

Childhood Poisoning Involving Transdermal Nicotine Patches

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ABSTRACT. *Objective.* To describe the circumstances, medical complications, and outcomes of children exposed to a transdermal nicotine patch (TNP).

Design. Prospective case series; postmarketing surveillance study over a 24-month period.

Setting. Thirty-four United States poison centers.

Patients. Children 0 to 15 years old exposed to a TNP.

Interventions. None.

Outcome Measures. Exposure circumstances, symptoms and signs of toxicity, complications, disposition, and hospital length of stay.

Results. Reports were received concerning 36 exposures to TNP in children younger than 16 years old (mean: 3 years old). Eighteen of these TNP exposures were dermal; 18 additional children had bitten, chewed, or swallowed part of a patch. All four commercial brands of TNP were represented; no brand was associated with more symptoms or an increased severity of illness. Fourteen children (39%) developed symptoms, including gastrointestinal distress (nausea, vomiting, diarrhea, abdominal pain), weakness, dizziness, or localized rashes. Occurrence of symptoms after a dermal exposure to a TNP was associated with an estimated nicotine dose .10 mg (.01 mg/kg body weight). Ten children were seen in the emergency department; two were admitted overnight. All recovered fully.

Conclusions. In this series, unintentional exposures to TNPs among young children usually involved used patches, were transient (<20 minutes duration), and required only skin decontamination and supportive care. Continued monitoring of inadvertent childhood exposures to TNPs is recommended to confirm these observations. *Pediatrics* 1997;99(5). URL: <http://www.pediatrics.org/cgi/content/full/99/5/e4>; nicotine, poisoning, transdermal nicotine patch, overdose, pediatric poisoning, intoxication.

ABBREVIATION. TNP, transdermal nicotine patch.

Transdermal nicotine patches (TNPs) are established systems of drug delivery that, in previous clinical trials, have demonstrated efficacy in helping

adults to curtail cigarette smoking.¹⁻⁸ These products were first made available commercially in the United States in 1992 on a prescription-only basis. Four brands of TNP deliver up to 22 mg of nicotine in a 24-hour period; however, 27% to 74% of the total nicotine may remain in a TNP after use. As much as 83 mg of residual nicotine may remain in a used TNP, the equivalent to the nicotine content of 4 to 7 cigarettes.

In 1996, TNPs were made available to the public without prescription to encourage cigarette smoking cessation. An estimated 16 million Americans will spend over one billion dollars on such over-the-counter nicotine replacement systems annually in an attempt to quit smoking.⁹ As the availability of these products increases, it is anticipated that physicians and poison centers will be contacted with increasing frequency concerning inadvertent exposures to them among children.

Therapeutic use of TNPs in adults has been associated with a variety of adverse effects, including rashes, allergic skin reactions, nausea and vomiting, sleep disturbances, headaches, and chest pain.¹⁰⁻¹² Early manifestations of nicotine poisoning in children, seen after the ingestion of cigarettes or nicotine-containing gum, include gastrointestinal complaints (nausea, vomiting, diarrhea), increased salivation, pallor (from peripheral vasoconstriction), diaphoresis, weakness, and dizziness.¹³⁻¹⁵ In one series, as little as .2 mg/kg of ingested nicotine derived from tobacco products caused mild toxic symptoms in children.¹⁴ Major neurological, respiratory, and cardiovascular complications of nicotine poisoning in children can include lethargy, seizures, coma, respiratory depression, apnea, hypertension, hypotension, and dysrhythmia.¹⁵⁻¹⁸ One 8-month-old infant developed progressive obtundation and respiratory depression after the ingestion of only two cigarette butts.¹⁶ In another case, a 17-year-old adolescent suffered cardiac arrest and died shortly after ingesting a concentrated nicotine-containing solution.¹⁸

Previous reports of pediatric exposures to patches containing other medications, such as clonidine, have suggested the potential for serious toxicity.^{19,20} Thus, there has been concern that children might be seriously poisoned from inadvertent exposure to a TNP. Adult volunteers who chewed on a new TNP quickly developed cardiovascular and other symptoms depending on the dose and type of patch.²¹ Also, although the dose of nicotine after ingestion of tobacco or nicotine-containing gum by a child might be limited by centrally mediated vomiting, a TNP applied dermally to the child's skin bypasses the oral route and might expose the child to higher blood-

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nicotine concentrations than ordinarily could be attained. The objective of the current study was to characterize the medical consequences of unintentional exposure of children to a TNP.

METHODS

Thirty-four United States poison centers (see Acknowledgments) were recruited to monitor incoming poisoning calls for instances of an unintentional exposure to a TNP among children. For the purposes of the present study, only reports of exposures to a TNP involving children <16 years old were considered for inclusion.

Participating poison centers completed data collection forms during a 24-month surveillance period from November 1992 through October 1994. Data were sent to a central collection site where results were compiled.

For all case reports, information about the date and time of the poisoning, circumstances of exposure, type and lot number of the TNPs involved, clinical symptoms and signs and their duration, clinical course, complications, management, and clinical outcomes were recorded. Concomitant exposures to other drugs or toxins were noted. Patients were triaged to home observation or to the emergency department. For those patients who remained at home, telephone follow-up for at least 24 hours was carried out. No child seen in an emergency department had blood or urine nicotine or cotinine levels sent for analysis.

A dose of nicotine was calculated from the estimated duration of time the child was exposed to the TNP as reported by the caretaker or other witness. Only those children with dermal exposures were included in the analysis of nicotine dose. No assumptions were made about differences in diffusion characteristics of new, compared to used, patches. Table 1 shows the rates of nicotine delivery by TNPs used to calculate dose.

Data were analyzed using descriptive statistics. Comparisons between groups were made using the χ^2 statistic or Fisher's exact test for dichotomous variables. The Student's *t* test was used for continuous variables. Evidence of significance was set at an α level of .05 or less. This study was approved by the Institutional Review Board for Human Subjects at the Children's Hospital, Boston, Massachusetts.

RESULTS

Demographics

Thirty-three cases of pediatric poisoning by exposure to a TNP were reported during the surveillance period. Three additional cases had been previously reported to the manufacturer before the time of study onset and have been included in the analysis. The mean age of the children was 3 years (range: 7 weeks to 13.5 years); there were 17 boys and 19 girls (see Fig 1).

TNP Type

All four brands of TNP from American manufacturers were involved in the reported exposures, although only one child was exposed to Nicotrol. Eighteen children were exposed dermally to the TNP; 16 children only chewed or sucked on patches. Two children may have ingested part of a patch. The

duration of dermal exposure to the patches ranged from only 1 minute or so to as long as 12 hours. Twenty-eight (78%) of the children were exposed to TNPs that had been previously used therapeutically.

Circumstances Of Exposure

The circumstances of exposure to the TNP were varied. In 21 cases, the narrative report simply indicated that the child had discovered a TNP, either new or discarded in the garbage, or had opened a package of new TNPs. In four other cases, the TNP had fallen off the adult's skin without his or her knowledge. In two others, the TNP evidently had come off while the parent and child were asleep in the same bed and then had become affixed to the child's skin. Three children took the TNP off the parent's skin without their knowledge; another child mistook a new TNP for a Band-aid. One used TNP became affixed to the child's pajamas while in the family wash, and then subsequently was inadvertently transferred from the pajama to the child's skin. A 5-week-old child went unnoticed while sucking on a TNP attached to the father's upper arm. Finally three adolescents intentionally applied or chewed on someone else's TNP; in one case the adolescent was attempting to self-medicate to quit smoking.

Symptoms and Signs

Table 2 and Fig 2 present the symptoms and signs of toxicity seen in these children. Twenty-two children (64%) suffered no toxic effects from the TNP exposure: 13 of the 18 children (72%) with oral exposures and 9 of the 18 (50%) with dermal exposures remained asymptomatic.

Toxicity After an Oral Exposure to a TNP

Significantly, the five children who became symptomatic after an oral exposure to a TNP had only transient and local signs of toxicity: gagging or a burning sensation of the mouth or tongue in three patients who were observed at home, a 1-year-old who vomited the gel matrix from a used 22-mg TNP and was observed at home, and excessive fatigue in a 7-month-old who chewed a TNP and was subsequently observed for <4 hours in the emergency department.

Toxicity After a Dermal Exposure to a TNP

By contrast, children with dermal exposures more often had systemic complaints. Seven of the nine children who were symptomatic after a dermal TNP exposure had nausea and/or vomiting. Five of the nine children were triaged to the emergency department and two were admitted.

Toxicity and Nicotine Duration/Projected Dose

Most of the children (N = 28) were exposed to a TNP that released approximately .9 mg of nicotine per hour. A TNP releasing nicotine at a rate of .3 mg/hour was implicated in only five cases; two of those children remained asymptomatic and three had only local symptoms: skin irritation (N = 2) or a burning sensation of the mouth (N = 1). A TNP releasing nicotine at a rate of .6 mg/hour was involved in three exposures, one of whom was symptomatic (case 6).

TABLE 1. Rate of Nicotine Delivery by TNPs

Nicotine Delivery	Nicotine Absorption Rate
22 or 21 mg/day	0.9 mg/h
15 mg/16 h	0.9 mg/h
14 mg/day	0.6 mg/h
10 mg/16 h	0.6 mg/h
11 mg/day	0.5 mg/h
7 mg/day	0.3 mg/h
5 mg/16 h	0.3 mg/h

Fig 1. Age and sex distribution of 36 children exposed to a TNP.

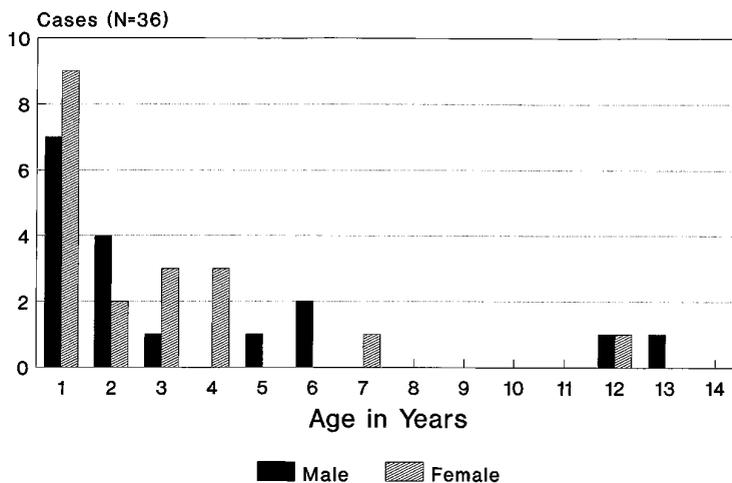


TABLE 2. Signs of Toxicity After Exposure to Transdermal Nicotine Patches in 36 Children

Oral Exposures* (N = 18)	Dermal Exposures† (N = 18)
No symptoms 13 (72%)	No symptoms 9 (50%)
Burning tongue 2	Nausea/vomiting 7
Gag/vomit 2	Dizzy/lethargic 3
Fussiness 1	Skin irritation 2
Fatigue 1	Pallor 1
	Diarrhea 1
	Tachycardia 1
	Fussiness 1

* One child in the oral exposures group had both vomiting and fussiness.

† Four children in the dermal exposures group had two or more symptoms.

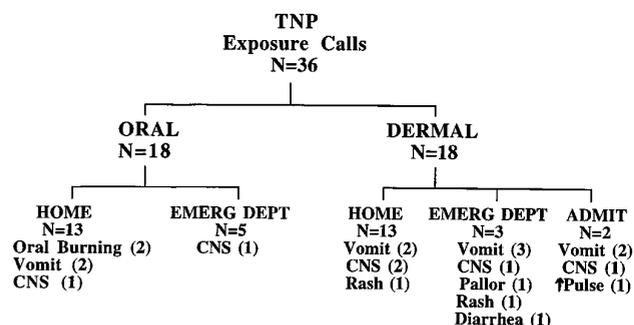


Fig 2. Triage and symptoms and signs of toxicity in 36 childhood TNP exposures. Numbers in parentheses refer to the number of patients with that symptom. Central nervous system (CNS) symptoms includes lethargy, irritability, headache, fussiness, or excessive fatigue.

A previously used TNP compared to a newly opened TNP was less likely to produce a symptomatic child: only 7 of the 28 children (25%) exposed to a used TNP experienced any symptoms as opposed to 6 of the 8 children (75%) exposed to an unused TNP ($P = .016$). One child (case 2) who placed two new 21-mg-nicotine patches on his skin developed marked vomiting, pallor, and lethargy and required observation in an emergency department.

Irrespective of route, the duration of exposure to the TNP patch was also roughly correlated with symptoms of toxicity. Almost all of the 18 oral exposures were of <10 minutes duration; only 5 of these children developed any symptoms. Of the 18 dermal

TNP exposures, 7 of 8 children (87.5%) exposed for 20 minutes or longer developed toxicity, as opposed to 2 of 10 children (20%) exposed for under 20 minutes ($P = .008$).

Table 3 presents the correlation of symptoms with the estimated nicotine dose absorbed from 18 children with dermal TNP exposures. Eight out of 10 children with estimated nicotine dermal doses of .1 mg or greater developed symptoms; only 1 of the 8 children with a nicotine dermal dose <.1 mg had any symptoms. Table 4 presents the correlation of symptoms with the estimated nicotine dose/kilogram of body weight for the 13 cases with verified weights. The mean estimated nicotine dose/kg for symptomatic children (.18 mg/kg; SD, .19 mg/kg) was higher than that of asymptomatic children (.006 mg/kg; SD, .004 mg/kg) ($P = .055$).

Management and Disposition

Figure 2 displays the disposition of the 36 patients. Ten patients (28%) were referred to the emergency department for observation and management. All were treated with supportive care; two patients were also treated with ipecac and one other patient received a dose of activated charcoal. Only two children were admitted for overnight observation (see cases 4 and 5).

Illustrative Examples

The following six cases illustrate the most severe manifestations of toxicity among the 36 children exposed to transdermal nicotine patches in this series.

Case 1

This 13.5-year-old boy had a history of cigarette smoking (1 to 2 packs per week for the previous 3 years). He applied one of his mother's unused TNP (21 mg) to his arm before going to school in an attempt to quit. Approximately 2 hours later he complained of

TABLE 3. Nicotine Dose Versus Symptoms in 18 Children With Dermal TNP Exposures

Calculated Nicotine Dose	N	Symptomatic Children	%
0.9–10.8 mg	6	6	100
0.1–0.89 mg	4	2	50
<0.1 mg	8	1	13

TABLE 4. Nicotine Dose/Body Weight Versus Symptoms in 13 Children With Dermal TNP Exposures

Estimated Dose (mg/kg)	N	Symptoms	%
0.1–0.5	4	4	100
0.01–0.099	2	1	50
<0.01	7	2	29

nausea and was sent to the school nurse, who removed the patch and washed the skin. Over the next hour or so he vomited three times. This subsided, although his nausea persisted for several more hours. He became asymptomatic about 6 hours after the patch was removed and required no medical interventions.

Case 2

This 6-year-old boy awoke feeling cold and clammy with marked pallor. While undressing him, the mother noted two TNPs (21 mg each) affixed to his skin. The exact duration of exposure was unknown but <6 hours. The patient was observed in an emergency department for about 6 hours and suffered repetitive vomiting. He remained unusually lethargic the following day but became asymptomatic within 18 hours after the exposure was discovered.

Case 3

A 7-year-old girl placed a new TNP (7 mg) on her open cut thinking that it was a Band-aid. The parent discovered the patch 15 minutes later, removed it and washed the skin, which appeared erythematous and irritated. The child was transported to the local emergency department 20 minutes later, complaining of abdominal pain, nausea, vomiting, and diarrhea. She was discharged home after a short period of observation.

Case 4

A 3-year-old girl found a TNP (21 mg) and placed it on her abdomen. The duration of exposure was about 15 minutes. After the patch was removed, the child developed nausea and vomiting and was transported to the emergency department. She became groggy and had an increased pulse (heart rate: 160 to 170 beats per minute). There was a question as to whether acetaminophen with codeine and propranolol were also ingested. No pills were observed in the emesis. The patient was admitted overnight, became asymptomatic, and was discharged the following morning. The plasma acetaminophen concentration was subtherapeutic but detectable.

Case 5

A 4-year-old girl applied an unused TNP (21 mg) to her skin for 1 hour. The child developed protracted vomiting with 5 to 6 episodes and was brought to the emergency department, where the TNP was removed and the area cleaned with soap and water. The vomiting subsided; nonetheless, the child was admitted for overnight observation. She was discharged asymptomatic the following morning.

Case 6

A 12-year-old girl applied her mother's TNP (14 mg) to her leg for 30 minutes. She developed a "severe" headache, nausea, and light-headedness. The patch was removed and the child bathed. She was observed at home; symptoms abated within 2 hours of removal of the patch.

DISCUSSION

The toxicity of inadvertent exposures to TNPs in young children has not been previously detailed. In the current study, a majority of pediatric patients experienced either no effect or transient, self-limited symptoms after the exposure. Symptoms included gastrointestinal complaints, skin irritation and rashes, pallor, lethargy, and irritability. There are several possible reasons for the relatively mild na-

ture of their symptoms: 1) the duration of the exposure was too short for significant absorption of nicotine to take place; 2) the exposure type (eg, chewing part of a patch) was such that an inconsequential dose of nicotine could be absorbed; and 3) many of the exposures were to used TNPs which are a less potent source of nicotine.

Most of the TNPs implicated in this case series released .9 mg nicotine per hour; exact doses of nicotine absorbed by the children were unknown because blood concentrations were not measured. However, the rough correlation between the presence of symptoms, duration of exposure, and the estimated dose of nicotine absorbed after a dermal exposure suggests a dose-response relationship. Children with an estimated dose of absorbed nicotine <.1 mg were unlikely to develop any symptoms.

The three adolescent cases noted in this series deserve special comment. Because of their over-the-counter status, TNPs are now more accessible to adolescents, who may purchase them in an attempt to quit smoking (although use by adolescents is not approved by the Food and Drug Administration). Intentional misuse of a TNP by two adolescents in this series who wished to experience the nicotine effects alone should serve as a warning to clinicians who provide medical care for this population. Adolescents may experiment with TNPs for the effect or may use them in an attempt at self-harm.

Four limitations of this case series might lead to an underestimation of the severity of childhood poisoning involving TNPs. The first limitation is that only one of the children in this series was exposed to more than one TNP simultaneously; exposure to multiple TNPs simultaneously would theoretically place the child at a higher risk for cardiovascular or neurologic dysfunction. The second limitation is that of the thirty-six patients in this series, 78% were exposed to used TNPs. It is likely that new TNPs would deliver a higher dose of nicotine. Dermal application or ingestion of a new TNP might cause more serious symptoms. The third limitation is that in this series most children with ingestion or dermal exposures to TNPs were discovered early and the TNP quickly removed. A prolonged application may be more deleterious. The fourth limitation is that the absorbed nicotine dose that we calculated should be viewed with caution, because it was based on estimated exposure times and also disregarded differences in nicotine diffusion between a new and used TNP. The calculation also assumed that skin absorption rates in adults could be extrapolated to children.

With the above limitations noted, we can still make some recommendations on the basis of this study. The circumstances of many of the inadvertent exposures in this series involved a child who discovered and retrieved a casually discarded, used TNP. The fact that TNPs are now available without prescription may mislead parents into thinking that the products have little potential for toxicity. Parents should safely store TNPs, as they would any other medication, in locked cabinets out of the reach of toddlers. Caretakers using TNPs should be vigilant that the patch does not fall off during sleep, or dur-

ing a shower, or that their toddler does not dislodge it from their skin without their knowledge. When they are finished using a TNP, parents should exercise caution in properly disposing of the patch so that a toddler cannot gain access to it.

Advice to parents and physicians confronted with a childhood TNP exposure should be based on an estimation of the likely dose of nicotine absorbed: the child's weight, the nicotine concentration in the patch, and the duration of exposure can be used in such a calculation. When there is only a brief exposure to a used TNP, immediate removal of the TNP and washing of the skin would seem reasonable advice for caretakers calling from home. Caretakers should be advised that gastrointestinal disturbances and minimum alteration of sensorium are to be expected. Ipecac-induced emesis would seem to be unnecessary when only part of a TNP has been chewed or ingested. Administration of activated charcoal should probably be reserved for those cases involving the ingestion of whole TNPs, although charcoal's efficacy in such circumstances is unknown. Indications for seeking medical attention would include protracted gastrointestinal distress, marked alteration of sensorium, or when the estimated dose of nicotine absorbed is .1 mg/kg body weight or higher.

CONCLUSIONS

In this series of pediatric patients, unintentional and brief (20 minutes or less) exposures to used TNPs resulted in few if any medical symptoms. Children with dermal exposures of longer duration were more likely to become symptomatic than children who had bitten or sucked briefly on a patch. Even with higher absorbed nicotine doses, most children experienced only mild gastrointestinal symptoms or skin irritation; however, some children with dermal exposures to new or used TNPs for longer than 60 minutes (a calculated dose of absorbed nicotine >.9 mg) manifested typical symptoms of nicotine poisoning.

Because TNPs are now available without prescription, children and adolescents are likely to have greater access to them. Clinicians should continue to monitor for and report toxic effects of pediatric TNP exposures. In labeling TNP packages, manufacturers should continue to advise caretakers to take appropriate precautions when these products are used in homes where there are young children. Finally more investigation is needed into both the circumstances surrounding pediatric TNP exposures and how such inadvertent poisonings can be prevented.

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This manuscript has been approved by the Board of Directors of the American Association of Poison Control Centers.

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