days (3 to 13 days). Mean hospital stay for clindamycin-plus-gentamicin group, 6.6 ± 1.9 days (4 to 14 days). No significant difference was found in the clinical outcomes of patients treated with moxalactam or clindamycin plus gentamicin.

**TABLE 4. Summary of mean patient charges ($) associated with moxalactam and clindamycin-plus-gentamicin therapy**

| Variable            | Patient charges ($) of therapy (mean ± SD) |
|---------------------|--------------------------------------------|
|                     | Moxalactam | Clindamycin + gentamicin |
| Laboratory          | 27.81 ± 9.39* | 76.39 ± 17.42*          |
| Medications         | 421.82 ± 247.25* | 539.45 ± 229.41*        |
| Supplies            | 305.92 ± 126.67 | 327.04 ± 109.58         |
| Hospital bed        | 869.57 ± 282.67 | 860.86 ± 252.12         |
| Total patient charges| 1,625.12 ± 611.11* | 1,803.74 ± 552.84*      |

* P < 0.05.  
* No significant difference in total patient charges was found when only treatment failures in the moxalactam and clindamycin-plus-gentamicin groups were evaluated ($3,684.48 ± 1,178.57 and $3,436.83 ± 1,779.79, respectively).
population, such as cesarean section patients with endomyometritis.

In a retrospective study, Rapp et al. (17) demonstrated that single-agent therapy with a cephalosporin is less expensive than combination therapy that included an aminoglycoside. These data suggest that dose frequency and agent toxicity (which determines laboratory monitoring costs) can influence the total cost of antibiotic therapy.

Based on results from a cost-simulation study, Dudley et al. (Letter) suggest that patient charge, not acquisition cost, should be the basis for cost comparison. Although patient charge for medication often includes pharmacy time involved in preparation of that agent, administration costs and laboratory costs are usually not included. Similar cost simulation analyses performed by other investigators also demonstrate that factors such as dose frequency and the formula used to calculate patient charges for preparation and administration can affect the cost of antibiotic therapy (15; Murray and O'Byrne, Letter).

Scheife et al. (18) reported that the cost for cefoxitin was significantly lower than for clindamycin plus an aminoglycoside in treating mixed aerobic-anaerobic infections in a prospective randomized trial. These investigators used the price allocation method for determining patient charge for medications and did not include monitoring or administration costs in their analysis. Schentag et al. (19) found no difference in drug costs between moxalactam given three times daily and combination therapy with tobramycin and clindamycin for treating abdominal sepsis. Although the cost of fluid administration sets was included in their analysis, the costs for tobramycin-level determinations, prothrombin times, and nursing and pharmacy time were not considered.

In a recent randomized study, Crots et al. (4) compared the costs of prophylactic therapy with moxalactam given every 12 h to those of gentamicin plus clindamycin for patients with penetrating abdominal trauma. Total cost of therapy included drugs, laboratory tests, personnel time, and supplies. These investigators demonstrated that although mean drug costs were similar for the two treatment groups, the mean total cost of therapy was $30.00/day higher for combination therapy than for moxalactam therapy when personnel time and laboratory and supply costs were added to medication costs.

Gill et al. (12) evaluated the cost of cefoxitin versus clindamycin-plus-gentamicin therapy in a retrospective analysis of 75 patients treated for perforated bowel secondary to abdominal stab wounds. Although the mean drug acquisition cost was higher for the cefoxitin group, overall drug therapy-related costs that included costs of supplies, administration, and pharmacokinetic and laboratory monitoring were significantly higher in the clindamycin-plus-gentamicin group.

In a prior study of postcesarean endomyometritis, Gibbs et al. (11) demonstrated similar cure rates for moxalactam (2 g i.v. every 8 h) and clindamycin (600 mg i.v. every 8 h) plus gentamicin (1 mg/kg i.v. every 8 h) in a double-blind randomized trial (89 versus 91%, respectively). In another double-blind randomized trial, Sweet et al. (20) reported equivalent responses for patients treated with either moxalactam or clindamycin plus tobramycin in a variety of obstetric and gynecologic infections. Our results also confirm that moxalactam is comparable to the combination of clindamycin plus gentamicin in treating postcesarean section endomyometritis; however, the cure rate for both treatment groups was lower than previously reported (11). The reason for these differing rates is not entirely clear, as the patient populations, entry criteria, and criteria for cure versus failure were similar. Although this was not significantly different, enterococci were more common in this series than in the earlier one (29 versus 22%). In addition, wound infections were a more common cause of antibiotic failure in this study (five cases versus one case).

Given the differences in cure rates between the drug regimens found in this study and a 5% significance level, approximately 2,000 patients would have been required to have a power of 80%. It is doubtful that a 6% difference in cure rates would be considered clinically significant, even if shown to be statistically significant in such a situation.

Our study demonstrates no significant difference in total cost of combination treatment with an aminoglycoside and clindamycin versus single-agent therapy with moxalactam for patients with endomyometritis. Since the difference in total hospital costs and total patient charges between treatment groups was approximately 10%, a much larger study population would have been necessary to demonstrate statistical significance. For these variables in the current study, the beta error was greater than 50%. However, had statistical significance been shown, we believe it would be of limited relevance in selection of one regimen over the other.

Despite the greater acquisition cost of moxalactam, the hospital cost for this broad-spectrum cephalosporin is offset by the cost of pharmacokinetic monitoring of the aminoglycoside and the additional preparation time for combination therapy. In recent years, administration of clindamycin, 600 or 900 mg every 8 h, rather than 600 mg every 6 h, has been increasingly used. If such a regimen had been used in this study, daily drug acquisition cost and charge to the patient would have been reduced for the 600-mg dosage regimen by $11.09 and $21.75, respectively, and for the 900-mg regimen by $0.15 and $1.04, respectively.

Although controversy concerning the appropriate monitoring schedule for aminoglycosides exists (8), some investigators may consider that our monitoring procedure (serum creatinine, blood urea nitrogen, urinalysis, and aminoglycoside levels) included some unnecessary tests. Omission of any of these tests would result in lower laboratory costs and charges for patients treated with clindamycin plus gentamicin. For example, if we had included only the aminoglycoside levels and serum creatinine concentrations in our assessments, the mean hospital cost for laboratory tests with combination therapy would be $10.71. This is still higher than laboratory costs associated with moxalactam therapy. In contrast, the mean patient charge would be $24.04, which is lower than the respective laboratory charge for moxalactam therapy. The lower charge reflects a relatively higher patient charge for a prothrombin time compared with that for a serum creatinine.

As a result of the relative lack of risk factors for aminoglycoside toxicity in the study subjects, the short-term nature of the course of therapy, and the lack of severe infections requiring more aggressive therapy, only 12 aminoglycoside-level determinations were performed during this study. If routine aminoglycoside-level determinations had been required in our study, the laboratory costs for the clindamycin-plus-gentamicin group would be higher, and the differences between the two treatment groups in terms of cost and hospital charge would have been greater.

It has been demonstrated previously that in-line i.v. volume control sets are less expensive to use than piggyback administration sets when total personnel and supply costs are considered (14). Administration costs are particularly minimized when in-line burettes are used for patients receiving multiple-dose combination therapy, since the amount of
supplies used daily is independent of the number of daily doses of the medication. If another administration method had been used in this study, supply costs would have been proportionally greater for combination therapy, resulting in a greater cost difference between the two treatment regimens.

In this study, we demonstrated that moxalactam is similar in efficacy and, despite its higher acquisition cost, comparable in total hospital costs and patient charges to the combination of clindamycin plus gentamicin in treating patients with endomyometritis after cesarean section. Because of reported coagulopathies, moxalactam is used less widely now in comparison with other newer cephalosporins. However, this study provides pertinent data applicable in estimating the cost of therapy with other broad-spectrum cephalosporins. This is particularly true for agents that have pharmacokinetics similar to those of moxalactam and that also have been found to be therapeutically equivalent to clindamycin plus gentamicin in a variety of pelvic infections (e.g., cefoperazone, cefotaxime, and cefotetan).

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