

Letters to the Editor

Low Back Pain and Case Control Studies

To the Editor:

I write this letter in regard to the article by Becker and Karch (*Becker LA, Karch FE: Low back pain in family practice: A case control study. J Fam Pract 9:579, 1979*). I raise the following points in order that future investigators using such a methodology are aware of their importance.

The first point deals with a basic flaw in the investigators' data collection on psychological problems. The null hypothesis tested in this study is that there is no association between low back pain and the prevalence of selected psychological problems. Had the null hypothesis been rejected in this study, it can be assumed that the authors would have proposed a potential causal relationship between psychological problems and low back pain. However, the investigators fail to inform the readers of the time sequence between the onset of back pain and the onset of psychological problems. This information is crucial if we are to distinguish between mere "association" and "causation." I refer readers who are interested in further details concerning "causation" and "association" to the classic work by MacMahon and Pugh.¹

A second and paramount point



for discussion is the inferences drawn by the investigators. The authors correctly point out that a causal relationship may exist, even though they did not detect an association. They point to underdiagnosis and the age groups which they studied as potential sources of error. An additional point which the authors of this and other studies should consider is the concept of "power." Power, which is a statistical concept, deals with the probability of rejecting the null hypothesis when it is false; and should not be confused with the "P-value" usually shown in published tables. The latter concept defines the probability of rejecting the null hypothesis when it is true.

The importance of the power of a study enters when one is considering whether "statistical significance" was not reached because of a small sample size. Unfortunately, this consideration usually takes place following the completion of the study, when nothing can be done about it. In the present study (Table 4), there was a tendency for an increase in the presentation of psychological symptoms in the LBP cases (relative risk estimate = 1.6). However, statistical significance was not reached. This may, in part, be attributed to the fact that it

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would have required approximately 600 cases and 600 controls to be 90 percent sure of rejecting the null hypothesis under similar circumstances (power = 0.90). Therefore, the authors should have included an inadequate sample size among their reasons for not detecting an association.

I refer future investigators to Schlesselman² for tables on a priori determination of sample size.

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References

1. MacMahon B, Pugh TF: Epidemiology: Principles and Methods. Boston, Little, Brown, 1970
2. Schlesselman JJ: Sample size requirements in cohort and case-control studies of disease. *Am J Epidemiol* 99:381, 1974

To the Editor:

I'm uncomfortable with the conclusion of Becker and Karch (*Low back pain in family practice: A case study. J Fam Pract* 9:579, 1979) that young women with low back pain "are no more likely to have psychological problems than similar patients who do not have low back pain."

First, low back pain is a symptom, not a diagnosis. Their patient population (retrospective review of ICHPPC 7289) appears to be heterogeneous. It seems likely that they included some women with chronic back syndromes, some with acute self-limited myofascial strains, and a miscellaneous category such as those who were later found to have urinary tract infection or the early stages of major organic disease.

Secondly, the authors indicate that their study patients visited their center significantly more often than matched controls. This in itself is suggestive evidence of behavioral difficulty manifested by dependent behavior, whether or not diagnoses of anxiety and/or depression were recorded.

The overall concept of the study, using matched controls, is commendable. Perhaps the authors could re-evaluate their data excluding patients with other than chronic backache, and include sick role behavior among the behavioral problems to be enumerated.

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The preceding letters were referred to Drs. Becker and Karch who respond as follows:

We are pleased to note that Dr. Shear must first put words into our mouths before finding anything to criticize about our conclusions. In a chart review study such as the one we performed, it is often impossible to obtain precise information about the onset of the symptoms under study. We would therefore most certainly have been in error if we had claimed to have clearly demonstrated that psychological problems cause back pain. However, in the practice of medicine, the knowledge that strong association exists may be extremely useful even before the precise causal relationships have been worked out. We felt that there would be important implications

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Warnings: Use with special caution in young children, because of variable response, and with extreme caution in patients with cirrhosis and other advanced hepatic disease or abnormal liver function tests, because of possible hepatic coma. Diphenoxylate HCl may potentiate the action of barbiturates, tranquilizers and alcohol. In theory, the concurrent use with monoamine oxidase inhibitors could precipitate hypertensive crisis. In severe dehydration or electrolyte imbalance, withhold Lomotil until corrective therapy has been initiated.

Usage in pregnancy: Weigh the potential benefits against possible risks before using during pregnancy, lactation or in women of childbearing age. Diphenoxylate HCl and atropine are secreted in the breast milk of nursing mothers.

Precautions: Addiction (dependency) to diphenoxylate HCl is theoretically possible at high dosage. Do not exceed recommended dosages. Administer with caution to patients receiving addicting drugs or known to be addiction prone or having a history of drug abuse. The subtherapeutic amount of atropine is added to discourage deliberate overdose; strictly observe contraindications, warnings and precautions for atropine; use with caution in children since signs of atropinism may occur even with the recommended dosage. Use with care in patients with acute ulcerative colitis and discontinue use if abdominal distention or other symptoms develop.

Adverse reactions: Atropine effects include dryness of skin and mucous membranes, flushing, hyperthermia, tachycardia and urinary retention. Other side effects with Lomotil include nausea, sedation, vomiting, swelling of the gums, abdominal discomfort, respiratory depression, numbness of the extremities, headache, dizziness, depression, malaise, drowsiness, coma, lethargy, anorexia, restlessness, euphoria, pruritus, angioneurotic edema, giant urticaria, paralytic ileus, and toxic megacolon.

Dosage and administration: Lomotil is contraindicated in children less than 2 years old. Use only Lomotil liquid for children 2 to 12 years old. For ages 2 to 5 years, 4 ml. (2 mg.) t.i.d.; 5 to 8 years, 4 ml. (2 mg.) q.i.d.; 8 to 12 years, 4 ml. (2 mg.) 5 times daily; adults, two tablets (5 mg.) t.i.d. to two tablets (5 mg.) q.i.d. or two regular teaspoonfuls (10 ml. 5 mg.) q.i.d. Maintenance dosage may be as low as one fourth of the initial dosage. Make downward dosage adjustment as soon as initial symptoms are controlled.

Overdosage: Keep the medication out of the reach of children since accidental overdosage may cause severe, even fatal, respiratory depression. Signs of overdosage include flushing, hyperthermia, tachycardia, lethargy or coma, hypotonic reflexes, nystagmus, pinpoint pupils and respiratory depression which may occur 12 to 30 hours after overdose. Evacuate stomach by lavage, establish a patent airway and, when necessary, assist respiration mechanically. A narcotic antagonist may be used in severe respiratory depression. Observation should extend over at least 48 hours.

Dosage forms: Tablets, 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. Liquid, 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of 1/2 ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

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for the investigation and treatment of patients with back pain if we had been able to demonstrate a strong association with psychological problems. We therefore limited our discussion to the question of whether or not an association existed without proposing any specific causal model.

Having taken us to task for conclusions we did not draw, Dr. Shear next criticizes us for not having done the impossible. He suggests that before starting the study we should have used the results of the study to calculate the optimal sample size. Unfortunately, the "relative risk estimate" of 1.6 calculated by Dr. Shear from our data was not available at the time we were planning our study. We were therefore forced to make our decision on the basis of the findings of other authors. From Gilchrist's¹ data for female patients in his general practice, it is possible to calculate a "relative risk estimate" of 4.0 for back pain in patients with psychological problems. Barton² found that psychological problems occurred eight times more frequently in his patients with back pain than in his total patient population. According to Schlesselman's formulae, our sample size would allow a 90 percent probability of detecting a relative risk of 3.3 or greater. Schlesselman points out that because of the greater efficiency of matched designs such as ours, use of his formulae tend to overestimate the necessary sample size in this type of study.³ We therefore cannot agree that our sample size was inadequate to support our conclusion that we were unable to demonstrate "the strong association with psychological problems suggested in other

studies of low back pain in the family practice setting."

The comments of Dr. Gillette reinforce our belief that many aspects of the problem of low back pain merit further study. Our patients were not as heterogeneous a group as one might expect. When we reviewed the diagnostic impression listed in the charts, 18 patients had "back strain," 16 had muscle pain or muscle spasm, and for 16 of the patients no etiologic explanation was attempted. In only one patient was the final diagnosis unrelated to the musculoskeletal system (premenstrual syndrome). There were only 9 patients who had chronic backache. Thus, the great majority of our patients had back pain due to acute musculoskeletal syndromes. We chose not to limit our study to patients with chronic backache because it represents a much smaller proportion of the problem as seen from the primary care perspective than do the acute syndromes exhibited by the majority of patients in our sample.

The question of sick role behavior and its relationship to back pain is a fascinating one. It, unfortunately, could not be adequately investigated by our design since entries in patients' charts do not reliably contain this type of information. Some people tolerate far more discomfort than others before consulting a physician, and it is reasonable to expect that patients who consult with relatively commonly experienced symptoms such as backache may represent a group which is more liberal in its use of physician services. It is not clear, however, that this necessarily represents excessive dependency or behavioral problems. In fact, the

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The safety of topical steroids in pregnant women has not absolutely been established. In laboratory animals, increases in incidences of fetal abnormalities have been associated with exposure of gestating females to topical corticosteroids, in some cases at rather low dosage levels. Therefore, drugs of this class should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time.

SYNEMOL® (fluocinolone acetonide) cream is not for ophthalmic use.

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The effectiveness of Valium (diazepam) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

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Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms (similar to those with barbiturates and alcohol) have occurred following abrupt discontinuance (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other antidepressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. *Adults:* Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. *Geriatric or debilitated patients:* 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) *Children:* 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

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different consulting rates may not represent a behavioral difference at all. It may be that patients who experience back pain represent a group which has more illness than patients who never get back pain. Further studies are obviously needed.

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2. Barton JE, Haight RO, Marsland DW, et al: Low back pain in the primary care setting. *J Fam Pract* 3:363, 1976
3. Schlesselman JJ: Sample size requirements in cohort and case-control studies of disease. *Am J Epidemiol* 99:381, 1974

Medical Education and the National Health Service Corps To the Editor:

As a recipient of a National Health Service Corps Scholarship for the last three years, it was with great interest that I read Roger Rosenblatt's essay, "Family Medicine and the National Health Service Corps" in the September 1979 issue (*J Fam Pract* 9:507, 1979).

I believe that payment for educational expenses is not the sole incentive for most of us who receive such scholarships. If that were so, we could have easily taken out loans. I sincerely believe that the

idealism and altruism that attract most individuals to the medical profession also play an integral role in enticing students to the NHSC program since it offers the opportunity to satisfy the need we all have to feel that we are making a significant contribution to society.

I agree wholeheartedly with Dr. Rosenblatt when he writes, "Family medicine has a stake in making the program [NHSC] work. . . . By working with these students . . . we can equip them for their future roles and maintain their enthusiasm and interest." Unfortunately, the present state of medical education, including family practice departments, is guilty of just the opposite. Many physicians and medical students feel that NHSC scholarship recipients have "sold out" and make no effort to hide their feelings. Furthermore, they blunt our enthusiasm by decrying practices in areas unequipped with elaborate equipment or facilities. They tell us that it is suicide, if not a downright impossibility, to be a solo practitioner. Yet many of those in the NHSC will practice in backward areas or by themselves. Such attitudes, when expressed by teachers and role models, are not only disheartening but very destructive.

I cannot agree more strongly with Dr. Rosenblatt that medical educators have a critical role to play in shaping the NHSC program. Whether the NHSC becomes a significant force in meeting the health needs of underserved areas or just another example of federal ineptitude rests largely on the attitudes and concern of medical educators.

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