A matched case-control study of risk factors for neonatal tetanus in Karachi, Pakistan

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Received : 19-07-04
Review completed : 16-08-04
Accepted : 01-10-04
PubMed ID : 15623963
J Postgrad Med 2004;50:247-52

ABSTRACT

Background: Previous studies have identified various risk factors for neonatal tetanus (NNT) in rural areas of Pakistan. The present matched case control study was conducted to further evaluate these risk factors in an urban setting.

Aim: The study was carried out to identify risk factors for NNT in Karachi.

Materials and Methods: Patients of NNT (n = 125) diagnosed from January 1998 to February 2001 were recruited through a surveillance system of Expanded Programme on Immunization (EPI). Two neighbourhood controls (n = 250) were matched for each case for gender and date of birth of the case.

Statistical Analysis: Conditional logistic regression was performed to assess the independent effect of factors associated with NNT.

Results: The final multivariable model identified subsequent application of substances on the umbilical cord (adjusted matched odds ratio [adj. mOR] = 5.1 [2.7-9.7]), home delivery (adj. mOR = 1.8; 95% CI: 1.1- 3.1) and illiterate mother (adj. mOR = 1.6; 95% CI: 1.0- 2.0) as risk factors for NNT after adjusting for other variables in the model. Population attributable risk per cent (PAR %) for subsequent cord application was 69% and PAR % for home delivery was 31%.

Conclusion: Health planners, while formulating control strategies through immunization programmes should also take into account the impact of post-delivery practices, such as 'subsequent cord application' along with pre-delivery practices. Health awareness regarding appropriate post-delivery practices should be promoted and counselling of pregnant women for giving preference to health care setting for delivery is also crucial.

KEY WORDS: Neonatal tetanus, Risk factors, Case-control study, Multivariate analysis, Pakistan

Neonatal tetanus (NNT) an acute, non-contagious and often fatal bacterial disease caused by an exotoxin of *Clostridium tetani*, has virtually been eliminated from developed countries.[1] It is one of the most underreported "notifiable" diseases and despite being eminently preventable, continues to be a leading cause of neonatal mortality in developing countries. Three of these countries comprise more than half of world's NNT deaths. India accounted for the highest number of deaths with more than 48000 neonates dying of this disease in 1999. Nigeria had the second highest with 34600 deaths followed by Pakistan with an estimated 21600 deaths.[2]

Several studies in the past have identified risk factors for NNT.[3-9] Application of ghee (clarified butter prepared from cow's milk) on the umbilical wound was identified as a risk factor by Traverso *et al*[7] but the underlying mechanism could not be explained. 'In use contamination of ghee' was demonstrated to be responsible for NNT in rural Punjab, Pakistan, as mothers were repeatedly manipulating samples of ghee by their own hands and applying it to the cord of the babies several times in a day. 'Initial' (immediate application at the time of delivery) and 'subsequent' (after a day of delivery) applications of ghee on the umbilical wound were identified as risk factors.[8] Bennett *et al*[9] documented that application of ghee heated with cow dung was associated with NNT when applied on the umbilical wound, and the effective use of a topical anti-microbial was recommended to reduce its usage.

NNT is common in rural or remote areas of Pakistan where access to health care is difficult. It remains hidden within the community and common traditional beliefs prevent parents from seeking medical care even in cities, where health care facilities are easily accessible. Karachi is the largest city of Pakistan with many slum areas, and risk factors are hypothesized to be different due to the multifaceted cultural dimensions of the city. The findings of urban risk factors along with the available knowledge could help government and public health workers in designing effective programmes for the control of NNT

in both urban and rural settings. Therefore, this study was carried out to identify the risk factors for the occurrence of NNT.

Materials and Methods

The study was conducted in Karachi, the capital of the province of Sindh. Approximately 40% of Karachi's 10 million inhabitants live in squatter settlements known as 'Katchi Abadis'. Different ethnic groups reside in these settlements. These mainly include the Urdu-speaking migrants from India and 'Pathans' from the Frontier province.[10,11] Karachi was divided into five districts at the time of the study: East, West, South, Central and Malir. The hospitals located in each of the five districts function as sentinel sites for NNT and report to the office of the Expanded Programme of Immunization (EPI). Only two hospitals viz. National Institute of Child Health and Civil Hospital Karachi cater to the needs of NNT cases.

Since NNT is one of the most underreported diseases in Pakistan and ascertainment of cases is difficult, we conducted a matched case control study to identify risk factors for NNT in Karachi. A total of 125 cases of NNT reported by two hospitals during the period January 1998 to February 2001 were recruited in the study. Addresses for the cases of NNT were obtained through the office of EPI in Karachi and mothers of cases were interviewed in their homes after obtaining signed informed consent from the head of the household. Control infants (n = 250) were matched on gender for the effects of circumcision in males, while matching on area of residence was undertaken to minimize the possible variations in delivery practices in different areas. Controls were selected from the same street in the district of residence of the case. Matching by date of birth was done to assure equivalent degree of recall among mothers of cases and controls.

A case of NNT was defined as one who had the following signs and symptoms occurring in sequence: history of normal suck and cry for the first two days of life; history of onset of illness between 3 and 28 days of age; history of inability to suck; stiffness and/or convulsions. We selected cases that met these criteria for case definition since diagnosis of NNT is based on clinical signs and symptoms and does not require bacteriological confirmation. We excluded NNT cases that were not born in Karachi because delivery practices outside Karachi could be different from our study setting.

Two controls matched on gender, area of residence and within two months of the date of birth of case, were selected from the infants who survived the neonatal period and whose mothers had no history of TT immunization. We excluded infants who had NNT in the past as controls because they could have been exposed to the hypothesized risk factors of our study during the neonatal period. Mothers who had history of one or more doses of TT were excluded because these hypothesized risk factors could be obscured by passive immunity transferred from mother to child. Recruiting infants of immunized mothers as controls could also underestimate the effects.

Statistical Analysis

Data were entered into EpiInfo version 6.04[12] and subsequently converted to a SAS file[13] for performing univariate and multivariable analysis. Frequencies of demographic and socio-economic variables e.g., education of parents, their occupations, and monthly income were computed. Mean and standard deviation was calculated for continuous variables. Univariate analysis was carried out by computing unadjusted matched odds ratios (mOR) and their 95% confidence interval to compare cases and controls for each variable of interest. The dependent variable was NNT status as a case or control and independent variables were the hypothesized risk factors. The category of independent variable with assumingly minimum level of risk for NNT was taken as reference.

Multivariable analysis was conducted through conditional logistic regression to identify risk factors independently associated with NNT. The criteria for selection of these variables for possible inclusion in multivariable analysis were based on both biological importance and p value of less than 0.25 in univariate analysis. Biologically meaningful interactions were also assessed for inclusion in the final model. Population attributable risk per cent (PAR%) was calculated[14] for dichotomous variable (home delivery) and for variables with more than one level of exposure (subsequent cord application).

Results

Three hundred and seventy five neonates (125 cases and 250 matched controls) were recruited in the study. Parents of two cases refused to participate in the study. The majority of cases in our study were males (70%). The mean age for the case mother was 26.4 years and for controls, it was 25.7 (Table 1).

Table 1: Distribution of NNT cases and their matched controls by demographic and educational characteristics of their parents

Variables	Cases (n=125)	Controls (n=250)
Average age of mother (years)	26.4	25.7
Ethnicity		
Pukhtoon	68 (54.4)	105 (42.0)
Urdu	16 (12.8)	44 (17.6)
Punjabi	11 (8.8)	45 (18.0)
Bengali	12 (9.6)	22 (8.8)
Sindhi	11 (8.8)	20 (8)
Balochi	7 (5.6)	14 (5.6)
Respondents		
Mother	114 (91.2)	236 (94.4)
Grand mother	8 (6.4)	13 (5.2)
Aunt	3 (2.4)	1 (0.4)
Father's education		
Illiterate	80 (68.0)	172 (68.8)
Read & write	4 (3.2)	10 (4.0)
Primary	17 (13.6)	14 (5.6)
Middle	7 (5.6)	16 (10.6)
Matriculate	14 (11.2)	32 (12.8)
Intermediate & above	3 (2.4)	6 (2.4)
Mother's education		
Illiterate	111(88.8)	204 (81.6)
Read & write	3 (2.4)	5 (2.0)
Primary	7 (5.6)	16 (6.4)
Middle	-	12 (4.8)
Matriculate	4 (3.2)	7 (2.8)
Intermediate & above	-	6 (2.4)
Father's occupation*		
Government job	5 (4.0)	8 (3.2)
Private job	48 (38.4)	91 (36.4)
Service provider	65 (52.0)	138 (55.2)
Unemployed	7 (5.6)	13 (5.2)
Mother's occupation†		
House wife	116 (92.8)	235 (94.0)
Service provider	9 (7.2)	15 (6.0)
Average monthly income (in Rs.)‡	3534	3603
Mean no. of children in family	3.9	3.4

*Government job: Employees in City Metropolitan Corporations, Private job: Independent jobs e.g., shopkeepers, tailors, fishermen etc., Service providers: labourers, carpenters, guards, waiters, bus conductors etc; † Service providers: labourers, housemaids, etc.; ‡ 1 Pak Rupee = 0.017 US$

Respondents were mothers in the majority of the interviews among cases (91.2%) and controls (94.4%). Fathers were illiterate in most of the cases (68%) and controls (69%). The proportion of illiterate mothers among the cases was 88.8% as compared to 81.6% of the controls. Most of the mothers were housewives for both cases and controls.

In univariate analysis, we classified various hypothesized factors associated with NNT into three groups: educational status of parents, delivery practices, and cord care practices. Univariate analysis for educational status of parents is summarized in Table 2. An illiterate mother was associated with NNT (mOR = 1.6; 95% CI: 1.2, 2.5) in this analysis. From among delivery practices, home delivery, non-professional delivery attendant, delivery surface, not washing hands, non-use of safe delivery kit, unclean perineum before delivery, application of substances on the perineum, intravaginal applications and application of feet during delivery were associated with NNT (Table 3). Cord care practices for their possible association with NNT are shown in Table 4. Cord-cutting instrument, condition of the instrument, cord length, cord tie, initial application of substances (immediate application during delivery), and subsequent application of substances (application after a day of delivery) were significantly related to NNT in univariate analysis.

The final conditional logistic regression model included the independent effects of subsequent cord application, place of delivery, and mother's education (Table 5). Subsequent application on the umbilical cord was a risk factor for NNT in the final model. The odds of applying mustard oil, ghee or surma on the umbilical wound in subsequent days among cases were 5.1 times the odds among controls (95%CI: 2.7, 9.7) after controlling for the effect of other variables in the model. Also,

Table 2: Univariate analysis of educational status of parents for their possible association with NNT

Variable	Cases =125 n (%)	Controls = 250 n (%)	mOR [95% CI]
Father's education			
Illiterate	80 (64.0)	170 (68.0)	1.1 [0.9, 1.6]
Mother's education			
Illiterate	111 (88.8)	204 (81.6)	1.6 [1.2, 2.5]

Table 3: Univariate analysis of delivery practices for their possible association with NNT

Variable	Cases = 125 n (%)	Controls = 250 n (%)	mOR [95% CI]
Home delivery *	108 (86.4)	176 (70.4)	2.7 [1.5, 4.8]
Non-professional delivery attendant †	101 (80.8)	176 (70.4)	1.8 [1.1, 2.9]
Delivery surface ‡			
Bed sheet	36 (28.8)	76 (30.4)	1.7 [0.9, 2.9]
Floor	43 (34.4)	41 (16.4)	3.7 [2.1, 6.6]
Straw surface	12 (9.6)	13 (5.2)	3.3 [1.4, 7.8]
Not washing hands before delivery	83 (66.4)	90 (36.0)	3.5 [2.2, 5.5]
Not using safe delivery kit	104 (83.2)	167 (66.8)	2.5 [1.4, 4.2]
Not cleaning perineum before delivery	101 (80.8)	152 (60.8)	2.5 [1.4, 4.2]
Applications on perineum during delivery §	53 (42.4)	136 (54.4)	1.6 [1.1, 2.3]
Intravaginal applications Q%	54 (43.2)	133 (53.2)	1.5 [1.0, 2.3]
Feet application	100 (80.0)	140 (56.0)	3.1 [1.9, 5.2]

*Reference category: Health care setting (hospitals, private clinics and maternity homes); † Non-professional attendant: dai, relative, self delivered; ‡Reference category: plastic sheet; § Applications of ghee, mustard oil or coconut oil; Q% Applications of ghee, mustard oil or coconut oil to facilitate delivery.

Table 4: Univariate analysis of cord care practices for their possible association with NNT

Variable	Cases = 125 n (%)	Controls = 250 n (%)	mOR [95% CI]
Cord cutting instrument *			
Old blade	20 (16.0)	10 (4.0)	6.4 [2.8, 14.6]
Kitchen knife	19 (15.2)	11 (4.4)	5.5 [2.4, 12.4]
Scissors	40 (32.0)	82 (32.8)	1.5 [0.9, 2.6]
Cord length of > 4 fingers	71 (56.8)	80 (32.0)	2.7 [1.8, 4.3]
Cord tie †			
Thread brought by attendant	27 (21.6)	37 (14.8)	3.6 [1.6, 7.9]
Thread used in home	86 (68.8)	154 (61.6)	2.7 [1.4, 5.4]
Initial cord application ‡			
Mustard oil/ghee/surma	17 (13.6)	13 (5.2)	8.7 [2.1, 35.7]
No application	105 (84.0)	217 (86.8)	3.2 [0.9, 11.1]
Subsequent cord application ‡			
Mustard oil/ghee/surma	106 (84.8)	135 (54.0)	5.7 [3.1, 10.9]
No application	6 (4.8)	19 (7.6)	2.3 [0.8, 6.9]

Reference categories: * New blade, † Clamp, ‡ Antimicrobials

Table 5: Final multivariable logistic regression model for the factors associated with NNT in Karachi

Variable	Adjusted mOR [95% CI]
Subsequent cord application *	
Mustard oil/ghee/surma	5.1 [2.7, 9.7]
No application	2.1 [0.7, 6.5]
Home delivery	1.8 [1.1, 3.1]
Mother's education Illiterate	1.6 [1.0, 3.0]

*Reference category: Anti-microbials

home delivery showed a statistically significant association with NNT in the final model (adj mOR = 1.8; 95% CI: 1.1, 3.1). Cases, as compared to controls were 1.6 times more likely to have been born to an illiterate mother (95% CI: 1.0, 3.0). The population attributable risk % for subsequent cord application was 69%, and for home delivery was 31% respectively.

Discussion

The findings of this matched case control study identified that subsequent application of substances (mustard oil, ghee or surma) on the umbilical cord, delivery carried out at home, and an illiterate mother of a child are risk factors for NNT. Our results in the multivariate analysis confirm the association between subsequent cord application and NNT that was previously reported in rural areas of Pakistan.[7] In rural Pakistan, ghee, clarified butter used for cooking, has been reportedly used for wound dressing purposes along with other substances such as mustard oil and surma.[9] Although both initial and subsequent applications have been identified as risk factors in previous studies[8] we could only identify subsequent application as a risk factor in our study. Initial cord application was highly correlated with the place of delivery since all those who were applying traditional substances (e.g., mustard oil, ghee or surma) at birth were delivered at home. We found differences in the frequency of initial and subsequent application, for which a plausible explanation could be that trained 'dais' (traditional birth attendants) are less likely to apply hazardous materials on the umbilical wound, in contrast to mothers and other relatives in the household who may start applying ghee and other traditional substances later.

Since spores of *Clostridium tetani* are present in the environment such as soil and animal dung 'in use contamination' of ghee through these environmental factors can be the possible cause of NNT as demonstrated by Bennett *et al.*[8] Environmental factors such as soiled hands could be the possible source of *Clostridium tetani* during 'in use contamination' in our study. The urban setting of the study was probably responsible for the absence of application of animal dung in our cases and controls.[9,16] The hazard of contaminated mustard oil or ghee increases in subsequent days because these spores germinate on devitalised cord tissue due to their anaerobic properties. Therefore, it is possible that the child becomes more susceptible to NNT when exposed in subsequent days during which the viability of the umbilical tissue may have declined, as compared to application on the day of delivery. The spores can survive boiling, so application of heated mustard oil or ghee would also prove ineffective in protecting the child against NNT. The role of surma (black cosmetic powder containing antimony and lead) application in our study was not analysed as a separate category because very few mothers/relatives were noticed to have applied it. However, its possible association has been reported with circumcision-related NNT in earlier studies.[17]

Population attributable risk per cent (PAR%) for subsequent cord application was 69% in our study. Our estimation suggests that more than two-thirds of the NNT cases would have been avoided if mustard oil, ghee or surma had not been applied on the umbilical cord of any baby in the population for days after birth. The PAR% for subsequent application of ghee was 43% in NWFP, Pakistan.[7]

Applying nothing to the umbilical wound has been shown to be significantly more hazardous than applying anti-microbial agents to the umbilical wound in rural areas of the Punjab province of Pakistan.[18] Our study could not confirm 'no application' as a significant risk factor in multivariate analysis when anti-microbial was taken as a referent category. The apparent absence of demonstrated hazard from 'no application' might have been due to the small numbers of cases and controls (6 among cases versus 19 among controls). It might also reflect a difference in the intensity of environmental contamination with tetanus spores between the previous studies in rural areas of Pakistan and our present study in Karachi i.e., the hazard of no application may be much greater in rural areas where animals and animal dung exist in close proximity to living areas and are likely to provide more intense exposure to environmental spores.

Deliveries conducted at home were identified as an independent risk factor in our study. Previously it could not be identified as a risk factor in rural Pakistan since almost all deliveries were conducted at home.[3] Deliveries in health care settings such as hospitals, and maternity clinics are attended by physicians, nurses and trained birth practitioners where the child is less likely to be exposed to applications of harmful substances on the umbilical cord. If the measure of association between home delivery and NNT (mOR = 1.8), is assumed to reflect relative risk, and if it is assumed that 70.4% of all neonates in the general population are born at home (frequency observed among controls), then the total curtailment of deliveries conducted at home could reduce the incidence of NNT by 31%.

Among the educational status of parents in univariate analysis, mother's education retained its association with NNT in the final multivariable model. Studies from developing countries have indicated that neonatal mortality is more closely related to maternal education than any other socio-economic factors and it plays an important role even after controlling for the effect of other factors such as educational and occupational characteristics of the father.[19] It is generally reasoned that maternal education acts as an independent determinant of neonatal mortality.[20] In Nigeria, a mother who was educated beyond the primary level was less likely to deliver in the non-medical establishment and was more likely to avail of antenatal care for herself.[21] In our setting, babies born to illiterate

mothers are expected to have higher NNT mortality rates since they tend to live in poor neighbourhoods with inadequate sanitation facilities. These mothers are more prone to practising unhygienic newborn cord care such as application of mustard oil, ghee or surma, thus making their child more susceptible to NNT.

One of the concerns for our study is the possibility of differential recall i.e., the accuracy of recall of past events for the mothers of NNT cases would be different from their comparison group of non-NNT controls. Since 55% of cases from 1998-2000 were located from the records of hospitals and their addresses from the EPI office, there could be an imperfect recall existing among these cases and controls for information on past exposures.

To eliminate NNT by the year 2005, there is an immediate need to address this public health menace. Subsequent application of substances should be discouraged through health awareness programmes in the community. Curtailment of this practice should become part of the NNT prevention programme. Deliveries in a health care setting should be encouraged because of routine aseptic cord care practices. Counselling of the pregnant mothers is crucial in this regard.

Acknowledgement

This study was funded by Aga Khan University's Research Council Grant (Project ID: 002F410WF) and was cleared by Ethics Review Board (51CHS/ERC-00) of the university. We are grateful to Dr John V Bennett (Visiting Professor, Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, Georgia, USA) for providing valuable feedback during the execution of project. We also take this opportunity to thank Dr. Mubina Agboatwalla who had been a great source in providing the EPI line listing for identification of cases from Civil Hospital and EPI Head Office in Karachi. We are thankful to Professor Zeenat Esani, Director National Institute of Child Health for giving us the permission to use EPI records of cases. We are grateful to Ms. Rubina Inam and Ms. Rukhsana Sadiq who organized themselves efficiently during the field work of the study.

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Expert's Comments

The challenges of eliminating neonatal tetanus

Child mortality has been declining rapidly over the past few decades. However, the decline in infant and neonatal mortality has not been nearly as dramatic. This has led to an increasing interest in neonatal mortality and what interventions might be most effective in this age group. Neonatal tetanus is a cause of neonatal death that has well defined risk factors and specific interventions that could be very effective in eliminating this cause of neonatal mortality.[1] Specifically, we have a vaccine that is effective, long lasting, safe to provide in pregnancy and whose impact extends to protect the neonate.[2] In addition, safe birthing practices, including cutting the cord with a clean blade, can be effective in preventing infection.[3] Other potential sources of infection are applications of various substances to the cord, a common practice in many cultures.[4-6] Much of the literature on risk factors for neonatal tetanus describes rural populations, where the risk may seem greatest. What is most interesting about the paper[7] in this issue of the journal is that it focuses on risk factors in an urban environment where access to care and hygiene conditions are presumed better than in rural areas. As in prior studies conducted in rural areas, maternal illiteracy, home delivery and applications to the cord independently put infants at greater risk for neonatal tetanus among those who have not been protected by maternal immunizations. These risk factors suggest interventions that are practical and feasible, although they require behavior change that is often challenging to effect. Safe birthing kits and the training of birth attendants in their appropriate use should be a focus in urban areas as well as rural

ones. Education regarding the risks associated with the application of traditional substances to the cord, perhaps recommending a substitution with inexpensive antiseptics may also have the potential to reduce neonatal tetanus risk as well as other cord infections. Finally, a safe an efficacious vaccine is available, and should continue to constitute a strategy to attain the goal of elimination of neonatal tetanus set by the World Summit for Children.

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