

The Journal welcomes Letters to the Editor. If found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with Journal style.

PROSTAGLANDIN AND INDUCTION OF LABOR

To the Editor:

Clarification is needed for those wishing to use prostaglandin E₂ in a clinical or research setting as described by Smith et al (Smith MA, Swan L, Caruthers BS, Heaton C: *Outpatient use of prostaglandin gel for ripening of the cervix and induction of labor. J Fam Pract* 1990; 30: 656-664). What was the usual dose of prostaglandin administered? It appears that 5-mL syringes containing 2 mg of prostaglandin were used. However, in the "recipe" described ("grinding a whole 20-mg suppository . . . and mixing it with 100 mL of sodium carboxymethylcellulose 2% gel), the concentration of prostaglandin would only be about 0.2 mg/mL or 1 mg/5-mL syringe.

Both dosage levels may be safe, but for comparisons with other studies, it is essential that this information be clearly stated.

John V. Jurica, MD
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The preceding letter was referred to Dr Smith and colleagues, who respond as follows:

A clarification was requested on the preparation of the prostaglandin E₂ gel used in our study. While it is correctly stated that the dose per gel was 2 mg/5 mL, the description of the gel preparation should have stated that two whole 200-mg suppositories are mixed with 100 mL of sodium carboxymethylcellulose 2% gel. The authors also appreciate and endorse the Commentary by Dr Steven Eisinger that accompanied our paper, and his cautionary note to physicians regarding the nonapproved status of prostaglandin gel for cervical ripening. Patients should be so informed

and further studies should be encouraged so that the safety and efficacy for both inpatient and outpatient use can be determined.

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To the Editor:

The series reported by Smith et al on outpatient use of prostaglandin gel in the June issue of the Journal was of great interest.¹ However, Dr Eisinger's commentary merits a response. He makes the appropriate point that additional larger studies of prostaglandin gel for ripening of the cervix need to be conducted, and he goes on to suggest breast stimulation and laminiaria as "nonpharmacologic" alternatives in the interim. He further comments that "safety, although always an issue, appears to be good" and suggests that breast stimulation can be applied by the patient at home.

A search of AMANET using key words "nipple stimulation" revealed 15 articles, four of which detailed serious or potentially serious problems with nipple stimulation. One of the articles described a case of placental abruption,² and the other three articles described hyperstimulation.³⁻⁵ Hill et al found that hyperstimulation was present in 45% of patients and noted that 21% of these had significant fetal bradycardia. His group concluded that "there is a relatively high incidence of exaggerated uterine activity in response to the breast stimulation stress test and close surveillance of mother and fetus are warranted during antepartum nipple stimulation."⁵

These studies would cast some

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WARNINGS: **Gastrointestinal effects:** Risk of GI ulcerations, bleeding and perforation with nonsteroidal anti-inflammatory therapy. Serious GI toxicity can occur at any time, with or without warning symptoms, during chronic treatment. The occurrence is about 1% after 3-6 months, 2-4% after a year. Patients should be informed of signs and symptoms of serious GI toxicity and what to do if it occurs. No subset of patients not at risk has been identified. Prior history of serious GI events and other risk factors of peptic ulcer disease, e.g., alcoholism, smoking, etc., have been associated with increased risk. The elderly and debilitated tolerate ulceration and bleeding less well. Higher doses probably carry a greater risk. GI ulceration and bleeding can occur without warning symptoms and chronically treated patients should be followed.

PRECAUTIONS: **Patients with impaired renal or hepatic function:** Use ANSAID and similar agents cautiously. Pharmacokinetics have not been studied in patients with decreased liver function.

Renal Effects: Rats develop renal papillary necrosis at dosages equivalent to human therapeutic levels, as do monkeys given 20-40 times the human dose. In clinical studies of ANSAID, kidney function tests were done monthly and renal effects were similar to those seen with other nonsteroidal anti-inflammatory drugs. A second form of renal toxicity has been seen in patients with prerenal conditions that reduce renal blood flow or blood volume. A nonsteroidal anti-inflammatory drug may cause dose-dependent reduction in prostaglandin formation and precipitate overt renal decompensation. Patients at greatest risk are those with impaired renal or hepatic function, heart failure, those taking diuretics or the elderly. Drug discontinuation usually leads to recovery. Patients at high risk on chronic treatment should have renal function monitored if they have signs or symptoms that may be consistent with mild azotemia, e.g., malaise, fatigue, loss of appetite. Occasionally BUN and serum creatinine may be elevated without signs or symptoms. Flurbiprofen is excreted by the kidneys and pharmacokinetics are changed by renal failure so patients with renal failure should be monitored and may require a reduction of dosage to avoid accumulation of flurbiprofen metabolites.

Liver tests: Borderline elevations of liver function tests may occur in up to 15% of patients, and may progress, remain unchanged or disappear with continued treatment. Patients with signs and/or symptoms or with an abnormal liver function test should be evaluated further.

Anemia: Patients treated long term who have initial hemoglobin values under 10 g/dL, should have periodic hemoglobin values.

Fluid retention and edema: Fluid retention and edema have been reported so use ANSAID with caution in patients with conditions such as cardiac decompensation or hypertension.

Vision Changes: Blurred and/or diminished vision has been reported. Patients with eye complaints should have periodic ophthalmologic exams.

Effect on platelets and coagulation: Platelet aggregation is inhibited and bleeding time prolonged; patients who may be adversely affected should be carefully observed.

Information for patients: Physicians and patients may wish to discuss potential risks and likely benefits.

Drug Interactions: **Anticoagulants:** Bleeding parameters are affected, clinical bleeding has been reported. **Aspirin:** Flurbiprofen levels were 50% lower. Concurrent use is not recommended. **Beta-adrenergic Blockers:** Pharmacokinetics and heart rate reduction are not affected; hypotensive effect of propranolol but not atenolol was attenuated. **Omeprazole:** Omeprazole causes a 13% increase in area under the flurbiprofen serum concentration curve. **Diuretics:** Patients receiving furosemide or thiazides should be closely observed to make sure the desired effect is obtained.

Carcinogenesis, mutagenesis, impairment of fertility: No evidence.

Teratogenic effects: **Pregnancy category B:** No effect in animals. Not recommended for use in pregnancy.

Labor and delivery, nursing mothers, pediatric use: Use is not recommended.

ADVERSE REACTIONS: 9.4% of 4123 patients dropped out of studies because of an a.d.r. **Incidence >1%:** **Gastrointestinal:** Dyspepsia*, diarrhea*, abdominal pain*, nausea*, constipation, GI bleeding, indigestion, elevated liver enzymes and vomiting. **Central nervous system:** Headache*, stimulation* (e.g., anxiety, insomnia, reflexes increased, tremor) and "inhibition" (e.g., amnesia, asthenia, somnolence, malaise and depression). **Respiratory:** Rhinitis. **Dermatologic:** Rash. **Special senses:** Dizziness, tinnitus and changes in vision. **Genitourinary:** Signs and symptoms suggesting a urinary tract infection* **Body as a whole:** Edema* **Metabolic/nutritional:** Body weight changes. *Reaction in 3 to 7% of patients.

Incidence <1% (Causal relationship probable): **Gastrointestinal:** Peptic ulcer disease (See Warnings), gastritis, bloody diarrhea, stomatitis, esophageal disease, hematemesis and hepatitis, cholestatic and non-cholestatic jaundice. **Central nervous system:** Ataxia, cerebrovascular ischemia, confusion, paresthesia and twitching. **Hematologic:** Decrease in hemoglobin and hematocrit, iron deficiency anemia, leukopenia, eosinophilia and ecchymosis, thrombocytopenia, hemolytic anemia and aplastic anemia. (See Precautions) **Respiratory:** Asthma and epistaxis. **Dermatologic:** Angioedema, urticaria, eczema and pruritus, photosensitivity, toxic epidermal necrolysis and exfoliative dermatitis. **Special senses:** Conjunctivitis and parosmia. **Genitourinary:** Hematuria and impairment of renal function, interstitial nephritis. **Body as a whole:** Anaphylactic reactions, chills, fever. **Metabolic/Nutritional:** Hyperurcemia. **Cardiovascular:** Heart failure, hypertension, vascular disease and vasodilatation.

Incidence <1% (Causal relationship unknown): **Gastrointestinal:** Periodontal abscess, appetite changes, cholecystitis and dry mouth. **CNS:** Convulsion, meningitis, hypertension, cerebrovascular accident, emotional lability and subarachnoid hemorrhage. **Hematologic:** Lymphadenopathy. **Respiratory:** Bronchitis, laryngitis, dyspnea, pulmonary embolism, pulmonary infarct, hyperventilation. **Dermatologic:** Alopecia, nail disorder, herpes, dry skin and sweating. **Special senses:** Ear disease, corneal opacity, glaucoma, retrobulbar neuritis, change in taste, transient hearing loss, retinal hemorrhage. **Genitourinary:** Menstrual disturbances, vaginal and uterine hemorrhage, vulvovaginitis, prostate disease. **Metabolic/Nutritional:** Hyperkalemia. **Cardiovascular:** Arrhythmias, angina pectoris and myocardial infarction. **Musculoskeletal:** Myasthenia.

DOSE AND ADMINISTRATION: 200 to 300 mg daily, administered bid, tid or qid. (Most experience in rheumatoid arthritis has been with tid or qid dosing). Dose should be tailored to severity of symptoms and patient response.

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doubt on safety of breast stimulation performed at home in an attempt to ripen the cervix, although undoubtedly couples have been doing it for centuries before the issue of the unripe cervix ever arose. Laminaria, although nonpharmacologic, are certainly not what our patients would describe as noninvasive.

On the basis of the case series of Smith et al, as well as other reports in the literature, prostaglandin gel instilled in a hospital setting with monitoring for perhaps 1 hour after application certainly seems an appropriate choice for the physician who is wondering what to do until trials comparing the various methods can be carried out.

Owen Panner, Jr., MD
Alturas, California

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2. Taylor RN, Green JR: Abruptio placentae following nipple stimulation. *Am J Perinatol* 1987; 4:94-97
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AMNIOTOMY AND DURATION OF LABOR

To the Editor:

In his study on amniotomy,¹ Dr Franks states that there has been only one previous randomized trial² examining the effect of amniotomy on the length of labor. Wetrich,³ however, conducted a randomized study in which he compared amniotomy with no amniotomy during labor at 6-cm dilatation. Patients whose membranes were ruptured had a 60-minute

average shortening of their remaining first stage of labor. Dr Franks showed a 155-minute shortening, but he measured from randomization to delivery, and the amniotomy was done earlier (3- to 6-cm dilatation).

Areas of further study might include the effect of amniotomy before 3-cm dilatation both in labor and not in labor. Also, in Dr Franks' study it would be helpful to know whether the membranes were ruptured in the active or latent phase of labor. This information could be determined retrospectively by examining the Friedman labor curves.

John W. Ely, MD
Columbia, Missouri

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1. Franks P: A randomized trial of amniotomy in active labor. *J Fam Pract* 1990; 30:49-52
2. Stewart P, Kennedy JH, Calder AA: Spontaneous labor: When should the membranes be ruptured? *Br J Obstet Gynaecol* 1982; 89:39-43
3. Wetrich DW: Effect of amniotomy upon labor: A controlled study. *Obstet Gynecol* 1970; 35:800-806

The preceding letter was referred to Dr Franks, who responds as follows:

I am grateful to Dr Ely for pointing out an additional randomized study examining the effect of amniotomy on labor. The omission resulted from my enclosure in the time capsule imposed by computerized literature searches. Regarding his additional points: amniotomy has been found to be more efficacious than oxytocin in labor induction¹; and we are unable to examine the modifying effect of the phase of labor on amniotomy since we do not construct labor curves.

Peter Franks, MD
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Reference

1. Bakos O, Backstrom T: Induction of labor: A prospective, randomized study into amniotomy and oxytocin as induction methods in a total unselected population. *Acta Obstet Gynecol Scand* 1987; 66:537-541

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care physicians would also find this approach useful in their practices.

Charlotte Levine, MD
Penslow Medical Center
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FAMILY FOLDERS

To the Editor:

Concerning the article "Is It Worthwhile to File by Family Folders in Family Practice?" (*Farley ES: An affirmative view. Schneeweiss R: An opposing view. J Fam Pract 1990; 30:697-703*) by Farley and Schneeweiss, I have written to you about this before, and I will say it again: I have been teaching family medicine residents for nearly 20 years, and every single physician who has practiced with me for periods of 2 to 6 weeks has been both intrigued and sometimes even excited by our family filing system. Some who have gone on to group practices have changed the filing systems there, and their colleagues have agreed that it is superior to file by family. Forgetting all the philosophical and pedagogical arguments, family physicians should file by family for several important reasons:

It is simpler.

It is faster.

It is cheaper.

It is more convenient.

It takes less space.

There are over 5000 patients in this solo practice and there is no way I shall ever again file by individual patient. Unless someone has personally worked with both systems, he should restrain his comments, intellectualism and logic notwithstanding.

There is a rejoinder: It is difficult to file by family in an institutional setting. The true efficacy of the system manifests itself best in small group or solo practices. We tried (heroically) in Harvard's family medicine pro-

gram some 20 years ago, but it was too cumbersome in spite of a relatively small group (five family physicians) and adequate secretarial help.

As for Dr Schneeweiss's comments about the Society of the Teachers of Family Medicine Records Committee and family medicine textbooks not recommending filing by family, a good portion of these physicians are institutionally based and their preferences are thus institutional. I believe it is imperative that we teach residents the organizational strength of filing by family. That is very difficult to do in a teaching hospital, where filing by individuals is more efficacious.

A dilemma.

Eugene Guazzo, MD
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The preceding letter was referred to Dr Schneeweiss, who responds as follows:

I appreciate the comments made by Dr Guazzo and am impressed with his conviction that for him as a solo practitioner filing by family folders is the only way to file his patients' records. I do wonder whether his assertion that family filing is simpler, faster, cheaper, more convenient, and takes less space would hold up to close scrutiny.

As one who has indeed used both systems extensively, I would be hard pressed to back up the above assertions with facts. It may be that it is impossible to prove them, and physician satisfaction is the only measure of the value of family filing—but even that has not yet been studied. Certainly there are no published articles that I am aware of that support the idea that family filing is simpler, faster, cheaper, more convenient, and takes less time. I would encourage those of my colleagues who have the interest in the topic to demonstrate those assertions to be true.

We should be willing to subject all

our cherished beliefs to the test of objective study and live with the results. I agree with Dr Guazzo that in the residency the difficulties of setting up filing by families is compounded and may be impractical. That was certainly our experience at the University of Washington.

I would be less sanguine than Dr Guazzo about discounting the absence of any mention about family filing by the STFM Records Committee. We have to ask why it is that the idea of filing by families has not yet captured the imagination and commitment of our colleagues.

A dilemma indeed.

Ronald Schneeweiss, MD
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To the Editor:

I was horrified to learn of the large number of family practice residencies that do not file charts in family folders. Of course, I realize that many physicians do not use genograms on a regular basis (unfortunately), but having all household charts in a simple folder provides very important opportunities for preventive care (not to mention preventing the physician from appearing foolish by forgetting important information about the family group). Well-child care provides me with the perfect setting in which to check on the parents' contraceptive choices and how they are working out. I find this particularly important for teenage mothers in whom the rate of repeat early pregnancies is unacceptably high. Numerous other examples of "windows of opportunity" spring to mind.

"True worth is in being" . . . but I don't see how we can "be" attentive to the family without a tool as basic as family charting.

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