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Disposition of Quetiapine in Biological Specimens from Postmortem Cases*

ABSTRACT: Quetiapine is a new atypical antipsychotic that was approved in 1997 by the U.S. Food and Drug Administration for the treatment of schizophrenia. It possesses a high affinity for 5-HT₂ receptors and a low affinity for D₁ and D₂ dopamine receptors. Because quetiapine has only been released recently to the U.S. market, little information exists regarding therapeutic, toxic, and lethal concentrations. This study reports the detection of quetiapine in 13 postmortem cases. Following a basic liquid-liquid extraction, quetiapine was identified and quantitated by capillary gas chromatography with nitrogen phosphorus detection. Confirmation was accomplished by full scan electron impact gas chromatography/mass spectrometry. Heart blood quetiapine concentrations ranged from 0.07 to 18.37 mg/L (N = 12, mean ± SD = 3.42 ± 5.67, median 0.62) and femoral blood concentrations ranged from 0.06 to 19.25 mg/L (N = 10, mean ± SD = 3.89 ± 6.12, median 0.81). The average heart blood/femoral blood ratio was 1.31 (range 0.55 to 2.57, N = 10). Urine, bile, and gastric contents were assayed in all cases in which they were submitted. In three cases, the cause of death was determined to be quetiapine toxicity. In these cases heart blood concentrations ranged from 0.72 to 18.37 mg/L (N = 3). These data may provide a basis for establishing levels associated with quetiapine toxicity as well as therapeutic concentrations in postmortem specimens.

KEYWORDS: forensic science, postmortem, quetiapine

Quetiapine fumarate (C₄₂H₅₀N₆O₄S₂ · C₄H₄O₄, Seroquel[®]) was approved in 1997 by the U.S. Food and Drug Administration for use in the management of the manifestations of psychotic disorders. Quetiapine (Fig. 1) which belongs to a new chemical class, the dibenzothiazepines, is structurally related to clozapine, and has been proposed to function through antagonistic binding to dopamine type 2 (D₂) and serotonin type 2 (5HT₂) receptors (1). Quetiapine has a molecular weight of 383.6 and is available for oral administration as the fumarate salt (formula weight = 883.1) under the tradename Seroquel[®] (AstraZeneca Pharmaceuticals LP). The tablet formulation is 100% bioavailable relative to solution. Quetiapine is 83% bound to plasma proteins at therapeutic concentrations. A single oral dose of 75 mg produced peak serum quetiapine concentrations averaging 0.28 mg/L (range 0.14–0.37 mg/L) and a 450 mg oral dose produced average peak serum concentrations of 0.40 mg/L (range 0.19–0.63 mg/L) (2). The recommended daily dose is between 300 and 400 mg (initial dose 25 mg with increasing increments of 25 to 50 mg) but doses as high as 750 mg/day have been evaluated. The safety of doses above 800 mg/day has not been evaluated. The time to peak plasma concentration is 1.5 h after oral administration, with steady state concentrations achieved after 2 days. Quetiapine has a plasma half-life of 6 h within the proposed clinical dose range. It is highly metabolized in the liver (principally by cytochrome P450 3A4 isozyme) initially by sulfoxidation to a sulfoxide metabolite and by oxidation to the parent acid metabolite. Both metabolites are pharmacologically inactive with 73% of a dose excreted in the urine. More than 20 metabolites have been detected (1) and less than 1% of the administered dose is excreted as

the unchanged drug. A pharmacokinetic drug interaction has been observed with the coadministration of ketoconazole (200 mg once daily for 4 days) (1). Ketoconazole reduced the oral clearance of quetiapine by 84%, resulting in a 335% increase in the peak plasma concentration of quetiapine.

Quetiapine may also enhance the effects of certain antihypertensive agents and antagonize the effects of levodopa and dopamine agonists (1). Adverse effects of quetiapine in overdose include somnolence, constipation, tachycardia, hypotension and prolonged QTc (1).

To date, very few assays for quetiapine have been published. These include quantitation in human serum by C2 cartridge solid phase extraction and liquid chromatography with ultra-violet absorbance detection (2); n-butylchloride basic extraction with gas chromatograph (GC) (nitrogen phosphorus detection (NPD) detection; and GC-mass spectrometric confirmation (3). Quetiapine may also be detected by thin layer chromatography using the Ansys Diagnostics, Inc., Toxi-Lab A system with a limit of detection of 0.50 µg/mL in urine (4). The parent drug has an R_f of 0.42 and exhibits a color in Stage I that is similar to that of olanzapine, doxylamine, and timolol. Quetiapine and metabolites turn pale pink in Stage II exhibiting a dull orange absorbance at Stage III. Since quetiapine has been recently released into the U.S. market, information on blood and serum concentrations in clinical and postmortem cases is sparse. This study, therefore, reports the quantitative determination of quetiapine in postmortem specimens.

Materials and Methods

Materials

Quetiapine was obtained courtesy of Astra Zeneca Pharmaceuticals LP (Wilmington, DE). Metabolites were unavailable. The internal standard, promazine, was purchased from Sigma Chemical Co. (St. Louis, MO). ACS grade ammonium hydroxide, sodium hydroxide, and sulfuric acid were purchased from Mallinckrodt Chemical Company (Paris, KY). HPLC grade n-butyl chloride and

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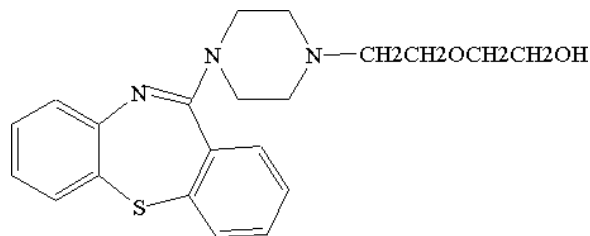


FIG. 1—Structure of quetiapine.

TABLE 1—GC and GC/MS temperature programs.

Temperature Ramp (°C/min)	Temperature (°C)	Hold Time (min)
8	GC (NPD)	
	120	3.0
	300	8.0
16	GC-MS (MSD)	
	150	1.0
	320	10.37

dichloromethane were obtained from American Burdick and Jackson Laboratories Inc. (Muskegon MI).

All buffers, dilute acid, and basic solutions were prepared using deionized water. Calibrators were prepared from a methanolic stock solution (100 mg/L) in drug-free human blood at the following concentrations: 0.20, 0.50 and 1.00 mg/L. Drug free blood was prepared and validated by the laboratory Quality Assurance officer prior to use. A positive control was prepared from a separate stock solution (100 mg/L) in methanol at a concentration 0.25 mg/L. Quetiapine concentrations were calculated from linear regression of the calibrator responses based on the peak area ratio (peak area quetiapine to that of the internal standard).

Instrumentation

A Hewlett Packard (HP) (Palo Alto, CA) 6890 or 5890 gas chromatograph (GC) with HP GC ChemStation with Windows REV. A.04.02 System software was used for initial screening and quantitation. Separation was achieved using a RTx-50, 50% methyl-50% phenylpolysiloxane capillary column (30 m × 0.32 mm i.d. × 0.25 μm film thickness) (Restek Corporation, Bellefonte, PA). The GC temperature program can be found in Table 1. The injection port was maintained at 260°C with 1.0 μL splitless injection.

Helium carrier gas was used at a flow rate of 3.0 mL/min. The nitrogen phosphorus detector temperature was 300°C. Quetiapine presence was confirmed using an HP 5973 mass selective detector (MSD) interfaced with an HP 6890 Plus GC and HP ALS 7673. The MSD was operated in the electron impact ionization mode with electron energy of 70 eV and a full scan mass-to-charge (m/z) ratio range of 30 to 550 amu. Separation was achieved using a RTx-50 column or equivalent (30 m × 0.32 mm i.d. × 0.25 μm film thickness) with capillary direct interface to the MSD. The GC-MS temperature program can be found in Table 1. Helium gas was used with a constant flow of 1.0 mL/min. The injection port and ion source were maintained at 260°C and 280°C, respectively.

Procedure

All reference solutions and case specimens were refrigerated at 5°C until time of analysis. In a 35 mL culture tube equipped with a

Teflon lined screw cap, 2 mL of 0.1 N sodium hydroxide was added to 5 mL aliquots of case specimens, calibrators or positive and negative (drug-free blood) controls. (For calibrators, 50 μL of drug standards were spiked into 5 mL of blank blood). A 1 mL aliquot of internal standard (5 mg/L solution of promazine) was added followed by 10 mL n-butyl chloride. Samples were rotated for 15 min and centrifuged for 5 min at 3000 rpm. Following centrifugation, the upper organic layer was transferred to a clean 16 mL culture tube and 3 mL 1.0 N sulfuric acid added. Samples were rotated again for 15 min and centrifuged for 5 min at 3000 rpm. The lower aqueous layer was transferred to a clean 16 mL culture tube and 0.5 mL concentrated ammonium hydroxide and 5 mL dichloromethane added to each sample. Rotation and centrifugation were repeated and 4 mL of the upper organic was removed and transferred to a clean 15 mL conical centrifuge tube. To this layer 200 μL isopropanol (IPA) was added. All tubes were then evaporated at 37°C using a TurboVap™ LV Evaporator (Zymark Corp., Hopkinton, MA) to the IPA layer until the meniscus was just below the 200 μL line. Extracts were vortexed briefly, and transferred to GC autosampler vials for injection into the instrument.

Results and Discussion

Quetiapine separated well on the RTx-50 column with a relative retention time of 1.59 min after thioridazine but before trazodone (Fig. 2). Calibration curves typically produced a correlation coefficient (r^2) > 0.99. A presumptive quetiapine metabolite was observed in all blood and urine extracts and was identified as a peak eluting approximately 5 min before the parent drug, near amoxapine, with relative retention time of 1.25. The assay was linear in the concentration range of 0.05 to 1.00 mg/L with a limit of detection of 0.02 mg/L.

Quetiapine by GC/MS (Fig. 3) has a base peak of m/z 210 with molecular ion at m/z 383. Other prominent ions were m/z 144, 239 and 321. A presumptive metabolite of quetiapine has a base peak at m/z 227, molecular ion at m/z 295, and other prominent ions at m/z 139, 210 and 239 (Fig. 4). Quetiapine was identified in 13 cases submitted to The Office of the Cuyahoga County Coroner in Cleveland, OH. Table 2 shows the demographic characteristics for each case. All decedents were autopsied except for case #2. The decedents had an age range between 24 to 81 years with a mean age of 47 years and median of 41. Six of the thirteen decedents were male (46%); eight decedents were Caucasian. In nearly every case, the decedent was found unresponsive at home or in a nursing facility. In cases #7 and #10, the decedent was taken to a hospital after cardiac arrest, but failed to respond to resuscitative efforts. Table 3 lists the quetiapine and other drug concentrations measured in each of the cases. Quetiapine was detected in heart blood for every case in which it was received and concentrations ranged from 0.07 to 18.37 mg/L (N = 12, mean ± SD = 3.42 ± 5.67, median 0.62 mg/L). In 58% of the cases, heart blood quetiapine concentrations were less than 1.00 mg/L. Quetiapine was also detected in femoral blood for each case it was submitted, with the exception of Case #3. Concentrations ranged from 0.06 to 19.25 mg/L (N = 10, mean ± SD = 3.89 ± 6.12, median 0.81). In general, the heart blood concentrations of quetiapine were higher than the corresponding femoral blood concentrations (7/11 cases) with an average heart blood/femoral ratio of 1.31 (range 0.55 to 2.57, N = 10). For Cases #9, 12 and 13, the femoral blood quetiapine concentrations were higher than the respective heart blood. However, for Case #9, the difference was not considered significant. These findings suggest that quetiapine exhibits postmortem redistribution. This may

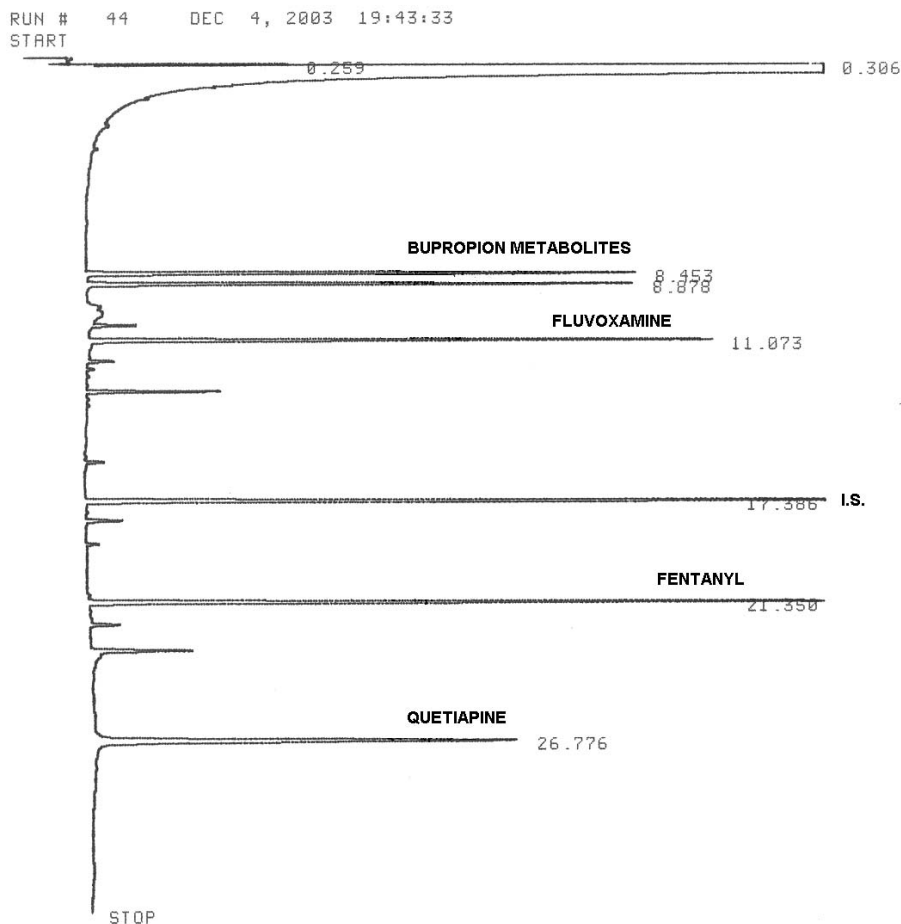


FIG. 2—Chromatogram of 1 mg/L quetiapine calibrator.

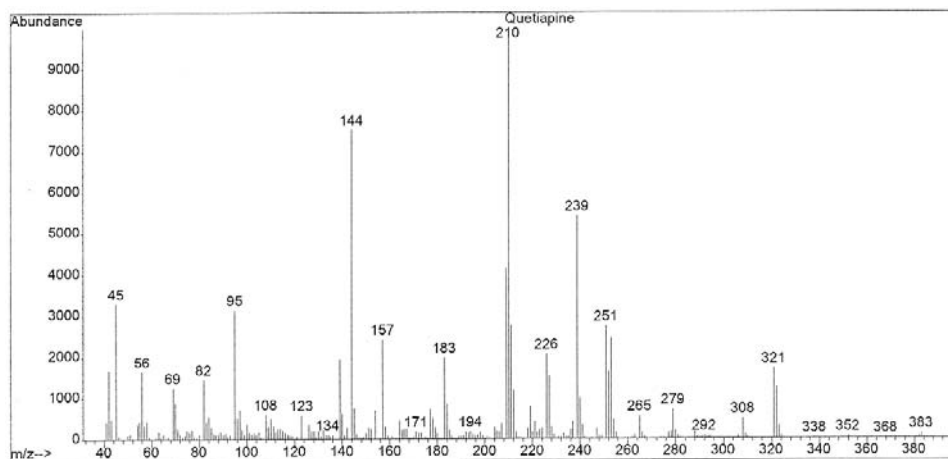


FIG. 3—Mass Spectrum of quetiapine.

be expected since quetiapine has a relatively large volume of distribution of 8 to 10 L/kg (5). Another study of postmortem quetiapine concentrations conducted in 2001 suggested that quetiapine exhibits postmortem redistribution (3). This latter study reported heart blood quetiapine concentration in seven cases of which only three had femoral blood concentrations.

In the current study, quetiapine was also detected in urine, bile, and gastric contents for each case in which these matrices were submitted. Urine concentrations ranged from 0.90 to 150.50 mg/L

(N = 9) and were several times greater than heart blood quetiapine concentrations. Quetiapine concentrations in bile were also greater than corresponding heart blood quetiapine concentrations. Quetiapine was detected in three vitreous humor samples (N = 6). Concentrations in vitreous humor were lower than in blood. In Case #6, the urine, bile, and vitreous humor were negative for quetiapine and the gastric contents contained 13 mg. Since quetiapine concentrations in urine and bile were high in the majority of the cases, these would make good screening matrices for quetiapine. Table 3

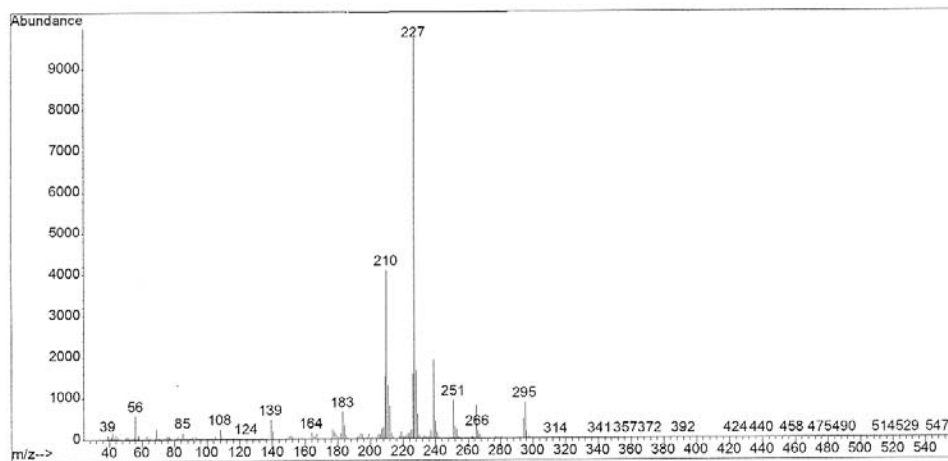


FIG. 4—Mass spectrum of quetiapine metabolite.

TABLE 2—Demographic information for 13 cases.

Case No.	Gender	Age (yrs)	Race
1	Male	27	Black
2	Female	81	Caucasian
3	Male	71	Caucasian
4	Female	39	Black
5	Male	32	Black
6	Male	24	Caucasian
7	Male	73	Caucasian
8	Female	51	Caucasian
9	Male	41	Caucasian
10	Female	32	Black
11	Female	56	Black
12	Female	50	Caucasian
13	Female	33	Caucasian

also lists other drugs detected in each case. Other drugs, typically present were opioids, antidepressants, or benzodiazepines.

Tissues and organs were assayed in Cases #1 and #4 (Table 4). In case #1, psoas muscle contained the highest quetiapine concentration (5.89 mg/kg) when compared to other tissue samples, and the lung contained the lowest (1.88 mg/kg). In case #4, the kidney contained the highest quetiapine concentration (20.64 mg/kg) and muscle tissue was determined to have the lowest concentration (3.69 mg/kg). Interestingly, quetiapine does not appear to be distributed into bone since both cases were negative. An alternative explanation may be that these were acute deaths so preventing assimilation into bone. In addition, liver tissue was assayed in Cases #8, 9 and 11 with resultant quetiapine concentrations of 1.17, 63.20, and 7.70 mg/kg, respectively. Case #11 was embalmed prior to autopsy and only gastric contents and liver submitted by the case pathologist for toxicological testing.

Quetiapine was determined to play a role in death in seven of the thirteen cases. (Cases: #1, 4, 5, 6, 8, 9 and 12). In Cases #4, 5, 8 and 12 the cause of death was determined to be acute intoxication by the combined effects of multiple drugs. Heart blood quetiapine concentrations in 4/7 of the cases (Cases: #4, 5, 9 and 12) were greater than 2.0 mg/L which exceeded the published recommended therapeutic concentration range. Quetiapine, as a single drug intoxication, was listed as the cause of death in Cases #1, 6 and 9 with heart blood concentrations of 0.72, 1.97, and 18.37 mg/L, respectively. In Cases #2, 3, 7, 10 and 13 where quetiapine was determined to play no role in the death, heart blood quetiapine concentrations

were below 0.60 mg/L and within the reported range of therapeutic blood concentrations.

There are several published studies that document cases of quetiapine overdose (6–12). Three papers reported quetiapine in post-mortem cases (3, 6, and 7). In instances of quetiapine overdose where the patient fully recovered, serum quetiapine concentrations were in the range of 1.8 mg/L to 12.7 mg/L. In all these cases, medical care was administered within 2 h post-ingestion. Medical care typically included administration of activated charcoal, gastric lavage, airway intubation, and/or saline for hypotension. Therefore, it is likely that a quetiapine overdose may be survived if medical care is administered within approximately 2 h post-ingestion. In a quetiapine related death, a male was found comatose with acute respiratory distress presumably a few hours after ingestion (7). The autopsy revealed cardiomegaly, with left ventricular hypertrophy and bilateral pulmonary congestion. Quetiapine and nicotine were the only agents found in the decedent's blood, with a quetiapine concentration of 18.3 mg/L. In another case, quetiapine was determined to be the only cause of death in which the cavity blood concentration was 170 mg/L (6). A recent report described the deaths of 8 individuals where quetiapine was quantitated in blood (13). The authors reported 6 of the deaths were determined to be unrelated to quetiapine, the blood (site not reported) concentrations ranged from 0.15–2.7 mg/L. However, a closer inspection of the cases reported in the paper of Hopenwasser et al. (13) showed that 2 cases in which blood quetiapine was measured at 2.7 mg/L were determined to be polydrug toxicity, one case of "overdose" in which the blood quetiapine concentration was 1.3 mg/L and 2 cases for which quetiapine concentrations were not reported. The authors described 2 cases in which the cause of death was cardiovascular disease, and the manner natural. In these two cases the blood quetiapine concentrations were 0.15 mg/L and 0.37 mg/L, respectively (13).

In the current study, cases of acute intoxication by quetiapine had heart blood concentrations ranging from 0.72 to 18.37 mg/L (Table 3). In Case #1, the concentration is near the upper limit of the reported therapeutic range, and the gastric contained approximately 11 mg of quetiapine. Cases #6 and 9 had quetiapine concentrations of 1.97 and 18.37 mg/L, respectively, which were several times higher than the therapeutic concentration range.

In conclusion, this report summarized data from 13 postmortem cases in which quetiapine was measured in multiple biological specimens. In cases where quetiapine was not considered a factor in the cause of death, heart blood concentrations ranged from 0.07 to 0.51 mg/L (mean = 0.30 mg/L, N = 5), which is within reported

TABLE 3—Drug concentrations in postmortem cases (N = 13).

No.	Quetiapine (mg/L)						Other Drugs Heart Blood (mg/L)	Cause of Death	Manner
	Blood		Urine	Bile	Vitreous Humor	Gastric mg			
	Heart	Femoral							
1	0.72	0.28	3.06	12.07	QNS	11.25	Haloperidol 0.02	Acute intoxication by quetiapine	Accident
2	0.51	N/A	N/A	N/A	N/A	N/A	none detected	Generalized atherosclerosis with atherosclerotic heart disease and fracture of ankle	Accident
3	0.44	NEG	0.9	N/A	QNS	1.59	Diazepam 0.27 Nordiazepam 0.13 Oxycodone 0.66 Hydroxyzine 0.38 Venlafaxine 2.08 Desmethyl Venlafaxine 1.98	Hypertensive atherosclerotic cardiovascular disease	Natural
4	11.20	7.35	N/A	86.0	QNS	26.37	Ibuprofen 29.4 Lidocaine 0.40 Verapamil 6.23	Acute intoxication by the combined effects of ibuprofen, quetiapine, tricyclic antidepressants and verapamil	Suicide
5	2.92	2.60	35.51	18.22	N/A	1.2	Diphenhydramine 3.56 Paroxetine 0.37	Acute intoxication by the combined effects of diphenhydramine, paroxetine and quetiapine	Suicide
6	1.97	1.34	NEG	NEG	NEG	13.25	Carbamazepine 6.5 Loxapine 0.05	Acute intoxication by quetiapine	Accident
7	0.07	0.06	1.16	11.17	N/A	0.92	Citalopram 0.16 Amantadine 0.50	Acute bronchopneumonia and organizing and acute pulmonary thromboembolism with pulmonary infarcts	Natural
8	0.22	0.22	12.63	9.24	NEG	1.01	Diazepam 0.19 Cyclobenzaprine 0.26 Fluoxetine 3.30 Norfluoxetine 0.72 Tramadol 0.39	Acute intoxication by the combined effects of diazepam, cyclobenzaprine, fluoxetine, tramadol, and quetiapine	Suicide
9	18.37	19.25	150.5	158.46	4.96	1251	none detected	Acute intoxication by quetiapine	Suicide
10	0.37	0.18	1.05	24.48	0.05	1.93	Desmethyl Sertraline 0.38 Sertraline 0.83 Benzoylcegonine 115 ng/mL Cocaine 96 ng/mL	Chronic asthmatic bronchitis with acute bronchial asthma	Natural
11	N/A	N/A	N/A	N/A	N/A	0.12	none detected	Remote, organizing and acute pulmonary thromboembolism with acute pulmonary infarct. (Embalmed)	Natural
12	4.1	7.43	33.56	N/A	1.4	POSITIVE	Fluvoxamine 17.4	Acute intoxication by the combined effects of fluvoxamine and quetiapine	Accident
13	0.13	0.19	2.86	10.03	NEG	3.32	Oxycodone 0.06 Bupropion mtbs POS Paroxetine 0.10 Δ9-THC-COOH 43 ng/mL	Aspiration of gastric contents with acute bronchopneumonia	Accident

QNS = Quantity not sufficient.
N/A = Specimen not available.
NEG = None detected.

TABLE 4—*Biological fluid and tissue quetiapine concentrations in two cases.*

Specimen	Quetiapine Concentration mg/L or mg/kg <i>Case 1</i>	<i>Case 4</i>
Heart Blood	0.72	11.2
Femoral Blood	0.28	7.35
CSF	1.92	QNS
Urine	3.06	N/A
Vitreous Humor	QNS	QNS
Bile	12.07	86
Gastric contents	625	220
Brain	1.24	11.26
Heart tissue	5.29	10.02
Kidney	4.2	20.64
Liver	3.9	8.09
Lung	1.88	9.1
Muscle	5.89	3.69
Spleen	2.28	10.22
Bone	NEG	NEG
Hospital Blood	N/A	5.36

Neg = Negative.

N/A = Not available.

QNS = Quantity not sufficient.

therapeutic concentrations. Since the presence of quetiapine was determined to be an incidental finding in these deaths, these data may serve as the basis for a database of biological fluid concentrations in postmortem specimens following therapeutic doses. However, there was overlap between these concentrations and concentrations found in quetiapine related deaths. Quetiapine toxicity was observed at a heart blood concentration range of 0.22 to 18.37 mg/L (mean = 5.64 mg/L, N = 7). In 57% of these cases quetiapine was present in addition to other drugs. For example, a low quetiapine concentration (heart blood = 0.22 mg/L) was measured in Case #8. The quetiapine was found in association with diazepam, cyclobenzaprine, fluoxetine and tramadol, and the cause of death was determined to be multiple drug intoxication. However, the heart blood concentration in Case #1 was 0.72 mg/L and determined to be a single drug intoxication. Therefore, it is important that quetiapine concentrations are evaluated in the context of the entire case when making determinations about the relative contribution of this drug to an individual's death.

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