

The Relationship Between Passive Smoking and Child Health: Methodologic Criteria Applied to Prior Studies

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Most studies investigating the relationship between passive smoking and child health have found a significant effect on respiratory illness and lung function. The wide range of findings is based on diverse types of studies which use multiple criteria for respiratory illness, smoke exposure, and outcome variables. The aim of this review is to examine these studies in an attempt to focus attention on methodological criteria which relate to the strength of the association and likelihood of a causal relationship between passive smoking and child health.

We examined 30 studies and judged their strength by examining (1) data collection, (2) surveillance bias, (3) definition of amount of smoking, (4) definition of illness, (5) detection bias, (6) outcome variables, and (7) control for confounding variables. Poor scores were noted in the use of "blinded" data collectors (37 percent of possible score), use of multiple specific outcome variables (51 percent), and definition of the quantity of smoking (56 percent). Good scores were noted in the detection of illnesses (98 percent), recall by study subjects of symptoms of illness (71 percent), control for confounding variables (81 percent), and definition of illnesses (86 percent). The range of scores for the studies was from 44 percent to 89 percent (of the total possible score).

While a few well-designed studies demonstrate a significant effect of passive smoking on child health, most studies had significant design problems that prevent reliance on their conclusions. Thus, many questions remain, and future studies should consider important methodological standards to determine more accurately the effect of passive smoking on child health.

During the past few years, the relationship between passive smoking and child health has received substantial attention in the medical literature. Most of the evidence suggests that there is a significant causal relationship between passive smoke exposure (defined as the exposure when children are in close proximity to the smoke from burning cigarettes, pipes, or cigars, or to exhaled smoke produced by smokers) and child ill-health [1-30]. A recent Surgeon General's report highlighted the risk of exposure to the non-smoking public by those who continue to smoke [31]. While most studies have found at least some relationship between passive smoke and child health, others have found little or no effect [32-33].

Even though this topic has been the focus of many studies, it is not clear when passive exposure to smoke begins to affect child health nor the extent of the dose-effect relationship. This information is important both for (1) public policy, which could be directed against the exposure of children to smoke; and (2) research policy, which could be directed toward the newer issues in this field such as the effect of prenatal exposure to passive smoke on fetal development.

Exposure to passive smoke has been associated with reduced birthweight [34,35]

and child height [10,12], increased incidence of childhood asthma [9,14,36], bronchiolitis [7], persistent wheezing [1], childhood cough [8,17,20,24], tracheitis and bronchitis [6], and respiratory illness in the first [18], second [22], and middle childhood years [16]. Passively inhaled smoke has also been shown to be associated with a reduction in pulmonary function in children [3,5,11].

Prospective, case-control, and cross-sectional study designs have been used to investigate the effect of passive smoking on child health. In the prospective study design, children are followed over time and examined at specific predetermined intervals; pulmonary function testing is often performed during these interval examinations and used as an outcome variable in these studies. In the case-control study design, smoke exposure is compared between those children who have or have not had a specific illness, such as bronchiolitis. In the cross-sectional study design, the strength of association between past smoke exposure and a specific outcome (i.e., cough or pulmonary function testing) at a specific time is tested.

Within any selected design, studies have demonstrated substantial differences with respect to the following: (1) the definition and quantification of smoking of all household members; (2) the accuracy of recording the amount of smoke to which a child is exposed, including in-home and outside-the-home exposure; (3) the definitions of symptoms and diagnostic criteria for respiratory illness; and (4) the measurements used to assess the effect and quantity of exposure to passive smoking. In addition, issues such as the need for "blinding" of research personnel during data collection and the frequent examination of study subjects have been addressed by only a few studies [7,21,24]. These methodologic shortcomings make it difficult to compare results of prior studies and to delineate the effect of passive smoking on child health.

Many of the problems are obvious even without critical review. Some investigators recorded smoking history by determining the number of cigarettes smoked per day by the mother and/or father (current and/or prior consumption), while others simply classified household smoking patterns as either the presence or the absence of smoking by both parents [3,26]. In other studies, researchers assigned the number of cigarettes smoked per day to a distinct category, such as 1-10, 11-20, or >20 cigarettes per day [6], or 1-14, 15-24, or >25 cigarettes per day [17].

Multiple or intermittent sources of passive smoke exposure have not been explored in prior studies. A child might spend four hours a day with a parent or other caretaker who smokes only when not in the child's presence. Would this amount of smoke exposure be the same as that experienced when the parent smokes four hours per day in the child's presence? The other case involves the parent who smokes outside the home. He or she would be categorized as a "smoker," but the child's smoke exposure would not be equivalent to that of the first case, nor to that of a child who is exposed continually to smoke by a "home smoker."

Quantitative examination of cotinine (a breakdown product of nicotine metabolism) in the urine, saliva, or blood, as a validation of exposure, has not been included in any of these studies. This chemical assessment of smoke exposure has been shown to be a reliable measure of passive smoke exposure in children [37-41].

Outcome variables have included one or more of the following: (1) symptoms and/or diagnoses of lower or upper respiratory tract illnesses (e.g., cough, bronchitis, tracheitis, bronchiolitis, pneumonia); (2) pulmonary function testing, primarily of older children; (3) height; (4) amount of functional disability; or (5) hospitalization or emergency room visits.

Definitions of respiratory illness have included self-report of symptoms of illness, review of medical records from physician's offices and/or hospital out- and inpatient sources, and categorical responses to lists of symptoms of illness. In the few studies with multiple sources of information, there have been no procedures to handle data that might differ according to the source of information (e.g., self-report, hospital records) [18,22]. Only one large prospective study contacted families at frequent intervals so that symptoms, home management, and physician contact could be accurately recorded [1,3].

To date, there have been no standardized methods developed to test the association between passive smoking and child health. The aim of this review is to examine specific methodologic criteria in studies investigating the relationship between passive smoking and child health. This examination may help to explain some of the variation found in these studies and provide a reference for some of the issues to be considered in future studies.

METHODS

All articles describing research which focused on the relationship between passive smoking and child health, published in the English language since 1970, were requested through the MEDLINE information service.

Articles were reviewed by the two authors independently to determine (1) the type of study, (2) the sample size, (3) the age of the study group, and (4) the outcome variables used to assess the effect of exposure to passive smoke on child health.

In addition, methodological criteria were adapted from Horwitz and Feinstein [43]. These criteria were chosen because they were important issues which may significantly affect the outcome of a study. Some of these criteria were used in a recent review of the association between breast-feeding and infection by Bauchner et al. [44].

The methodological criteria used in our review are listed below.

1. *Data Collection: The Use of "Blinded" Data Collectors:* It is important that research personnel know as little as possible about the details of the hypotheses being tested, and not know the smoking status of study participants during (1) pulmonary function testing and (2) the questioning of study subjects regarding symptoms of illness. This lack of information is to ensure that interviewer technique is unbiased and standardized. If the examiner knows that the subject is a heavy smoker, he or she may expect a great number of symptoms related to respiratory illness in the subjects' children compared to those of subjects who are not smokers. The result could be a falsely elevated number of symptoms detected in smokers' families, compared to non-smoking families.

2. *Surveillance Bias:* In many prospective studies, recall of children's symptoms of illness by parents is often used as an important outcome variable. Ideally, the period of time used for recall should be minimal. We arbitrarily defined a reasonable period of recall as at least twice in a twelve-month period.

3. *Definition of Smoking Exposure:* Smoke exposure can occur at (1) home, (2) day care, (3) school, or (4) wherever a child spends most of his or her time. The evaluation of this variable should also include an assessment of current and prior smoking exposure by parents, household members, and child care providers. This information is particularly important in view of the large number of children attending day care [46]. Chemical analysis of the breakdown products of nicotine metabolism is also an important element of verification of the amount of smoke exposure.

4. *Definition of Illnesses:* This category is important for generalizability of findings. Whether using reported symptoms of respiratory illness or diagnostic definitions related to upper or lower respiratory tract disease, criteria for illness should be established prior to the start of the study. This information may be obtained from self-reported results, direct interview with a subject, or abstraction of information from medical records. The methods and questions used to obtain this information should be described by study investigators.

5. *Detection Bias:* All study participants should have an equal chance for detection of the target symptom or disease by the study group interviewer or medical record abstractor. Adherence to this criterion may help to eliminate bias if children living in families where there are a lot of smokers are seen more frequently in health care facilities than children from families where there are no smokers. Children from smokers' families would show a higher number of symptoms and therefore be assumed to have a higher amount of morbidity related to the quantity of smoke exposure in the household. All children should be seen an equal number of times by members of the study team assigned to assess respiratory symptoms, measure pulmonary function, or test the chemical by-products of nicotine metabolism.

6. *The Use of Multiple Outcome Variables:* The results of multiple outcome variables will enable the investigator to compare data from multiple sources; that is, those obtained through chemical analysis or by questionnaires. This information can either strengthen the results of the study (all of the data suggests a single result) or weaken the results (conflicting results according to the source). Outcome variables in these studies include: (1) the verbal report by one or both parents of all symptoms of respiratory and other illnesses, (2) pulmonary function testing, (3) hospitalization rates, (4) disability or activity restriction, and (5) emergency room visit.

7. *Control for Confounding Variables:* The causal relationship between passive smoking and child health should be adjusted for potential confounding variables. For example, when examining the relationship between passive smoking and a symptom such as cough, it is important to recognize different potential reasons (other than exposure to cigarette smoke) for increased coughing among children in a family. Increased cough could be due to exposure to common respiratory viruses in other family members and have no relationship to passive smoke exposure. If there is a significant relationship between cough and these variables during preliminary bivariate analysis, they should be included in appropriate multivariate analyses to determine what effect they have on the relationship between passive smoke exposure and cough.

As shown in Table 1, each study was examined for adherence to the principles of each of the seven criteria. A four-point scale was used for each criterion. A "0" score meant that the criterion was not applicable to the study. A "1" score meant there was poor adherence to the criterion. A "2" score meant there was moderate adherence to the criterion. A "3" score meant there was complete adherence to the criterion. Any disagreement between authors was resolved by consensus opinion. A "good" score was defined a priori as ≥ 75 percent.

RESULTS

Thirty research articles focusing on the relationship between passive smoking and child health were reviewed [1,3,5-30,32,33]. Table 2 shows the type of study, sample

TABLE 1
Scoring Guidelines for Methodological Criteria

Criteria ^a	Score			
	0	1	2	3
Data collection	NA	No “blinding”	Some “blinding” documented	“Blinding” documented
Surveillance bias	NA	Subjects seen less than yearly	Subjects seen yearly	Subjects seen more than once per year
Smoking	NA	Current smoking by parents	Current and prior smoking by parents	Considered child care and home exposure since conception of child
Illness	NA	No clearly defined illness categories	Minimal definitions of illness	Clearly defined illness categories with criteria
Detection bias	NA	No attempt to see all subjects	Some attempt to see all subjects	All subjects seen an equal number of times
Outcome	NA	Examined only one variable	Examined two variables	Examined PFT, symptoms, cotinine (≥ 3)
Confounding	NA	None	Control for <3 variables	Control ≥ 3 variables

^aConsult text for complete definitions of criteria.

NA: not applicable

PFT: pulmonary function test

size, age of subjects, and outcome variables. Fourteen of 30 (47 percent) of the studies were prospective, and 15 of 30 (50 percent) studies were cross-sectional. One study was a case-control study. Sample sizes ranged from 276–15,000 subjects. The ages of study subjects ranged from birth to 19 years. Fourteen studies (47 percent) used pulmonary function testing, and 24 (80 percent) studies used symptoms of respiratory illness as outcome variables. Only 10 of 30 (33 percent) studies used both pulmonary function testing and reports of symptoms of respiratory illness. No studies used quantitative assessment of nicotine metabolism to validate the verbal report of smoking history by study subjects. Table 3 shows the results of the methodological criteria evaluation. Two scores were used in the evaluation of the criteria. The first was the score (0–3) for each criterion added across all studies ($n = 30$). The maximum score for any one of the seven criteria was 90. The second score was based on the performance of the individual study in each of the seven methodological criteria (total of all criteria scores/total score possible).

1. *Data Collection: The Use of “Blinded” Data Collectors:* Only two of 30 (6.7 percent) studies recognized the potential impact of biased data collection on study results. In one study “the reading aloud of all study questions without any subjectivity by the research assistant” was performed [24]. In the second study, “interviewers were not aware of study hypothesis or the case/control status of subjects” [7]. Undoubtedly other studies included this concern in data management but failed to note this fact in their publications. This criterion had the lowest score of any of the seven methodological criteria (33 of 90, or 37 percent).

2. *Surveillance Bias:* In 16 studies, subjects were evaluated once due to the use of a case-control or cross-sectional study design. Four studies (4 of 14 = 29 percent) adhered to this criterion by contacting study subjects more than once a year. Pedreira

TABLE 2
Basic Methodologic Structure of Passive Smoking Child Health Studies

Study [Reference]	Type of Study ^a	Sample Size	Age of Subjects (years)	Outcome Variables ^b		
				PFT	Symptoms	Other
Berkey [10]	P	9,273	6-11	-	-	+
Berkey [11]	P	7,834	6-10	+	-	-
Bland [20]	CS	5,835	Secondary school	-	+	-
Bonham [19]	CS	37,000 households	0-16	-	+	+
Burchfield [14]	CS	3,482	0-19	+	+	-
Cameron [27]	CS	695	0-16	-	+	-
Charlton [8]	CS	15,000	8-19	-	+	-
Chen [29]	CS	571	8-16	+	-	-
Chen [30]	P	1,163	0-1½	-	+	-
Colley [18]	P	2,205	0-5	-	+	-
Colley [17]	CS	2,426	6-14	-	+	-
Dodge [23]	P	525	8-10	+	+	-
Ekwo [24]	CS	1,355	6-12	+	+	-
Evans [13]	CS	276	4-17	+	-	+
Fergusson [21]	P	1,180	0-1	-	+	-
Fergusson [22]	P	1,265	0-3	-	+	-
Gortmaker [9]	CS	3,072	0-17	-	+	-
Harlap [16]	P	10,672	0-1	-	+	+
Hasselblad [25]	CS	16,689	6-13	+	-	-
Lebowitz [32]	CS	1,655	0-14	-	+	-
Leeder [26]	P	2,149	0-1	+	+	-
McConnochie [7]	CC	53 cases 106 controls	8.4 (mean)	-	+	-
Pedreira [6]	P	1,144	0-1	-	+	-
Rona [12]	P	5,903	5-11	-	-	+
Schilling [33]	CS	816	7-17	+	+	-
Tager [3]	P	444	5-9	+	+	-
Tager [5]	P	1,156	5-9	+	+	-
Tashkin [28]	CS	971	7-17	+	+	-
Ware [15]	P	10,106	6-9	+	+	-
Weiss [1]	P	650	5-9	+	+	-

^aCC: case-control; CS: cross-sectional; P: prospective

^bPFT: pulmonary function testing; Symptoms: symptoms and/or diagnoses of respiratory illness; Other: height, activity restriction, hospitalizations, and emergency room visits; +: outcome variable examined; -: outcome variable not examined

et al. were able to check all study subjects during their well-baby examinations during the first year of life [6]. Weiss et al. and Tager et al. contacted study families by telephone every two weeks for a two-year period and collected information about symptoms of respiratory disease [1,3]. Fergusson et al. contacted study subjects at four and twelve months of age [21].

3. *Amount of Smoking Exposure:* Ten studies (33 percent) examined current smoking habits of parents. Twenty studies (67 percent) examined current and prior smoking habits of parents. No study examined other potential sources of passive smoking exposure such as child care exposure. The amount of smoking was classified as either the presence or absence of smoking in each parent [23-25,27], household

TABLE 3
Results of Assessment of Passive Smoking/Child Health Studies

Study [Reference]	Methodological Criteria ^a and Score ^b							Proportional Score ^c %	
	1	2	3	4	5	6	7		
Berkey [10]	1	2	1	3	3	2	3	15/21	71
Berkey [11]	1	2	1	3	3	1	3	14/21	67
Bland [20]	1	0	2	3	3	1	2	12/18	67
Bonham [19]	1	0	1	3	3	1	3	12/21	57
Burchfiel [14]	1	0	2	3	3	2	3	14/18	78
Cameron [27]	1	0	1	1	3	1	1	8/18	44
Charlton [8]	1	0	2	1	3	1	3	11/18	61
Chen [29]	1	0	2	0	3	2	3	11/15	73
Chen [30]	1	1	2	2	3	2	3	14/21	67
Colley [18]	1	2	2	1	3	1	1	11/21	52
Colley [17]	1	0	2	1	3	1	1	9/21	43
Dodge [23]	1	2	1	3	3	2	1	13/21	62
Ekwo [24]	2	0	2	3	3	1	2	13/18	72
Evans [13]	1	0	1	2	3	2	3	12/18	67
Fergusson [21]	1	3	1	3	3	1	3	15/21	71
Fergusson [22]	1	2	1	3	3	1	3	14/21	67
Gortmaker [9]	1	0	1	2	3	1	3	11/18	61
Harlap [16]	1	0	2	3	3	2	1	12/18	67
Hasselblad [25]	1	0	2	3	3	2	3	14/18	78
Lebowitz [32]	1	0	2	3	3	1	1	11/18	61
Leeder [26]	1	2	2	2	3	2	2	14/21	67
McConnochie [7]	3	0	2	3	3	2	3	16/18	89
Pedreira [6]	1	3	1	3	1	1	1	11/21	52
Rona [12]	1	1	2	3	3	1	3	14/21	67
Schilling [33]	1	0	2	3	3	2	3	14/18	78
Tager [3]	1	3	2	3	3	2	3	17/21	81
Tager [5]	1	2	2	3	3	2	3	16/21	76
Tashkin [28]	1	0	2	3	3	2	3	14/18	78
Ware [15]	1	2	2	3	3	2	3	16/21	76
Weiss [1]	1	3	2	3	3	2	3	17/21	81
Proportional Score ^c	33/90	30/42	50/90	75/87	88/90	46/90	73/90		
%	37	71	56	86	98	51	81		

^aMethodological criteria 1: Data collection; 2: Surveillance bias; 3: Smoking; 4: Illness; 5: Detection bias; 6: Outcome; 7: Confounding

^bScore 0: not applicable; 1: poor adherence to criteria; 2: moderate adherence to criteria; 3: adhered to criteria

^cProportional Score = $\frac{\text{Total of all category scores}}{\text{Total score possible}}$

smoking pattern which included past and present smoking habits [3,15], and the total number of cigarettes smoked per day by each parent [11]. Perhaps the most extensive classification of smoke exposure was by Burchfiel et al. [14]; five measures of passive smoking were used in that study. The five were: current and past smoking habits of both parents (each parent rated either never, current, or all others), number of parental smokers during the child's lifetime (0, 1, or 2), number of current household smokers (0, 1, 2, 3, or more), and duration of parental smoking [14]. Chen and Wan Xian used the total amount of cigarette exposure (from birth) during a child's life (e.g., ten

cigarettes per day for ten years equals a total of 3,650 cigarettes/year \times 10 years = 36,500 cigarettes) [29–30]. No study validated the reports of parental smoking with an analysis of the metabolites of nicotine metabolism.

4. *Definition of Illness*: Most studies defined specific criteria for respiratory illness using either symptoms of respiratory disease [17,26] or specific diagnostic categories [6,16]. Several studies used the Epidemiology Standardization Project Questionnaire [47] to record symptoms of illness [5,7,15,24,25,28,32]. Fergusson created his own a priori definitions of respiratory illness based on a diary of symptoms kept by study participants during their children's first three years of life [22].

5. *Detection Bias*: In most studies (29 of 30) (97 percent), all subjects were examined the same number of times. Only one study examined subjects an unequal number of times. In that study, illnesses which were managed at home were not surveyed [6], which could have reduced the incidence of respiratory illness detected in either the smoking or non-smoking family group. This criterion had the highest total score of any of the seven criteria (88 of 90, or 98 percent).

6. *Use of Multiple Outcome Variables*: There were a variety of outcome variables examined in studies. These included one or more of the following: pulmonary function testing, symptoms of a respiratory illness, height, activity restriction, hospitalizations, and emergency room visits. Fourteen studies (47 percent) examined one outcome variable. Sixteen studies (53 percent) included two outcome variables.

7. *Control for Confounding Variables*: Twenty-three of 30 (76.7 percent) of the studies included some adjustment of results for potential confounding variables. The variables which were considered included gestational age, maternal age, race, education, number of children in the family, family living standards, duration of breastfeeding [21], parental smoking habits, gender of child, illness in other children [26], and type of cooking gas [24]. Most of the studies that included confounding variables considered at least four different variables in their statistical analyses (equal to a score of "3" on the methodological criteria assessment).

DISCUSSION

Several recent reviews have documented the effects of passive smoking on pulmonary function and on the incidence of respiratory disease [2,45]. This study focused on the specific methods of data collection and definitions of smoke exposure, illness criteria, and outcome variables in order to determine the reason for the range of findings noted in these reviews. These methodologic differences can have significant effects on outcome and produce bias in study results.

This review demonstrates the lack of uniformity in basic issues of methodological approach to this research question. Of particular note are the poor scores of those criteria focusing on (1) data collection, (2) the number and type of outcome variables examined, and (3) the evaluation of all potential sources of smoke exposure in study subjects. Studies using personal interviews to evaluate symptoms of respiratory disease are highly dependent on the training of the research team. Part of this training includes methods of unbiased objective evaluation of subject responses. Furthermore, the failure to "blind" research personnel to the smoking habits of study subjects can adversely affect their responses and therefore bias results. If the examiner knows the subject is a heavy smoker, his or her questioning and evaluation of responses could be biased. In such a case, research personnel may expect more symptoms from the heavily

smoking group and may prompt those subjects more, as compared to those subjects who are not heavy smokers.

Most studies examined only one or two outcome variables, including pulmonary function testing and symptoms of respiratory illness. No study considered either infectious or non-infectious illnesses other than respiratory illnesses which may have been affected by passive smoke exposure.

Most studies examined the quantity of passive smoke exposure as the result of current and/or prior smoking habits by parents. No study addressed the issue of other sources of smoke exposure. Children can be exposed to significant amounts of passive smoke exposure outside the home. This fact is important in view of the recent increase in child care alternatives used by parents [46]. No study validated verbal reports of smoking by using a quantitative analysis of a metabolite of nicotine metabolism. In view of the reasonably good correlation between cotinine levels and reported passive smoke exposure, this relatively inexpensive assay would be of substantial value in future studies [38–41].

The reason for the wide range of effects of passive smoke exposure on child health is still unclear. Nine out of the 30 (30 percent) studies scored ≥ 75 percent. Those studies which had the highest score on methodological criteria generally support the hypothesis that passive smoke affects child health. McConnochie and Roghmann found passive smoking directly related to the risk of developing bronchiolitis (odds ratio = 3.21, $p = .004$) [7]. Tager et al. found a direct measurable effect of passive smoking on pulmonary function, although no relationship was found between parental smoking and respiratory illness [5]. Weiss et al. found a significant relationship between parental smoking and persistent wheeze ($p = 0.012$) and pulmonary function [2].

Therefore, even though a large number of studies have been completed on this subject, further work remains to delineate the precise “dose-effect” relationship of this toxin. Both public and research policy would benefit from a more standardized approach to research in this field. Public policy might benefit by defining the benefits reasonably to be expected from intervening at specific times to prevent ongoing exposure to passive smoke. Research policy might benefit by developing a clearer approach toward the experience of studying this toxin and applying this knowledge to other new areas in the smoking arena, such as in studies of the effects of smokeless tobacco.

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