Deaths Related to Propoxyphene or Codeine or Both

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ABSTRACT: Ninety-nine deaths involving propoxyphene or codeine or both were investigated through interviews with surviving relatives and associates. The criterion for admission to this study was the presence of propoxyphene or codeine in the body fluids or tissues, determined analytically. The codeine-related group included more ethnic minority persons, more histories of primary drug addiction, more users of street drugs, and more accidental deaths. In the propoxyphene-related group there were fewer histories of drug addiction and more persons with mental illness and more suicides. Most victims had considerable past experience with one or both of the drugs and other drugs as well. Propoxyphene was usually obtained by physician prescription. Codeine was often obtained illegally.

KEYWORDS: toxicology, propoxyphene, codeine, death, suicide, accident, overdose, drug abuse

Propoxyphene (Darvon[®]) is an analgesic frequently prescribed for the relief of mild to moderate pain. Since it was first marketed in 1957, more than 20 billion doses of propoxyphene have been issued [1]. In the early 1970s, medical examiners began reporting increasing numbers of deaths occurring both as suicides and accidents related to propoxyphene [2-4]. Finkle and colleagues [5,6] have comprehensively reviewed the postmortem toxicology of propoxyphene as reported by medical examiners from 1972 to 1978.

In 1977, propoxyphene-containing compounds were placed in Schedule IV of the Controlled Substance Act. In 1979, extensive public hearings were held by the Food and Drug Administration (FDA) Abuse Advisory Committee to determine whether further controls were appropriate. No further controls on prescriptions were recommended. (Later, in 1980, quotas were placed on manufacturing.) A number of important questions were raised concerning the people at risk of becoming propoxyphene-related deaths [7]. What were their demographic and psychological characteristics? More specifically, how many of the deaths associated with propoxyphene are suicides: how many are accidents resulting from use or misuse; and how many are accidents resulting from normal use? Several participants suggested that it would

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¹Co-Director, Institute for Studies of Destructive Behaviors and the Suicide Prevention Center, Los Angeles, CA and clinical professor, Department of Psychiatry, University of California at Los Angeles, School of Medicine.

²Behavioral scientist, Institute for Studies of Destructive Behaviors and the Suicide Prevention Center, Los Angeles, CA and behavioral science consultant, Medical Examiner/Coroner's Office, County of Los Angeles.

³Data analyst, Institute for Studies of Destructive Behaviors and the Suicide Prevention Center, Los Angeles, CA.

be useful to compare propoxyphene deaths with deaths related to the use and abuse of codeine, also a popular analysis drug. In California, codeine-related deaths outnumber propoxyphene-related deaths. Significant contributions to the understanding of the toxicology of codeine-related deaths have been made by the Medical Examiner's office in Los Angeles County [8].

Method of this Study

During a twelve month study period (1 July 1979-30 June 1980), the Los Angeles County Medical Examiner's office certified 141 deaths related to propoxyphene (50 cases), codeine (85 cases), or a combination of both drugs (6 cases). Death "related" is defined here as meaning that propoxyphene, codeine, or both drugs were found postmortem in body fluids or tissues by toxicological analysis. Sometimes, the analgesic drugs were found only in trace amounts and death was because of heart disease, large amounts of other drugs, or gunshot wound.

Table 1 indicates cause and mode of death. The majority of deaths were caused by a combination of propoxyphene/codeine with other drugs, especially alcohol, but also including multiple other drugs. Table 2 presents a listing of drugs that contributed to the cause of death in some cases. The data reported here are based upon investigations of the first 100 cases (50 propoxyphene cases and 50 codeine cases) made available to us. After eliminating

TABLE	1_Cauca	of doath

_	Suicide	Accident	Undetermined or Natural	Total
Propoxyphene alone	5	4	1	10
Codeine alone	5	6	1	12
Propoxyphene and alcohol	7	3	0	10
Codeine and alcohol	2	4	1	7
Propoxyphene and multiple drugs	11	5	3	19
Codeine and multiple drugs	8	9	4	21
Propoxyphene not important	1	2	4	7
Codeine not important	2	3	3	8

TABLE 2-Multiple drug deaths.

Drugs Reported	Propoxyphene	Codeine	Total
Barbiturates	4	12	16
Diazepam	4	2	6
Alcohol	4	2	6
Meprobamate	. 4	1	5
Trichlorethanol	2	2	4
Heroin, morphine,			
methadone	1	2	3
Tricyclic antidepressants	1	2	3
Ethchlorvynol	2	1	3
Acetaminophen	1	2	3
Flurazepam	2	0	2
Methaqualone	1	1	2
Glutethimide	0	2	2
Methyprylon	1	0	1
Pentazocine	1	0	1

deaths involving both drugs (five) and cases with insufficient informants (one) a final sample of 94 cases were obtained.

We investigated these deaths through interviews with surviving relatives, friends, physicians, and other knowledgeable informants. The purpose was to obtain information on the developmental background, personality, life style, medical history, drug and alcohol ingestion habits, recent stress, and crisis behavior of the deceased. The psychological autopsy protocol, originally designed to assist in the certification of mode of death [9] was modified in this study for special exploration of drug related deaths.

Interviews were conducted with three informants for each case. Where possible, the informants included a relative, a friend or co-worker, and a physician. A codebook was constructed to tabulate and quantify the informants' responses to approximately 100 items included in the interview schedule.

Demographic Data

In this report, we use the letter "P" to designate propoxyphene-related deaths, and the letter "C" to designate codeine-related deaths. Table 3 provides a demographic comparison. The P group (median age 35) was slightly younger than the C group (median age 39). There was no significant difference in the categories of sex, religion, marital status, or prior employment. Males were in the majority (56%). Only 30% of the subjects were married. The modal marital status was divorced or separated. A significantly larger proportion of the C group belonged to black or Spanish surname ethnic minorities. Nearly all of the subjects had prior employment with significantly better work quality reported for the P group.

Use and Abuse of Prescription Drugs

Data concerning the use and abuse of prescription drugs are summarized in Table 4. Ninety percent of the subjects were known to have used some sort of medication prescribed by a doctor during the last five years, with no difference between the groups. However, in the C group there were significantly more persons who had been using P/C medication for more than four years, and a significantly greater number had been using prescription drugs daily. Similarly, many more persons in the C group used prescription sleeping pills, mainly barbiturates. As is to be expected, the C group was more involved with codeine and codeine combinations, and the P group was more involved with propoxyphene and propoxyphene combinations. In answer to an interview question about the length of time during which subjects had been using propoxyphene combinations, there were five members of the C group who had been using propoxyphene more than five years while there were only three members of the P group who had used propoxyphene more than five years. Finally, the C group had significantly more problems such as overdoses, accidents, and arrests resulting from drug use and abuse.

	Propoxyphene	Codeine	Both P and C	Total
	S	EX		
Male	24	29	4	57
Female	22	19	1	42
	ETHNIC BA	CKGROUND		
White	43	33	3	79
Black	3	11	2	16
Spanish surname	0	4	0	4

TABLE 3-Demographic data.

TABLE	4-Use	and	abuse	of	prescription	drugs.
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	Propoxyphene	Codeine	Significance
Use of P/C before death			
less than 4 years	25	12	
more than 4 years	9	22	P < 0.01
no specific information	12	14	
Frequency of use of prescription drugs			
daily	24	36	
less than daily	10	0	P < 0.01
no specific information	12	12	
Used prescription sleeping pills			
yes	10	24	
no	34	21	P < 0.01
Problems resulting from drug use			
(overdoses, accidents, arrests)	13	26	P < 0.05

Use and Abuse of Nonprescription Drugs

Data concerning the use and abuse of nonprescription drugs are summarized in Table 5. About half the subjects had a history of prior use of nonprescription drugs. In this category, as in the use of prescription drugs, the C groups had a history of longer and more frequent use. There was a significant difference in the source of the drugs related to the deaths of the subjects. For the P group the major source of propoxyphene and other drugs related to the deaths were medical prescriptions. By contrast, for the C group there was a slight preponderance of deaths as a result of drugs obtained from nonmedical sources or in combination with drugs obtained from nonmedical sources. Significantly, more members of the C group used il-

TABLE 5—Use and abuse of nonprescription drugs.

	Propoxyphene	Codeine	Significance
Prior use of nonprescription drugs			
yes	22	27	N ^a
no	24	20	
Frequency of nonprescription drug use			
daily	12	24	P < 0.05
weekly	5	1	
occasionally	9	0	
Source of drugs related to deaths			
medical prescription	29	23	P < 0.05
nonmedical source or combination of			
medical and nonmedical	12	25	
Use of specific nonprescription drugs			
marijuana	22	25	N
barbiturates	17	34	P < 0.001
amphetamines	11	23	P < 0.05
cocaine	10	17	N
LSD	4	12	P < 0.1
heroin	6	17	P < 0.01
PCP	5	12	N
Drug related arrests	8	21	P < 0.01
Prior drug overdose	11	24	P < 0.05
Decedent felt drugs were a problem in			
his/her life	11	25	P < 0.05

^aN = not significant.

legally secured barbiturates, amphetamines, heroin, and lysergic acid diethylamide (LSD). The C group had significantly more drug-related arrests and prior drug overdoses caused by nonprescription drugs, and more of the C subjects had expressed the idea that they knew drugs were a problem in their lives.

Alcohol Use and Abuse

Approximately 80% of the subjects were known to have used alcohol with no significant difference between the two groups. However, the C group had significantly more problems as a result of alcohol (Table 6). For instance, they had 20 cases of having been arrested under the influence of alcohol, compared to three instances for the P group. Significantly, greater numbers had been observed intoxicated under the influence of alcohol, and more had sought help for alcoholism. Approximately 40% of the subjects had alcohol present in the blood at death, with no significant difference between the two groups.

Social and Psychiatric Data

The chief difference from the standpoint of having been arrested, was the number of arrests (Table 7). More members of the P group had been arrested only once (6 to 2), but almost twice as many members of the C group had been arrested two or more times. C group had significantly more persons who had become involved in physical fights and who had had accidents in the last year of life. The life styles of the C group persons were judged to be significantly more unstable. The major psychiatric diagnoses for the C group were drug addiction, primary alcoholism, or primary polydrug abuse. For the P group, the predominant diagnoses were psychiatric, including affective disorder, schizophrenia, and "other psychiatric diagnoses." More persons in the C group had a history of hospital psychiatric treatment, usually for drug abuse.

In tracing the historical development of the drug use and abuse, we noted five categories. There were about equal numbers of the persons in both groups who had a history of drug abuse, with no chronic pain. Many members of the C group had a history of primary drug abuse during which they injured themselves through automobile accidents, burns, overdose experiences, or other mishaps; after which, they suffered from chronic pain so that their drug abuse represented a need for pain relief superimposed upon the original primary drug abuse. There were equal numbers in both the P and C groups of persons who had suffered chronic

	Propoxyphene	Codeine	Significance
Prior use of alcohol			
yes	36	39	P < none
no	10	9	
Problems because of alcohol	13	26	P < 0.05
Arrested under the influence of alcohol	3	20	P < 0.001
Observed drunk under the influence of			
alcohol	4	14	P < 0.05
Sought help for alcoholism	3	10	P < 0.1
Blood alcohol level			
0.1% or more ethanol	9	7	
less than 0.1%	8	12	
not present	29	28	P< none
untested	0	1	

TABLE 6-Alcohol use and abuse.

TABLE 7-Social and psychiatric data.

	Propoxyphene	Codeine	Significance
Number of prior arrests			
one time only	6	2	P < 0.05
two or more times	13	25	• • • • • • • • • • • • • • • • • • • •
Involvement in physical fights	10	22	P < 0.05
Accident in last year of life	5	15	P < 0.05
Lifestyle of decedent			
stable	24	16	
in-between	7	5	
unstable	15	26	P < 0.05
Psychiatric diagnosis			
drug addiction and alcoholism	14	28	
other psychiatric diagnoses including		_	
primary affective disorder	32	20	P < 0.01
Prior psychiatric hospitalization	8	17	P < 0.01
Category of drug use			
primary drug abuse or addiction	14	30	P < 0.05
primary pain syndrome or mental			
illness	26	16	
Historical development of drug use			
drug abuse no chronic pain	14	16	P < 0.05
drug abuse then chronic pain	2	11	
chronic pain then abuse	11	11	
chronic pain no abuse	8	3	
no pain or abuse	11	6	

pain as a primary early symptom, and then had developed addiction and abuse secondarily. Finally, there was a preponderance of P group persons who gave histories of having suffered chronic pain syndromes without drug abuse or histories of having had neither pain or abuse, but rather of having obtained the propoxyphene (or codeine) directly for the purpose of suicide. To summarize these data: a special feature of the C group was a history of primary drug addiction followed by accidental self injury, followed by the development of a chronic pain syndrome combined with addiction. A special feature more typical of the P group was a history of pain without drug abuse, or of no chronic pain at all, together with using propoxyphene, or in some C group cases, codeine, intentionally for suicide.

Illustrative Cases

Case 1-Drug Abuse, No Chronic Pain

A 42-year-old black male, divorced, with one daughter and three grandchildren, lived with his mother. He was a long-term heroin addict and, at the time of his death, was attending a methadone clinic. In the past, he had episodes of depression, and had made several suicide attempts by overdose. He had not worked since he had been injured on the job ten years before. During the immediate period before his death, he had told several people that he wished he were dead. The night of his death, he purchased an unknown number of tablets from a friend. In the morning, he was dead, leaving a note that stated "I am not wanted around here anymore, so goodbye. Burn me." Blood contained: no ethanol; codeine, 4.7 mg/L; and caffeine, 29 mg/L. In this case, the undiagnosed major effective disorder had been masked by the heavy drug addiction.

Case 2-Drug Abuse, No Chronic Pain

A 24-year-old white male had started experimenting with street drugs in high school. He served a year in the army and was discharged because of severe psoriasis. He worked as a furniture refinisher. He frequently used marijuana, barbiturates, amphetamines, and both codeine and propoxyphene. There was no history of pain. Friends noted that at times he was confused and "dopey." He had several car accidents while under the influence of drugs or alcohol. He had been on a weeklong alcohol and propoxyphene "binge," taking eight to ten tablets daily. At a party on Halloween night, he ingested a six pack of beer and six Darvon tablets within a few minutes. Friends left him alone for 10 min and returned to find him dead. Blood contained: propoxyphene 5.4 mg/L; norpropoxyphene, 4.9 mg/L; and ethanol 0.19 mg%.

Case 3—Drug Abuse Leading to Chronic Pain and Chronic Drug Abuse

A 35-year-old white male had been a user and dealer of heroin, cocaine, and codeine since he was a teenager. Five years before his death he was shot by the police and, as a result, was a paraplegic, always in great pain. On many occasions he stated he would rather be dead than living as a paraplegic. He was treated at a psychiatric clinic with antidepressants, tranquilizers, and codeine for chronic pain. Two days before his death, he received a prescription for 60 units of codeine compound. All were gone. Blood contained codeine, 9.6 mg/L.

Case 4-Chronic Pain Syndrome Leading to Chronic Drug Abuse

A 44-year-old female who lived alone fell at work injuring her back. This introduced years of chronic back pain treated with prescription drugs, which she took in high doses. She was often "groggy"; friends worried about her slurred speech. Once, she fell and broke her arm. The paramedics were called four times to treat her for accidental overdoses. For a while, a day nurse took charge of her medication. During her last year of life, she was receiving prescriptions for 100 Tylenol® with codeine every two weeks. She also received barbiturates for insomnia. Her death was certified as accidental as a result of a combination of codeine (4.1 mg/L) and Tuinal® (20 mg/L).

Case 5—Chronic Pain Without Drug Abuse

A 30-year-old female nurse was recently divorced and her mother was being treated for cancer. At the same time, the subject developed severe migraine headaches for which she took propoxyphene in recommended amounts without abuse. Her employer, an internist, prescribed 30 units of Darvon. A week later, she committed suicide by taking all that remained. Blood contained: propoxyphene, 2.3 mg/L.

Case 6-No Pain, No Chronic Drug Abuse

A 53-year-old white male became depressed after his marriage was dissolved. He had brief psychotherapy and made a good recovery. He was respected at work where he managed a warehouse and he resumed social activities. However, he felt he had been rejected by a second woman and rather unexpectedly committed suicide by ingesting propoxyphene (1.5 mg/L) and amitriptyline (5.2 mg/L).

Table 8 summarizes data concerning crisis events in the last three months of life. Both groups tended to have crises connected with health problems. More of the P group had crises connected either with loss of money or job or increased responsibility on the job. Significantly, more of the C group had been arrested in the last three months of life.

	Propoxyphene	Codeine	Significance
Pregnancy, abortion, or birth			
of a child	3	1	N^a
Arrested	2	11	P < 0.05
Loss of money or job	16	9	P < 0.1
Increased responsibility	9	4	P < 0.1
Health problems	24	34	N
Change of address	5	6	N

TABLE 8-Crisis events in the last three months of life.

Certification of Death

We evaluated the degree to which P and C were the direct cause of death (Table 9). In this aspect, there was no difference between the two groups. The two drugs were responsible for deaths regardless of the other drugs or other factors in 14 cases, and they made a major contribution in combination with other factors in 30 cases. The contribution to death was minor or irrelevant in 20 cases.

As indicated in Table 10, a majority of the propoxyphene deaths were classified as suicide or probable suicide and the majority of codeine deaths were classified as accidental or probably accidental. Accidental deaths related to these analgesic drugs were associated almost invariably with lifestyles of chronic addiction or repetitive polydrug abuse. Persons involved in these patterns of drug abuse died unintentionally, sometimes rather suddenly and unexpectedly, often with surprising large high amounts of P or C in the body fluids.

For the P group, the blood levels of propoxyphene varied from 0.1 to 29 mg/L. The mean for the suicide deaths was 5 mg/L compared with a mean of 4.1 mg/L (of propoxyphene) in the accidental death group. The difference was not significant.

For the C group, blood levels of codeine varied from 0.1 to 45 mg/L, with a mean of 6.3 mg/L for the suicide deaths and 1.2 mg/L for the accidental deaths. The difference was statistically significant, P < 0.05.

Interviews with Physicians

Whenever possible, we sought out and interviewed the subjects' physicians, obtaining data for 64 of the cases. The median number of tablets or capsules of Darvon of codeine prescribed by these doctors for the patients on the occasion of their last prescription was 50

	Propoxyphene	Codeine	Total
Caused death regardless of	· · · · · ·		
other factors	9	5	14
Major contribution in combination			
with other factors	15	15	30
Contributed equally with other			
factors	13	17	30
Minor contribution; other factors			
major	6	10	16
P/C irrelevant	3	1	4

TABLE 9-Degree to which P/C caused death.

^aN = not significant.

TABLE	10-Degree	of	suicide	intention.

	Propoxyphene	Codeine
Suicide or probable suicide	24	15
Accident or probable accident	14	24
Natural or undetermined	8	9

units. Many of the physicians had a preference between propoxyphene and codeine, although frequently, doctors that preferred propoxyphene had prescribed codeine for patients and vice versa (Table 11). For example, 20 of the physicians said they usually preferred to prescribe propoxyphene but they had prescribed codeine to five of the persons who died in a codeine-related death. The doctors were asked their reasons for their preference between P and C. Table 11 indicates the reasons that were given with some of the physicians having more than one reason. The physicians who preferred codeine often were vague about the reasons, saying only that it was easier to prescribe. About half of the physicians reported that because of recent publicity in the medical literature, they had become more careful in prescribing codeine and propoxyphene. Six physicians stated that their main reason for prescribing codeine was Medi-Cal acceptance, and six physicians stated that they prescribed propoxyphene because their patients requested it.

Concerning these particular deceased patients, physicians stated that in their opinions, the patients' problems were mainly physical in 80% of the cases, mainly psychological in 12%, and mainly a combination of both physical and psychological pain in 14%. The doctors had recorded symptoms of depression in about half of the patients they had seen. Direct clues to suicide were perceived in only four of the patients, all of whom went on to commit suicide. Only one of the cases was known to have made a previous suicide attempt. We concluded that in the majority of cases, the doctors had not been in close contact with the patient, nor were they well informed about their patients, although there were many exceptions, and, in one case, the doctor made a tremendous effort to secure psychological help for that particular patient.

Propoxyphene and Codeine Related Deaths In Los Angeles County

We obtained informal reports from the Los Angeles County Medical Examiner/Coroner concerning the incidence of codeine- and propoxyphene-related deaths in Los Angeles County

TABLE 11—Physicians preference—propoxyphene/codeine.

	Propoxyphene-Related Deaths	Codeine-Related Deaths
Usually preferred to prescribe P $(n = 20)$	15	5
Usually preferred to prescribe C		
(n=35)	13	22
REASONS	FOR PHYSICIANS' PREFERENCE	
"Less addictive"	9	7
"More pain effective"	12	9
"Fewer side effects"	4	1
Medi-Cal acceptance	0	6
Patients requests	6	0
Easier to prescribe	1	8

Calendar Year	Propoxyphene	Codeine	
1977	97	119	
1978	66	119	
Project year 1 July 1979			
through 30 June 1980	50	85	
1980	39	120	

TABLE 12—Propoxyphene- and codeine-related deaths in Los Angeles County reported informally by the Chief Medical Examiner/Coroner.

in recent years. These are tabulated in Table 12. For the project year, 1 July 1979 through 30 June 1980, the coroner's office referred to us: 85 codeine-related deaths, 50 propoxyphene-related deaths, and 6 combined codeine and propoxyphene-related deaths. It appears propoxyphene-related deaths have decreased substantially since 1977, while the number of codeine-related deaths is relatively unchanged.

Discussion

There are significant differences between the P and C population, although they do, of course, have much in common. There are many more histories in the C group of primary drug addiction, primary polydrug abuse, and primary alcoholism. The C group is more involved with street drugs and all varieties of substance abuse. A majority of the C deaths were accidental. By contrast, the P group includes more persons with depressive mental illness, pain without addiction, and histories that suggest that the P was obtained with the intention of committing suicide. When propoxyphene was important in causing deaths, two thirds were suicide. The C group includes a higher proportion of persons from ethnic minorities. The histories of patients and the interviews with the physicians indicate that to a considerable extent, P and C, together with their combinations, have been prescribed interchangeably. There is a strong suggestion in the interviews with the physicians and in the reports from the coroner, that both of these drugs are being used somewhat more cautiously by physicians. This is particularly true of propoxyphene. We infer that the education campaign conducted by the FDA and the manufacturer is showing positive results. By contrast, codeine, which is being used to a much greater extent than propoxyphene by the drug abusing portion of the population, is less subject to control by physician education. We note that with few exceptions, persons who died propoxyphene- or codeine-related deaths had considerable experience in the past with one or both of these drugs and other drugs as well.

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Address requests for reprints or additional information to Robert E. Litman, M.D.

The Institute for Studies of Destructive Behaviors and the Suicide Prevention Center 1041 S. Menlo Ave.

Los Angeles, CA 90006