PREDICTING ACUTE MAXILLARY SINUSITIS

TITLE: Predicting acute maxillary sinusitis in a general practice population
AUTHORS: Hansen JG, Schmidt H, Rosborg J, Lund E
JOURNAL: *British Medical Journal*
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Clinical questions. **Do any signs or symptoms have diagnostic value in patients suspected to have acute maxillary sinusitis? Are the erythrocyte sedimentation rate (ESR) and C-reactive protein useful diagnostic tests in patients suspected of having acute maxillary sinusitis?**

Background. Previous investigators have found that a history of purulent secretions (especially unilateral), unilateral maxillary pain, a lack of response to decongestants or antihistamines, and purulent secretions on examination can help distinguish between acute maxillary sinusitis and other upper respiratory tract infections.[1,2] Imaging studies, such as plain radiography, computed tomography, ultrasonography, and magnetic resonance imaging, are of diagnostic value but are often unavailable in office settings and are expensive. Our current understanding of clinical predictors of sinusitis may be flawed because most prior studies of acute maxillary sinusitis have been done in referral populations or have not used an appropriate reference standard for diagnosis.

Population studied. Consecutive patients aged 18 to 65 years who presented to eight general practices in Aalborg, Denmark, and who were suspected of having acute maxillary sinusitis were invited to participate. Patients were excluded for pregnancy, previous surgery of the maxillary sinuses, malignant disease of the ear, nose or throat, current antibiotic treatment, collagen vascular disease, treatment with steroids, or immunotherapy. Of 282 potential subjects, 24 did not meet the study criteria, 53 declined participation, and 31 patients changed their minds during the study (probably because of fear of antral puncture) and were withdrawn from analysis. The 31 patients did not differ significantly from the participants in sex, median age, symptoms, signs, and laboratory test results. The final sample had a median age of 35, and 70% were women.

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Study design and validity. This is a cross-sectional descriptive study, a proper design for evaluating the sensitivity and specificity of signs, symptoms, and laboratory tests. The authors used an appropriate diagnostic reference standard of antral puncture, aspiration, and culture. The sample for this study was drawn from Northern European general practices, so the results probably have good generalizability for white North Americans. The statistical analysis is sound, although the cutoff *P* value of .05 is somewhat high for a study making this many comparisons; with 23 predictor variables, it is possible that some may be related to sinusitis by chance alone.

Outcomes measured. Predictor variables measured included the signs and symptoms thought to be associated with acute maxillary sinusitis, the erythrocyte sedimentation rate (ESR), and the C-reactive protein.

Results. Of 21 signs and symptoms studied, only unilateral facial pain (odds ratio 1.9, 95% confidence interval [CI], 1.0 to 3.4) and maxillary toothache (odds ratio 1.9, 95% CI, 1.0 to 3.5) were significantly more common in patients with acute maxillary sinusitis than in those without. C-reactive protein and ESR were both significant predictors when the cutoff value for C-reactive protein was 10 mg/L and the cutoff for the ESR was 10 for men and 20 for women. These were the only significant independent predictors of sinusitis in the logistic regression. The table includes a summary of test characteristics.

The authors conclude, incorrectly, that clinical examination is "more or less worthless," and that the ESR and/or C-reactive protein are useful tests for sinusitis. Of all of the patients presenting with upper respiratory infection symptoms, which is the true denominator for this question, the authors have neglected that the clinicians were correct for 53% of the patients they suspected had acute sinusitis and referred to the investigators! That is a positive predictive value of 0.53 for clinical signs alone, compared with 0.76 for clinical signs plus ESR and 0.68 for clinical signs plus C-reactive protein. I am not convinced that these small increments justify testing. I would happily treat an extra one in five patients with antibiotics to spare all of them testing. Also, the negative predictive values of both tests are quite low: 0.62 for the ESR and 0.66 for C-reactive protein. This means that more than one third of those with negative tests will truly have sinusitis but will not receive needed treatment. In the sample studied, 22% of the 174 patients would have had a false-negative ESR and would have been denied needed treatment. Of course, patients not suspected by the clinicians of having sinusitis were not referred and, hence, were not

Table. A Summary of Test Characteristics from a Study Predicting Acute Maxillary Sinusitis

Test	Sensitivity	Specificity	Predictive Value of a Positive Test	Predictive Value of a Negative Test
Clinical examination alone	NA	NA	0.53	NA
Clinical examination + ESR + C-reactive protein	0.82	0.57	0.68	0.74
Clinical examination + ESR	0.56	0.80	0.76	0.62
Clinical examination + C-reactive protein	0.74	0.60	0.68	0.71

NA denotes that the value could not be calculated from the available data; ESR, erythrocyte sedimentation rate.

enrolled in the study. Therefore, this study does not address the issue of false-negative clinical diagnosis of sinusitis.

Recommendations for clinical practice. **My interpretation of this study supports the work of Williams and colleagues[2]: when clinicians suspect acute maxillary sinusitis, they are often correct. The ESR and C-reactive protein are not accurate enough to be useful diagnostic tests for sinusitis. If you and your patients do not mind treating two patients with antibiotics to benefit one, treat empirically based on the results of a careful history and physical examination.**

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CHOLESTEROL-LOWERING AGENT IN MEN WITHOUT CHD

TITLE: Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia
AUTHORS: Shepherd J, Cobbe SM, Ford I, et al
JOURNAL: *The New England Journal of Medicine*
DATE: November 16, 1995; 333:1301–7

Clinical question. **Can we improve survival in patients without known coronary heart disease (CHD) by using a cholesterol-lowering agent (pravastatin)?**

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Background. Cholesterol-lowering agents have been known for some time to reduce the risk of myocardial infarction (MI), but the cardiac benefits in previous studies have been counterbalanced by significant increases in deaths from other causes, resulting in no net improvement in the survival of treated patients. Recently, the Scandinavian Simvastatin Survival Study (*Lancet 1994; 344:1383–9*) showed improved 5-year survival in men aged 35 to 70 years with known coronary heart disease, but convincing evidence has been lacking that patients without known cardiac disease would receive similar benefits from treatment with hydroxy-methylglutaryl CoA (HMG-CoA) reductase inhibitors.

Population studied. Subjects were 6595 men in Western Scotland, 45 to 64 years of age, with a total cholesterol level of 272 mg/dL (minimum 251 mg/dL), a mean low-density lipoprotein (LDL) cholesterol of 192 mg/dL (minimum 155 mg/dL and maximum 232 mg/dL), and a mean high-density lipoprotein (HDL) cholesterol of 44 mg/dL. Only men without a history of MI were eligible, but 5% of the subjects had stable angina. Forty-four percent of the subjects were current smokers, 34% were ex-smokers, 15% reported hypertension, and mean alcohol consumption of the study participants was 11 drinks per week. This is clearly a high-risk group for myocardial infarction.

Study design and validity. This was a well-designed and well-executed study. Subjects were randomly assigned to take pravastatin 40 mg each evening or an identical-appearing placebo and were followed for 5 years. The baseline characteristics of the treatment and placebo groups were nearly identical. Subjects were seen every 3 months and both groups received the same intensity of clinical evaluation. No patients were lost to follow-up and the analysis was intention-to-treat, ie, the subjects were analyzed in the group to which they were randomly as-

signed. The latter is important because ignoring patients who drop out of the study could make the treatment look better than it actually is.

Outcomes measured. The primary endpoint was nonfatal MI or death from CHD. The investigators also analyzed deaths from noncardiac causes and compared overall survival among the treatment and placebo groups.

Results. In the placebo group, 7.9% of the men suffered a nonfatal MI or death from CHD, compared with 5.5% in the group receiving pravastatin. The number needed to treat (NNT) is the most appropriate statistic for practitioners to use in judging the magnitude of a treatment effect, and these percentages correspond to an NNT of 42; ie, we would need to treat 42 men for 5 years to prevent one MI or CHD death. The cardiac benefits were similar in men with multiple CHD risk factors: 12.7% in the placebo group vs 10.2% in the pravastatin group had a cardiac event, corresponding to an NNT of 40. Deaths from noncardiac causes were similar in the two groups. Elevations of hepatic enzymes and creatine kinase were similar to those seen in other studies, dropout rates were similar in treatment and placebo groups, and no serious side effects were reported. Overall, the 5-year mortality rate was reduced in the men receiving pravastatin: 4.1% vs 3.2%, corresponding to an NNT of 111.

Recommendations for clinical practice. **This study complements the recent Scandinavian Simvastatin Survival Study by demonstrating that pravastatin reduces both the number of MIs and deaths from CHD in hyperlipidemic men and slightly improves overall 5-year survival. The benefits and risks of pravastatin therapy over the longer term are unknown and the costs are considerable (more than $100 per month per patient). The situation in women remains much less certain. This study did not include women, and while the Scandinavian Simvastatin Survival Study showed a reduced rate of coronary events, it also found a small (not statistically significant) decrease in overall survival among women treated with simvastatin. There remain insufficient data to recommend cholesterol-lowering agents for patients greater than 70 years of age who have no known coronary artery disease.**

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CONSERVATIVE TREATMENT OF PROSTATE CANCER

TITLE: Long-term survival among men with conservatively treated localized prostate cancer
AUTHORS: Albertson PC, Fryback DG, Storer BE, Kolon TF, Fine J
JOURNAL: *JAMA*
DATE: August 23, 1995; 274:626–31

Clinical question. **Do men between the ages of 65 and 75 years with conservatively treated localized prostate cancer live longer than the general population?**

Background. One of the most controversial dilemmas faced by primary care physicians is whether to screen for prostate cancer. As if this controversy were not enough, we face the additional problem of which treatment, if any, to offer patients once prostate cancer is diagnosed! The literature to date fails to provide support in favor of screening or early aggressive treatment. Decision analyses[1] show that the magnitude of benefit does not appear to outweigh the additional morbidity and cost of screening. A Swedish study[2] found that once prostate cancer has been diagnosed, "watching and waiting" is a reasonable option. This study, however, has been criticized because the patients studied were older, it used cytology to confirm the diagnosis, and the sample included a large number of men with low-grade tumors. Finally, an analysis of men with localized prostate cancer found that men receiving therapeutic interventions actually experienced a poorer disease-specific quality of life.[3]

Population studied. The current study included all men in the Connecticut Tumor Registry (CTR) who were between the ages of 65 and 75 and had localized prostate cancer initially diagnosed between 1971 and 1976. Men were excluded from the study if the diagnosis was made at autopsy (n = 58), if the tumor was an incidental finding during cystectomy (n = 5), or if they had undergone radical prostatectomies (n = 111). Men were also excluded if their medical records were unavailable (n = 158) or incomplete (n = 7), if their initial treatment could not be determined (n = 3), or if the diagnosis could not be confirmed by either pathology report or review of the original slides (n = 19). After exclusions, the authors analyzed results from 451 men. It should be noted that the men in this study had diagnostic tests for prostate cancer on the basis of either a palpable nodule or prostatic

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hypertrophy because prostate-specific antigen (PSA) testing was not available at the time of their initial diagnoses (1971–76).

Study design and validity. This is a retrospective cohort study. After identifying the subjects through the CTR, the hospital records were abstracted and pathology specimens or reports reviewed. Death certificates were reviewed and the cause of death was recorded for all patients identified by the CTR as deceased. The staff who abstracted the records and the pathologist who reviewed the slides and reports were blind to the status of the subject. The authors then performed survival analyses for subgroups of men. Finally, the authors used standard life tables to compare the survival in the subjects with the age-adjusted survival rate for the general population.

Outcomes measured. The primary outcome measure was survival. Because survival is determined by many factors, the authors looked at confounders, such as age at diagnosis, race, year of diagnosis, method of diagnosis, results of metastatic evaluations, and initial treatment (immediate or delayed hormonal therapy). The authors also measured the number and severity of comorbid conditions, and a pathologist assigned a Gleason score to each subject. (A Gleason score is a numeric rating of histopathologic features of prostate tissue. On a scale of 0 [benign] to 10 [anaplastic], the score correlates to tumor aggressiveness.[4,5]) Death certificates were used to identify the cause of death.

Results. The mean age at diagnosis for the 451 men was 70.9 years. The authors were able to follow the subjects for an average of 15.5 years, 40 (9%) of whom were still alive at the time of last contact. Among the deaths, 154 (34%) were attributed to prostate cancer, 221 (49%) were attributed to other causes, and for 36 (8%), no cause was identified. Hormonal therapy was started immediately in 202 men and the remaining 249 men received no therapy during the first 3 months after diagnosis.

The age-adjusted survival for men with low-grade disease (Gleason score of 2 to 4) was not significantly different from that of the general population. As severity of disease increased, survival rate declined. The most powerful predictors of survival were tumor grade and comorbid conditions. Unfortunately, the authors do not directly address the impact of early vs delayed treatment on survival.

Recommendations for clinical practice. **The incidence of prostate cancer and the rates of prostate surgery have risen since the 1980s. Much of the increase in radical prostatectomy rates occurred among older men. Since the authors excluded men receiving prostatectomy, we should be cautious about extrapolating the results to today's practice. Nonetheless, the results of this paper support the notion that conservative therapy without surgery or radiation is a reasonable option for older men with low-grade prostate cancer (Gleason score 2 to 4).**

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PAP SMEARS AFTER HYSTERECTOMY

TITLE: Cytologic screening after hysterectomy for benign disease
AUTHORS: Piscitelli JT, Bastian LA, Wilkes A, Simel DL
JOURNAL: *American Journal of Obstetrics and Gynecology*
DATE: August 1995; Volume 173:424–32.

Clinical question. **Are Papanicolaou (Pap) smears necessary after hysterectomy for benign disease?**

Background. Vaginal Pap smears after hysterectomy are recommended by the American College of Obstetricians and Gynecologists (ACOG) based on a patient's risk factors, but ACOG does not address either specific risk factors or screening intervals. The US Preventive Services Task Force did not address this topic, and the Canadian Task Force on Cervical Cancer Screening Programs determined that women did not need vaginal cytologic screening after undergoing hysterectomy. Screening for a disease should be based on evidence that (1) the disease is common enough or serious enough to warrant screening, (2) a diagnostic test has the ability to accurately detect the disease, and (3) better outcomes are obtained for those with early detection over those without screening.

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Population studied. Charts were reviewed from 733 women with a history of a hysterectomy who received care at an academic obstetrics and gynecology practice. Patients' average age was 39 years at the time of hysterectomy, with a standard deviation of 9.2 years. Further information regarding sociodemographic characteristics of the population is not given. Subjects were excluded if they had a history of invasive gynecologic malignancy prior to hysterectomy or no vaginal smears obtained after hysterectomy. There were 697 remaining eligible charts. Sixty-five women had a history of prior cervical cytopathologic abnormalities.

Study design and validity. The follow-up averaged 13.7 years per patient. There were 1266 Pap smears performed, with a mean of 1.8 per patient. The time from hysterectomy to first and subsequent cytologic examinations varied. This simple and inexpensive research design seems sufficient to document clinical effectiveness of screening, the likelihood of detecting a significant vaginal lesion, and the extent of downstream testing likely to occur to follow up abnormal cytologic results. It has, however, the weaknesses of an observational study without the gold standard testing of experimental vs control groups (ie, randomization of patients to those screened and not screened). Survival analysis statistics were applied to this cohort to determine "time to failure," defined as presence of an abnormal vaginal smear.

Outcomes measured. The principal outcome was abnormal vaginal cytologic findings. Proof of dysplasia by biopsy was considered to be the gold standard even though biopsy was not universally performed. Biopsy was performed selectively to patients with abnormal cytologic results only as deemed necessary by the attending physician.

Results. There were 33 cases (4.7%) of abnormal Pap smear findings. Seven were reported with mild dysplasia, two with moderate dysplasia, one with severe dysplasia, and the remainder with atypia. No cases of cancer were detected. Seven patients underwent biopsy. One patient with mild dysplasia was found to have mild dysplasia on biopsy. One patient with moderate dysplasia on cytologic testing declined further investigation and was asymptomatic at the close of the study period. Biopsy of the other patient with moderate dysplasia showed normal tissue. The patient with severe dysplasia was found on biopsy to have mild dysplasia. Thus, only 6% of patients with abnormal cervical cytologic findings were ultimately shown to have mild to moderate dysplasia on biopsy. Women with a history of cervical cytologic abnormalities prior to hysterectomy were 4.67 times more likely to have abnormal vaginal cytologic results (95% confidence interval, 2.1 to 10.6). Patients with gynecological symptoms at the time of cytologic examination were no more likely than symptom-free women to have abnormal vaginal cytologic findings. The survival analysis with an endpoint of abnormal vaginal Pap smear is meaningless in this study since the abnormalities were of questionable clinical significance.

Recommendations for clinical practice. **The burden of proof for implementing a clinical policy for screening is evidence that an accurate test is able to detect disease in a way that leads to improved patient-oriented outcomes. Vaginal cytologic testing for women who have undergone hysterectomy for benign disease fails to meet this criterion. In this study, vaginal cytologic examination resulted in abnormal test results in over 4% of women, potentially leading to more invasive testing, anxiety for the patient, and increased cost without documented benefit. The authors recommend that vaginal cytologic screening should be performed every 10 years for women without prior cervical abnormalities and every 5 years for women with prior cervical disease, but this recommendation is not supported by the study results.**

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EPIDURAL ANALGESIA IN LABOR

TITLE: Randomized trial of epidural versus intravenous analgesia during labor
AUTHORS: Ramin SM, Grambling DR, Lucas MJ, Sharma SK, Sidawi JE, Leveno KJ
JOURNAL: *Obstetrics and Gynecology*
DATE: November 1995; Volume 86:783–89

Clinical question. **Does epidural analgesia interfere with labor and consequently increase the risk of complications?**

Background. Currently, labor epidural analgesia (LEA) enjoys great popularity among both physicians and patients. The evidence suggests, however, that despite superior pain relief, labor epidural analgesia has drawbacks, including increased duration of labor, increased need for oxytocin augmentation, and increased rate of cesarean section for failure to progress. As randomized studies of this subject are rare and have included few patients, the

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authors set out to conduct a large randomized investigation of the effects of LEA on labor compared with intravenous meperidine.

Population studied. The population consisted of women with low-risk term pregnancies presenting in spontaneous labor. These are precisely the patients for whom family physicians provide obstetric care. Labor was diagnosed in the setting of regular uterine contractions and cervical dilatation >3 cm. Women with complicated pregnancies, cervical dilatation >5 cm on presentation, and other than singleton cephalic gestations were excluded. Of the 2608 women who were identified as possible subjects, only 1330 (51%) agreed to participate. Demographics of those who accepted and those who refused participation were similar.

Study design and validity. In an effort to maximize participation, consent involved agreement to be randomly offered either epidural (bupivacaine-fentanyl) or IV (meperidine) analgesia for the initial treatment of labor pain. Patients were free to refuse the designated treatment or to elect the alternative during labor, which led to an unexpectedly high crossover rate. Routine intrapartum management as well as protocols for oxytocin augmentation, dystocia diagnosis, low forceps use, and epidural and intravenous analgesia administration were standardized. Blinding was impossible because of the nature of the treatments. Data were obtained from obstetric data sheets and maternal and neonatal discharge charts.

Outcomes measured. Using intention-to-treat analysis, the only primary outcome measured was cesarean section delivery rate. Secondary outcomes including subjective pain rating, duration of labor, oxytocin augmentation, chorioamnionitis, low forceps deliveries, Apgar scores, umbilical artery blood pHs, and birthweight were reported only for allocation-compliant groups, ie, patients who did not cross over after assignment.

Results. There was an increased rate of cesarean section delivery secondary to dystocia in women allocated to the LEA group (9% vs 5%, $P=.008$). After controlling for parity, race, maternal age, neonatal weight, admission to delivery interval, estimated gestational age at delivery, and cervical dilatation on admission, statistical analysis of the entire cohort still indicated an increased rate of cesarean section delivery for dystocia in women who received LEA (odds ratio 1.98; 95% confidence interval, 1.14 to 3.51). This increased risk was significant for both parous and nulliparous women. Because of the inherent patient freedom in this study's consent, postrandomization self-selection was high. Of the 664 patients randomized to receive epidural analgesia, 232 did not follow the allocated protocol. Likewise, of the 666 patients randomized to receive intravenous analgesia, 229 did not follow the allocated protocol. Analyses based on allocation-compliant groups were significant among women who received LEA with respect to the following variables: increased satisfaction with pain relief (60% vs 22%, $P<.05$), increased labor duration (mean of 7.2 vs 5.7 hours, $P<.001$), increased rate of chorioamnionitis (23% vs 5%, $P<.001$), increased need for oxytocin augmentation (32% vs 23%, $P=.004$), and increased rate of low forceps delivery (8% vs 1%, $P<.001$).

***Recommendations for clinical practice.* Labor epidural analgesia is a superior method of pain relief; however, it can increase the risk of cesarean section delivery for dystocia, the duration of labor, the need for oxytocin augmentation, and the rate of forceps delivery. Family physicians who provide obstetric care should openly discuss the advantages and disadvantages of LEA with their patients. Women should be involved on an individual basis in determining whether the benefits of LEA pain relief outweigh the potential risks of dystocia and cesarean section delivery.**

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IMPACT OF MEDICAL STUDENT TEACHING

TITLE: Impact of medical student teaching on family physicians' use of time.
AUTHORS: Vinson DC, Paden C, Devera-Sales A
JOURNAL: *The Journal of Family Practice*
DATE: March 1996; Volume 42; 243–249

***Clinical question.* Does the presence of a medical student affect the family physician's use of time?**

Background. As medical schools expand the amount of primary care ambulatory experience required of students, the authors think it important to determine how and to what extent working with a student affects a physician's practice. Previous studies have not compared physicians' use of time with and without a medical student present.

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Population studied. Private, nonacademic (n=22) and academic (n=12) family physicians were observed with and without a medical student present. Most students were in their fourth year and had completed at least 2 weeks of a 4-week course. Different results might be expected with students who are at an earlier point in their clinical rotations.

Study design and validity. A research assistant continuously observed the physician-teachers, recording their activities at preselected random 2-minute intervals. Each private physician was observed for 2 full days on the same day of the week: 1 day with a student present and 1 without. The observation continued through the lunch period. The academic physicians were observed for at least 2 half-days with a student and 2 half-days without; the majority were observed for a total of 8 half-days. Academic physicians were not observed during lunch. Physicians were asked to record any time spent at the office beyond regular work hours.

Outcomes measured. The authors were interested in answering three questions: (1) does the presence of a medical student affect the amount of time a physician spends at work? (2) does productivity change, as measured by number of patients seen per working hour? and (3) how does the physician's use of work time change? Differences between academic and private physicians were also examined.

Results. The presence of a medical student significantly increased the amount of time private physicians spent working by 52 minutes, while significantly decreasing the number of patients seen per hour, from 3.9 to 3.3. For academic physicians, there was no change in the amount of time spent working or in productivity, ie, 2.3 patients per hour. The 10,328 observations were fairly evenly split between private (55%) and academic (45%) physicians as well as with respect to the presence of a medical student. For both academic and private physicians, the amount of time spent in patient-centered activity decreased significantly by 47.5 and 27 minutes, respectively. The time spent in student-centered activities was 63 and 71 minutes per day for academic and private physicians, respectively. Compared with academic physicians, private physicians spent more time socializing with students, primarily during the lunch hour.

Recommendations for clinical practice. **Private family physicians who volunteer to teach medical students are aware of how much time teaching requires. This study indicates that the presence of a medical student not only increases time spent working but also may negatively affect productivity. Both types of physicians, however, as well as medical schools, should keep in mind the potential costs of teaching ambulatory medicine in a busy practice setting.**

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