Duration and recurrence of otitis media with effusion in children from birth to 3 years: prospective study using monthly otoscopy and tympanometry

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Abstract

Objective: To monitor the natural course of otitis media with effusion.
Design: Prospective, longitudinal assessment of the state of the middle ear by otoscopy and tympanometry at monthly intervals from birth to 3 years.
Setting: Domiciliary visits to family homes.
Subjects: 95 full term infants born between August 1991 and November 1993.
Main outcome measures: Observed and simulated data (Monte Carlo) for the duration of single episodes of otitis media with effusion.
Results: 17 of the children had unilateral or bilateral otitis media with effusion for more than half of their first three years of life. Thirty three of the 95 children had tympanograms suggestive of otitis media with effusion at more than a third of observations; the remaining 62 had such tympanograms at less than a third of observations. The data of each group were described by a first order Markov model, yielding a mean duration of unilateral effusion episodes of 5-6 weeks in both groups; the mean duration of bilateral effusion was 6 and 10 weeks in the low and high incidence groups, respectively. However, the main difference between the groups was the time spent between episodes of effusion: effusion free periods were, on average, three times longer in the children who experienced less otitis media with effusion.
Conclusion: Children who are susceptible to otitis media with effusion tend to have more separate episodes of effusion rather than an increased overall duration of episodes. Such children are primarily distinguished by the likelihood with which they acquire the disease than by their ability to recover from it.

Introduction

Otitis media with effusion, a broadly defined condition that includes secretory, non-suppurative, and serous otitis, as well as acute otitis media,[1] is highly prevalent among young children. Effusions produce a conductive hearing loss that averages 20 dB but can be as great as 50 dB.[2] A major problem in determining the sequelae of otitis media with effusion is the assumptions made about the occurrence and duration of otitis media with effusion. The fluctuating nature of otitis media with effusion, its occurrence in either or both ears with variable time courses, and the medical management of identified cases all make the analysis of data documenting the natural course of otitis media with effusion difficult. In general, previous studies have examined the natural course in one of three ways: by basing the study on high levels of medical contact,[3] by monitoring effusion after acute otitis media,[4 5] or by regular prospective cohort sampling.[6-8]

The studies that have investigated the duration of otitis media with effusion after an acute infection defined onset as the day of diagnosis or treatment.[4 5] The state of the middle ear was monitored either until the effusion had resolved or to the point of surgical intervention or other arbitrary cut off point. These studies have therefore been unable to specify events, beyond the numbers of effusions in a selected population, that persisted during predetermined intervals.

Otitis media with effusion is often asymptomatic and, thus, only prospective studies have the potential to monitor accurately "silent" effusions. Several Scandinavian studies of the natural course of otitis media with effusion have sampled paediatric populations at intervals of three months or more and have commented on the dynamic nature of the condition.[6-8] The costs of more frequent monitoring have limited the number of studies with a temporal resolution of less than three months. However, to gain an understanding of the natural course of otitis media with effusion that is both precise and unbiased more regular sampling is desirable. We investigated the time course of otitis media with effusion by examining its duration, laterality, and recurrence during the first three years of life by frequent monitoring and mathematical modelling.

Subjects and methods

Between 1991 and 1993, 112 full term (38-42 weeks' gestation) healthy infants in the Oxford area who had uneventful birth histories were recruited soon after birth, without regard to sex or socioeconomic or ethnic group. The health visitors of each of five general practices gave parents an introductory letter, to which they replied if they were interested in participating. The study had ethics committee approval, and parental consent was obtained at the outset. Infants were examined about every month for the first three years of life. Each ear was examined otoscopically to check that there was no obstruction of the canal. A Lucas Grason Stadler GSI 33 middle ear analyser was used to obtain tympanograms at 226 Hz from both ears when infants were not distressed or unhappy.[9] Tests in which a tympanogram was unobtainable because of a lack of cooperation or the accumulation of wax were disregarded. The tympanograms were categorised as type A (compliance ≥ 0.2 ml, pressure ≥ -150 daPa (decaPascals)), type C (compliance ≥ 0.2 ml, -400 daPa $<$ pressure ≤ -151daPa), or type B (compliance < 0.2 ml, pressure ≤ -400 daPa). If type B was recorded at either or both ears for three successive months the parents were asked to consult their general practitioner. Particular attention was paid to instances of otitis media with effusion after an acute infection as the administration of antibiotics or antimicrobial drugs may have influenced the duration of the effusion.

For modelling purposes types A and C represented an effusion free state and type B an instance of otitis media with effusion. At each observation an infant was, therefore, in one of four states: binaural otitis media with effusion (B type tympanograms in both ears), effusion in left ear, effusion in right ear, or no otitis media with effusion in either ear. Given the assumption that the probability of an infant being in any state depended only on the state at the previous observation, a stochastic model (first order, four state Markov process) of the time course of otitis media with effusion was developed. A state transition matrix (T), which defined the probability of all possible transitions between each state, was computed from the observed data.[10] This matrix therefore provided the information needed to calculate the duration of episodes of monaural and binaural otitis media with effusion on the basis of likelihood (see fig 1). The mean duration for each state (d) was computed from the diagonals of T, using the relation $d = 1/(1 - p_{nn})$, where p_{nn} was the probability of a particular state remaining unchanged from one observation to the next.

Two model forms were investigated. The first assumed that the time course of otitis media with effusion was similar in all children and that the variations in the observed data were simply the result of sampling. The second assumed several different time courses, based on the overall prevalence of otitis media with effusion (see Results). Monte Carlo techniques were used to assess whether the models were consistent with the observed data. Simulation programmes used a random number generator optimised for long sequences of uncorrelated, pseudorandom numbers.[11]

Results

Of the 112 infants who were enrolled, 95 had (at 31 January 1995) participated for more than a year, 67 for more than two years, and 31 for more than three years. Only 17 infants (15%) left the study during the three years. Three infants had bilateral grommets (ventilation tubes) at 12-23 months. Their ears were categorised as B when tympanometry indicated that the grommet was not patent and there was a concurrent, flat tympanogram. For infants followed up

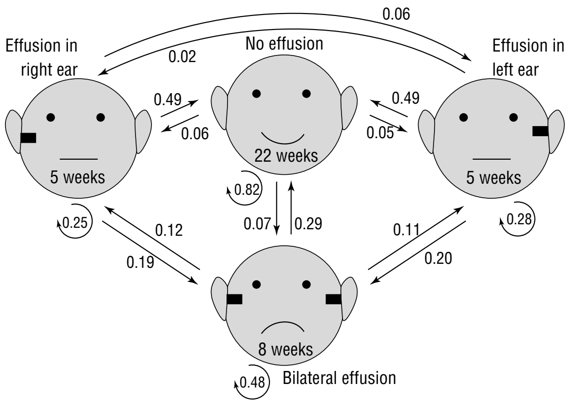

Fig 1 State transition matrix. Numbers within circular arrows show probability (pnn) that each effusion state was maintained between tests. Straight arrows show probability of change to another state between tests. Mean duration (d) of individual times in each state was computed using relation d=1/(1−pnn) and is the larger number on each face

to 1, 2, and 3 years of age the modal value for the number of home visits was 11 (range 3-13 visits), 21 (14-24), and 32 (26-35) respectively. The mean interval between visits was 33.6 (SD 10.4) days with a modal value of 28 days.

Preliminary modelling was used to compare the duration of all effusions in children who had a history of acute otitis media associated with effusion (clinically diagnosed and treated with antimicrobial agents) with all effusions of children without such a history. Mean durations of otitis media with effusion (bilateral or unilateral) did not differ between the two groups (5 weeks for unilateral effusion, 9 weeks for bilateral effusion in those with acute otitis media associated with effusion, 5 weeks for unilateral effusion, 8 weeks for bilateral effusion in those without such disease). No distinction was made between children according to whether they had acute otitis media in the remainder of the analysis.

The state transition matrix for the entire observed dataset (95 children) is presented schematically in figure 1. These data show that (*a*) there was a low probability of changing between unilateral states (from the left to the right ear being affected or the other way round), (*b*) there was a comparatively high probability of remaining in a bilateral state (either free of effusion or with bilateral effusion), and (*c*) about one half of the unilateral states reverted to normal (effusion free) after just one observation.

Analysis of this T matrix gave the following mean durations for each state: 22 weeks for no effusion, 5 weeks for effusion in the right or left ear, and 8 weeks for bilateral effusion (fig 1).

The observations were modelled by age (in years) for the first three years. The mean duration of unilateral (6 weeks) and bilateral (9 weeks) effusions did not change with age. Strikingly, however, the mean effusion free period in each of the first and second years (23 weeks) was less than half of that in the third year (51 weeks).

The data were further analysed on a child by child basis, and the amount of time that each child was affected by otitis media with effusion was computed. This was simply the number of positive observations of otitis media with effusion (unilateral or bilateral)

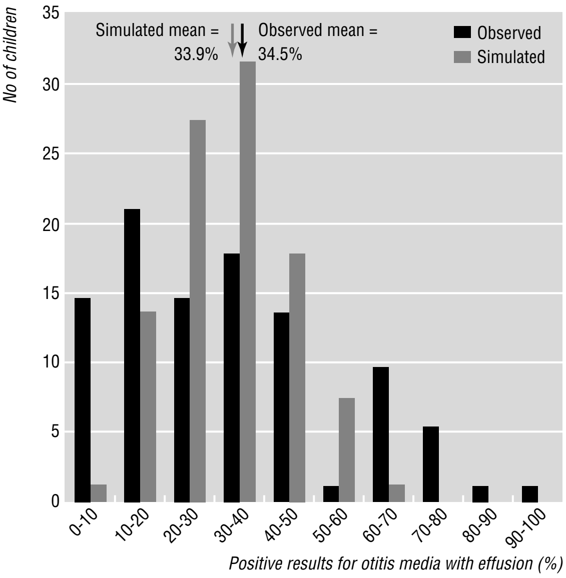

Fig 2 Proportion of positive diagnoses of otitis media with effusion for observed and simulated data

divided by the total number of observations for that child (fig 2). There was a broad spread of observed prevalence, with an appreciable minority of children (17) having the disease more than half of the time. Monte Carlo simulations were performed to assess whether this variation would be expected from a first order Markov model. The observations had a broader spread than the simulated data (fig 2), although the means of the two sets were the same. This suggested that the distribution of observed episodes of otitis media with effusion across individual children was not random.

The data were divided, initially, into two groups on the basis of whether children had otitis media with effusion for more (n = 33; "high") or less (n = 62; "low") than the mean affected time (34%). Each group was analysed using the same Markov modelling techniques. The state durations and probabilities for the two groups (fig 3) differed from those for the whole sample (fig 1). The high incidence group had a greater chance of remaining with bilateral effusion than did the low incidence group, showing a 1.7-fold increase in the duration of bilateral effusion. Interestingly, there was no difference between the groups in the duration of unilateral otitis media with effusion, suggesting that unilateral otitis media with effusion may differ qualitatively from the bilateral form. However, the main difference between the two groups was the mean time between episodes of otitis media with effusion (10 weeks compared with 31 weeks). Thus, the high incidence group were primarily distinguished by the likelihood with which they acquired the disease rather than by their ability to recover from it.

To examine further the hypothesis that children who are susceptible to otitis media with effusion tend to have more frequent episodes of the disease, the data were divided into four groups (of about equal size) by the proportion of time spent with otitis media with effusion (fig 4). The interval between episodes decreased noticeably as the proportion of time with otitis media with effusion increased. By contrast, there was a small associated increase in the mean duration of each bilateral episode. Slightly more than one quarter of the children formed the group with the lowest prevalence of effusion. For these children the time free of effusion lasted, on average, more than 60 weeks and was then interrupted by either a unilateral or bilateral effusion of comparatively short duration (about 4 weeks) before they returned to the effusion free state. At the other end of the range a group of children who had otitis media in more than 45% of tests had an average of 9 weeks free of effusion, followed by either unilateral (averaging 6 weeks) or bilateral effusion (averaging 10 weeks), and then by another comparatively short time free of effusion (9 weeks). When the data are considered in this way the cyclical and dynamic course of the effusion process can be fully appreciated

Discussion

We found that the mean durations for episodes of unilateral and bilateral otitis media with effusion were 5 and 8 weeks, respectively. Nearly one fifth of children had either unilateral or bilateral otitis media with effusion for more than half of their first three years of life. An increased susceptibility to the disease was more likely to be associated with more frequent episodes than with an overall increased duration of individual episodes.

Despite the prevalence of otitis media with effusion, there have been few attempts to analyse the

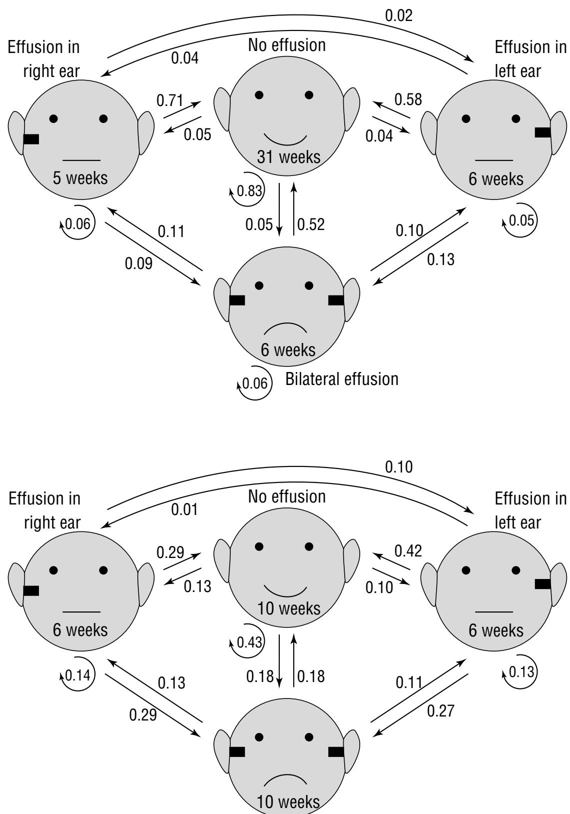

Fig 3 State transition matrices for children who had otitis media with effusion for less (top) or more (bottom) than mean affected proportion of time (34%). Details in figure 1

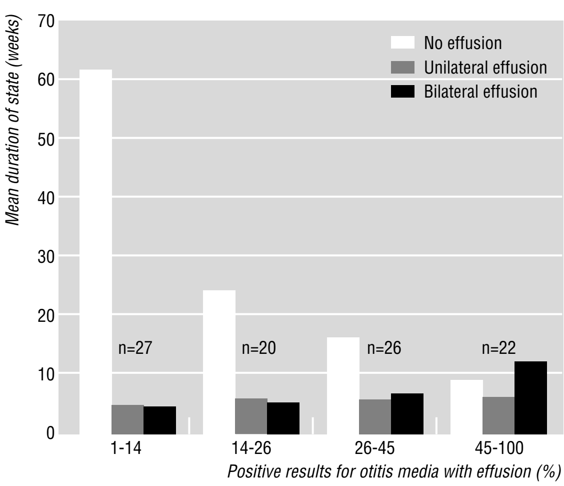

Fig 4 Mean durations of states for groups with varying experience of otitis media with effusion. Each bar represents duration of either an effusion free state or presence of unilateral or bilateral effusion. Abscissa indicates number of positive tests for effusion as percentage of total number of effusions

duration of episodes or the interval between episodes. This information may be important for understanding the consequences of the disease and for defining treatment procedures. For example, otitis media with effusion in infancy has been associated with a reduced level of binaural unmasking in later childhood,[12 13] presumably leading to a reduced ability to detect target sounds in noisy environments. It would seem desirable to know what aspect of otitis media with effusion (type, laterality, duration, associated hearing impairment, etc) leads to this problem, partly to target treatment to the appropriate children and partly to help in understanding how early hearing loss may affect neural development in general.[14]

Another treatment issue is raised by the specific findings that the average length of otitis media with effusion episodes is 1-2 months and that children who are more susceptible tend to have more frequent rather than longer episodes. Clinical practice in the United Kingdom is that children detected with otitis media with effusion should undergo a period of "watchful waiting" before surgical intervention. If this practice is maintained our results suggest that examination about every six months should detect cases of recurrent otitis media in children susceptible to effusion. Children who are less susceptible would not normally be expected to have a recurrence during this time. Our analysis suggests that children under 2 years of age are more susceptible to recurrent effusion than children in their third year. This result differs from that of an American study, in which children under 2 years old were estimated to have a greater (fourfold) persistence of effusion after acute otitis media than older children.[4] However, the clinical implication from both studies is that children under 2 years of age are likely to have more otitis media with effusion than older children and that particular attention should be given to infants.

The finding that unilateral otitis media with effusion did not differ in duration between the high and low groups suggests a possible qualitative difference between unilateral and bilateral effusions. It may be, for example, that the site or mode of acquisition of the disease vary, with bilateral effusions deriving from systemic factors and unilateral effusions deriving from more peripheral and local disease. This idea is highly speculative, but it may be of interest to examine the causes of unilateral and bilateral otitis media with effusion separately to see whether any of the hypothesised risk factors—for example, breast feeding, birth weight—are more commonly associated with either laterality.

Key messages

- This prospective, longitudinal study analysed the duration and recurrence of otitis media with effusion by monthly monitoring with otoscopy and tympanometry
- A first order Markov model described the observed data adequately
- The model predicted that episodes of unilateral and bilateral otitis media with effusion have a mean duration of 5 and 6-10 weeks, respectively
- An increased susceptibility to otitis media with effusion was primarily associated with more frequent episodes

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Conflict of interest: None.

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Commentary: Reduced confusion over ear effusion?

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Otitis media with effusion (glue ear) is resource consuming and confusing because of its fluctuating course, eventual age related remission, and variability both in presentation and consequences. The cumulative incidence is extremely high, and the point prevalence distributions for severity (degree of hearing loss) and for persistence (time spent with otitis media with effusion) have no discontinuities; only a statistical cut off point is therefore feasible between a case and a non-case.[1] A treatable instance cannot be defined by an examination or test on one particular day, which merely confirms diagnosis. This importance of total histories requires two medical responses: (*a*) much reliance on parental reporting of detail and extent, accompanied by vigilant awareness that some parents underreport, and (*b*) selective referral on the basis of risk factors for more objective tests to offset such underreporting.

The work of Hogan *et al* updates our understanding of otitis media with effusion in several ways. It offers accurate descriptive data on early histories with frequent time sampling, summarised by parameters of the long established Markov class of model. Although this class needs to be tested against deterministic alternatives—for example, chaotic oscillatory models—for goodness of fit, its parameters probably offer useful descriptors for children, risk factors, and treatments. The finding that apparent persistence is due chiefly to recurrence further questions the value of a single test on an arbitrary day, and hence of any universal screen for otitis media with effusion. It also supports an important recent revision of our view of the cause of the disease. The new view invokes a continuing low grade infection maintained by the effusion that can flare up, leading back to a subacute inflammatory state, without evident exposure to new infection immediately beforehand. The effusion aspirated at myringotomy often does not culture bacteria by conventional methods, but it is not sterile as formerly thought. Many such culture negative samples contain bacterial DNA, suggesting viable bacteria.[2] Meta-analysis shows that, although antibiotics are effective in acute otitis media, the magnitude and duration of their effect in otitis media with effusion do not currently offer a satisfactory treatment policy.[3] Drug resistant bacteria are bred from overprescription of antibiotics in the community, largely for otitis media,[4] though resistant strains in themselves are unlikely to explain the allegedly increased prevalence of otitis media with effusion in recent decades. The evidence for partial efficacy of antibiotics in this disease suggests two future possibilities: (*a*) more scope for new medical treatments and (*b*) a large pragmatic effectiveness trial to define prescription constraints for medium length courses of antibiotics as temporising management for otitis media with effusion, thereby potentially covering one part of the continuum of high parental demand. The *Royal Society of Medicine Encyclopaedia of Child Health* may be pardoned for telling parents at this point that otitis media with effusion is not primarily caused by infection,[5] as more epidemiology, management trials, and dissemination of information are still required to put this revised account of the disease fully to work.

The guerilla war fought in the pharmacokinetic backwaters of the middle ear mucosa between bacteria synergised by viruses and the immature immune system, sometimes aided by modest local antibiotic concentrations, is too easily ignored. Its slowness and precarious complexity make the longstanding confusion of professionals and parents less surprising.

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Commentary: Markov models of medical prognosis

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continued over

Named after a turn of the century Russian mathematician, Markov models are used to describe stochastic processes—that is, random processes that evolve over time. Increasingly, such models are being applied in medical and health services research.[1] Hogan *et al* use a Markov model to address an epidemiological question; such methods have also been used in clinical[2] and economic evaluations.[3 4]

The most common application of Markov models in health is to characterise the possible prognoses experienced by a given group of patients. This entails modelling the progress over time of a notional group of patients through a finite number of health states. Patients are initially placed in one of the health states, and the probabilities of transition to the other states in the model are defined within a given time period, known as a Markov cycle.

Alternative forms of Markov models exist, differing in how transition probabilities are defined. Markov processes describe a model in which the state probabilities are allowed to vary as the number of Markov cycles increases. This is particularly appropriate for modelling life expectancy, in which the risk of death in each period clearly increases with age. A Markov chain, as used by Hogan *et al*, is when the transition probabilities of the model are assumed to be constant over time. An intuitive presentation of the model is given in figure 1 of their paper, and these state transition diagrams are commonly used to illustrate Markov models. The disease states of the model are represented by the faces and the arrows between the circles give the possible transitions.

Markov models can be analysed in several ways. One of the most common is known as cohort simulation. A hypothetical cohort of patients begins the model in any of the disease states and the cohort is then tracked for the duration of the model. The proportion of the cohort in any of the states at any point in time and the mean duration in each state can be calculated. An alternative approach, adopted by Hogan *et al*, is Monte Carlo simulation. Many hypothetical patients are passed individually through the model and their disease pathways recorded. The advantage of the Monte Carlo approach is that estimates of the duration dispersion can be obtained from the individual simulation data.

As with all models, Markov models are simplifications of the real world. An important limitation of Markov models is that they lack a memory. This is termed the Markovian assumption—that is, the probability of moving from one state to another is independent of the history of the patient before arriving in that state. This assumption is pertinent to the analysis presented by Hogan *et al* as they argue that the discrepancy between the predictions of their model and the observed data, in terms of the dispersion of the positive test results for otitis media with dispersion given in figure 2, can be explained by the existence of two groups of children characterised by high or low susceptibility to the disease. An alternative explanation might be that a history of acute events in otitis media with effusion affects the probability that such events recur, which the Markov model does not allow for. The extent to which the Markovian assumption is limiting in this case is a matter of clinical opinion, on which we are not qualified to judge. Although the limitations of the Markovian assumption should be kept in mind, the adept modeller will often find ways around the assumption using a combination of time dependent transition probabilities and distinct states for patients with different medical histories.

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A PAPER THAT CHANGED MY THINKING

Are patients a myth?

The big idea of this paper is that medical histories, as presented on ward rounds, are part of a historic oral narrative tradition.[1] The paper uses the oral-formulaic theory of two classical scholars (Parry and Lord) to compare the narrative of a typical case presentation to Homer's *Iliad*.

An oral formula is "a group of words which is regularly employed under the same metrical conditions to express a given essential idea." A bardic performer would use a series of formulae (often noun adjective phrases—for example, "much enduring divine Odysseus" or "the goddess grey eyed Athene"). These are then linked together by verbs or brief snatches of free text. Starting from a source story, the skilled bard would create a recognisable brand of dramatic narrative within a live performance.

Compare the bardic process with a medical clerking. The patient narrates the source story: "Oh doctor, I've been feeling so tired all the time, and I'm getting these terrible headaches and funny feelings in my left knee. I really don't know why I'm so run down. I've been wondering if it's to do with this new microwave my Fred bought me? I'm right off my food."

This history is then retold on a ward round one week later. The italics indicate the formulaic phrases, comprising 30 out of the 42 words): "*This is the first admission of this* 47 year old housewife, *with the main complaint of* lethargy. *She was in good health until* three weeks *prior to admission, when she experienced* lassitude and tiredness *of gradual onset. There are associated* headaches, anorexia, etc."

The narrative has been edited and remodelled to an oral formulaic tradition. The presentation is stylised with characteristic intonation, gesticulation, and facial control, mimicking a bardic recital. Whose story *is* this story? We are distanced from the patient's own account. The patient has become a Homeric myth.

Ratzan compares the process of apprenticeship of doctors and bards. Trainee bards underwent a system of sitting in, then learning by imitation, and finally singing before a critical audience. The technical demands of the performance produce a concern with the form of expression, over and above the needs of communication. If we consider a junior doctor presenting a case in the ritualistic setting of a traditional "grand round," substituting senior doctors for tribal elders, little of the process would change.

The justification for superseding the patient's "illness" narrative is that we use the medical "disease" model to determine treatment. Ratzan asserts that there is a second purpose—that of the novice earning membership of the tribe. The medical tribe has become distanced from the tribe of the patient. A student wears the white coat, just as an apprentice bard would proudly display his harp. He or she learns to intone the mysteries of our craft, to move from the margins, and become accepted within the tribe.

Yet we do not set out to erase students' understanding of renal function when they move from a medical to a surgical firm. Why then does our system of medical education erase so much of students' lay understanding of "illness" when we teach them the disease models of the medical tribe? If in medical training one "set" of language is destroyed then the cognitive world associated with it will disappear also. Must the doctor's bardic chant drown the patient's whispered tales of illness?

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We welcome filler articles of up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk.