Mercury in Traditional Tibetan Medicine – panacea or problem?

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Running title: Mercury in Traditional Tibetan Medicine

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ABSTRACT

SUMMARY

Symptoms of mercury toxicity, biochemical changes, and blood / urine mercury levels were evaluated in a small case series. Six patients attending Delek Hospital, Dharamsala, India, taking mercury-containing Traditional Tibetan Medicine (TTM), (Group I), were compared to 3 patients taking non–mercury containing TTM (Group II) and to 2 healthy volunteers (Group III). Quantitative estimates of mercury ingestion based on chemical analysis were compared to US regulatory standards.

Results

Group I were significantly older (mean 55 yrs) than other participants, took TTM on average for 51 months and had a mean of 2.5 non-specific, mercury-related symptoms. Group I had higher mean diastolic pressures (85 mm Hg) than Group II (73 mm Hg) (p=0.06) and more loose teeth. Mean daily mercury intake in Group I was 674 µg estimated as 10µg/kg /day. (Established ref. dose for chronic oral exposure; 0.3µg/kg /day). Blood mercury levels were non-detectable but mean urinary mercury levels for Group I were 67µg/L (EPA levels <20 µg /L). Renal and liver function tests were not significantly different between groups and within normal clinical range.

Conclusions

Prolonged ingestion of mercury containing TTM is associated with absent blood but relatively high urinary levels. Further studies are needed to evaluate toxicity and therapeutic potential.

Key words: Tibetan Medicine, Precious Pills, Mercury toxicity.
INTRODUCTION

The growing popularity of Asian traditional medicines has aroused concern over the presence of heavy metals added either as ingredients, or present unintentionally due to contamination \(^1\text{-}^3\). Documented case studies have reported serious signs of toxicity from lead, arsenic and to a lesser extent mercury while random samples of herbal medicines collected in India and the US have revealed significant levels of heavy metals \(^6\text{-}^{10}\).

**Traditional Tibetan medicine (TTM)** is an ancient holistic system of health care that utilizes a complex herbal and mineral pharmacopia \(^11\text{-}^{12}\).

**Mercury** is an important constituent of specific Tibetan medicines known as **Precious Pills**, multi-ingredient formulas used to treat a wide variety of conditions. Before mercury is incorporated into these pills however, it first undergoes a lengthy process of "detoxification" to produce **Tsothel**, a substance traditionally considered safe for patient use while possessing important therapeutic properties.\(^2\text{-}^3\).

High levels of mercury have been detected in Tibetan medicines \(^10\), however until now, specific evidence of toxicity due to mercury poisoning has not been documented. The current small case series represents the first time that Traditional Tibetan medicines (TTM) containing mercury have been chemically analyzed and their clinical, biochemical and toxicological effects evaluated in a small group of patients using them over a prolonged period of time.

METHODS

**Study Design:** An open, small case series of patients constituting the initial, feasibility stage of a large, future, prospective, clinical study.

**Setting**
The outpatients department of Delek Hospital, Dharamsala, Himachel Pradesh, India, a Western style hospital serving the Tibetan refugee, local Indian and tourist population.

**Patients**
A volunteer non-randomized sample of 9 Tibetan patients attending Delek Hospital outpatient department, who in addition to taking conventional, western medications prescribed by Delek hospital physicians were also using TTM prescribed by traditional doctors from the nearby Men-Tsee-Khang (Tibetan Medical & Astrological Institute).

Study participants included 6 patients **(Group I)** regularly taking TTM in the form of "**Precious Pills**" which contained "detoxified" mercury as an ingredient and 3 patients **(Group II)** regularly taking TTM, without "detoxified mercury in its composition in which mercury was not an intentionally added ingredient.

In addition 2 volunteers **(Group III)** recruited from personnel working at MTKI, in good general health and taking neither Western nor Tibetan medicine served as controls for clinical, serum and urinary mercury evaluation.

**Inclusion Criteria**
- Regular use of **TTM** for at least **1 month** prior to the present study.
The absence of any serious or life threatening disorders diagnosed in the period before commencing TTM therapy.

Since patients were recruited from a western style OPD, several were also taking conventional medication in addition to TTM. These patients were included in the study but were requested to give the generic names, doses and duration of these medications to the research staff.

**Exclusion Criteria**

Documented evidence from Delek Hospital of Hepatitis A or B, a pre-existing kidney disease, psychiatric, neurological or serious cardiac condition, that pre-dated and was diagnosed according to conventional criteria prior to the current TTM treatment, carcinoma, HIV, or working in an environment exposed to mercury including the pharmacy of MTKI.

The study was approved by the local IRB/Ethics committee of Men-Tsee-Khang Institute of Traditional Tibetan medicine (MTKI) and Delek Hospital according to the Declaration of Helsinki.

All patients considered eligible for the study were requested to sign an informed consent form, following a full explanation of the nature and purpose of the study by the project's research staff.

**Intervention**

The 9 patients recruited into the study were questioned by local research staff from MTKI and Case Report Forms completed including demographic data, present and past conventional medical history, current treatment with TTM, including duration, dosage, frequency, name of formula and concomitant treatment if any, with conventional medication.

The presence of 23 non-specific symptoms of mercury toxicity compiled by the researchers from a review article on the subject were evaluated by questioning each patient and included; metallic taste, burning sensation and/or mouth or throat pain, nausea, vomiting, hematemesis, diarrhea, abdominal pain, excess saliva, fatigue, depression, headaches, weakness, loss of concentration, easy blushing, extreme shyness, excessively emotional, anxiety, insomnia, anorexia, weight loss, delirium, and dizziness.

Patients currently suffering from any of the above symptoms were retrospectively questioned as to whether these symptoms had been present before or developed after taking TTM and whether at the present time, they would consider them to be better, worse or unchanged since TTM.

A general physical examination was performed by Western trained physicians working at Delek hospital who were informed only that the study participants were taking Tibetan Medicine but not whether this medication was mercury containing (Group I) or non mercury containing (Group II). Physicians conducted a full physical examination particularly for signs of mercury toxicity including; cardiovascular evaluation (hypertension), dermatological examination (skin discoloration, rashes), neurological examination (abnormal reflexes, slurred speech, paralysis, tremor, peripheral sensory and motor neuropathy, tunnel vision) and oral examination evaluating presence of loose teeth, decay and dental fillings.

Any laboratory tests that patients had previously undertaken at Delek hospital or elsewhere were added to the Case Report Forms.
Laboratory analysis
Blood for renal and liver function was taken from all patients in the study and evaluated in the laboratory of Delek hospital for levels of sodium, potassium, urea, creatinine, bilirubin, SGOT, gamma-GT, alkaline phosphatase and γGPT. Urine samples were obtained from participants and tested on site for the presence of red blood cells and protein, using a dip-sticks method.

For urinary inorganic mercury levels, a freshly voided urine sample was collected in a standard glass test tube from each of the participants and 2 controls. For blood inorganic mercury concentrations, an additional 5 cc of venous blood was taken from participants and controls and added to an EDTA tube placed on ice. All samples were refrigerated at 4°C for the duration of the study. For transportation to Israel, blood and urine samples were packed on ice, and taken by an air courier to Israel, where they were delivered by hand to the Dept. of Toxicology, Sheba Medical Center, Tel Aviv, Israel

Analysis of whole blood and urine for inorganic mercury concentrations was performed using Flow Injection Mercury System (FIMS) equipped to an Atomic Absorption Spectrometer (Perkin Elmer Analyst 800 A). (Detection limit of 0.4µg/L).

Materials
All Traditional Tibetan Medicines taken by the study participants was locally made in the pharmacy of MTKI and consisted of complex formulas containing a variety of herbal and minerals ingredients formulated according to classical Tibetan pharmacopoeial texts.11

Mercury in the form of "Tsothel", or "Detoxified mercury" was an ingredient of specific Tibetan Medicines known as "Precious Pills" of which the following 4 varieties were used by Group I patients in the current study; Tso-Tru Dashel, Mangjor Chemno, Ratna Sanphel, and Jumar 25 15.

Chemical Analysis
Analysis of the 4 types of Precious Pills used in the study all containing detoxified mercury (Tsothel ) and a sample of Tsothel alone in the form of a fine black powder, was performed at the Chemistry Dept. of Liverpool University, UK.
All Samples were digested in a microwave accelerated reaction system using nitric acid (3 mls), hydrochloric acid (2 mls) and hydrofluoric acid (1ml) followed by micro-wave for 40 minutes at 200°C producing a clear precipitate free solution. Analysis of mercury and other heavy metals were performed on ICPAES (Inductivity Coupled Plasma Atomic Emission Spectrometer) Spectro. CCD model and analyzed against standard calibration lines. Carbon, hydrogen and nitrogen were analyzed by decomposing samples at high temperature (1050°C) and any carbon present detected as C02, hydrogen as H20 and nitrogen as N2, using a CHN Analyzer (Carlo Erba model 1106).

Data Analysis
The non-parametric Mann-Whitney Test was used to compare quantitative, continuous variables between Groups I and II and the Kruskal-Wallis Test between 3 groups. For qualitative variables the Fishers Exact Test was applied.

RESULTS
Group I was significantly older (mean 55 yrs ± SE 6.4) compared to Group II (26.7yrs ±SE 5) and Group III (32.5yrs ± SE 0.5) (p=0.05). Mean duration of treatment with TTM, was 51 months for Group I (range 2-96 mths) and 24 mths for Group II.(range 0.5 – 72mths ) (NS). (Table 1)

Group I had an overall prevalence of 10.9 %, non-specific, mercury related symptoms (15 out of a possible total of 138 (23x6) ) with a mean of 2.5 symptoms /patient, (±SE 0.22) (range1-3). The most common symptoms reported were headaches (5 patients), weakness (2), nausea (2), dizziness (2), insomnia (2), blushing (1), depression (1).
Group II had a prevalence of 21.7% mercury related symptoms (15 out of a possible total of 69 (23x3)) with a mean of 5 symptoms/patient (± SE 2.3) (range 1-9). (p=0.058). (Table 2)

In Group I only 4 symptoms (2.3%) developed after taking TTM compared to 3 (4.7%) in Group II (NS), none of which were reported as worsening during treatment.
The mean systemic blood pressure in Group I was 122.5 mm Hg (±SE 5), Group II 106 mm Hg (±SE 7) and Group III 122 mm Hg (±SE 2.5) (NS). Group I had higher mean diastolic pressures 85mmHg (±SE 2.2) compared to Group II, 73 mmHg (±SE 3.3)) and Group III, 75 mmHg (±SE 5). (p=.062).

At the time of the study two patients in Group I were concurrently treated with conventional medication for essential hypertension.

Group I patients had significantly more loose teeth than Group II. (83% v 0%) (p=.015) together with some evidence of decay. No significant differences in the prevalence of fillings were found.

Other aspects of Physical examination including skin evaluation were normal, with the exception of a slight tremor detected in a single Group I patient who was concurrently taking the drug Nifedipine for hypertension.

Laboratory tests
Mean serum levels for liver and renal function tests were within the normal clinical range and did not differ significantly between groups. All urine samples were negative for red blood cells and protein.

Blood mercury levels were non-detectable in all groups. Mean urinary mercury levels for Group I were 67 µg/L (±SE37.3) (range 0 –173 µg/L), Group II 1.7 µg/L (1 sample positive) and non detectable in Group III. Environmental Protection Agency (EPA), Biological Exposure Index (BEI) for urinary mercury levels in chronic oral exposure is <20 µg/L.10

Chemical Analysis.
The composition of the mercury containing powder Tsothel demonstrated: mercury 44.7%, calcium 1%, sulfur 42.5%, silver 0.4%, iron 1.5% and copper 0.5%. Most mercury was in the form of mercuric sulfide (HgS) with smaller amounts as mercuric sulphite (HgSO₃) and mercuric sulphate (HgSO₄).

Analysis of the 4 types of Precious Pills used by Group I patients is shown in Table III. Mercury content ranged from 1.4 -2.3mgs.

Calculation of daily mercury ingestion compared with regulatory standards
The mean weekly consumption of mercury in Group I was calculated as 4720 µg (range 2300-9800 µg) equivalent to 674 µg/day (range 329-1400 µg) (Table 4).

Assuming an average body weight of participants as 70kgs, the average intake of mercury in Group I was estimated as approx. 10 µg/kg/day (range 4.7-20 µg/kg/day).

Environmental Protection Agency (EPA) established reference doses (RfDs) for oral chronic exposure is 0.3 µg/kg/day for mercuric chloride.

DISCUSSION

In this small case series, the toxicological effects of mercury were evaluated in patients taking Precious Pills, a form of Traditional Tibetan Medicine (TTM). Although representing only the feasibility stage of an intended larger clinical trial, these initial findings present for the first time a chemical analysis of Precious Pills and a preliminary attempt to correlate their high mercury content ranging from 1.4-2.3 mgs with potential toxicity in patients.

Mercury toxicity is essentially a multi-system disorder with symptoms of acute and chronic poisoning associated with often wide spread deposition of mercury in various tissues. Clinically elemental, inorganic or organic mercury poisoning can be accompanied by central nervous system dysfunction, renal damage ranging from asymptomatic, reversible proteinuria to fully developed nephrotic syndrome, oedema and hypoproteinemia, as well as liver damage and characteristic skin rashes.

In the current study, 6 patients taking Precious Pills for an average of over 4 yrs, had a mean daily estimated intake of mercury of approx. 10 µg/kg/day an amount well above the EPA established reference doses for mercuric chloride of 0.3 µg/kg/day. Although this ingested mercury appeared to be mainly in the form of mercuric sulphide, toxic effects at these levels whatever the counter ion in the mercury salt have been well documented in the past.

Despite this prolonged intake however, blood levels of mercury in this case series were non-detectable by Atomic absorption spectrometry although urine levels, (mean 89 µg/L), were significantly greater than the normal reference levels (<20 µg/L).

These findings suggest that while most of the ingested mercury from Precious Pills, probably in the form of mercuric sulfide (Hgs), is harmlessly excreted in the stool, some mercuric compounds are absorbed.

Amongst Group I patients, renal and liver dysfunction based on serum examination was not demonstrated, findings which cannot be wholly explained by our exclusion criteria. Although patients with serious kidney disease were not enrolled in the current study this exemption was applied only to participants with pre-existing conditions where conventional diagnosis had pre-dated TTM treatment.

Patients did demonstrate several non-specific signs and symptoms of mercury toxicity. Group I patients had more loose teeth and higher mean diastolic pressures levels (although within normal limits for age) than Group II. In addition a single Group I patient concurrently using Nifadapine for hypertension, exhibited a slight tremor.

Amongst Group I patients however, were significantly older (55 yrs) than the other participants and both essential hypertension and poor dental care have been documented as common amongst older Tibetans. Nifadapine a calcium channel blocker used for hypertension has also been associated with tremor.
The prevalence of other non-specific symptoms of mercury toxicity obtained from questionnaires was low in Group I (2%), with no symptoms reported as worsening and dermatological signs not detected.

Whether the above findings are due to prolonged mercury ingestion or secondary to other factors however cannot be conclusively answered from this study. A case series such as this with small groups, uncontrolled for age, general health or use of conventional medicines and not fully blinded evaluations presents significant limitations to interpretation. In addition the ability of patients to accurately relate their symptoms introduces a significant recall bias making the data derived from the questionnaires of limited validity. Nevertheless we do believe that these early findings have raised a number of important questions relating to the inclusion of mercury compounds in Traditional Tibetan Medicines.

Mercury’s disruption of normal cell physiology is thought to arise principally from its covalent binding to sulphydral groups (SH) and to phosphyl, and amide groups, interactions considered to cause the toxic effects associated with mercuric compounds through widespread disruption of enzyme systems, transport mechanisms, membranes and cell structure. Although beyond the range of this study, it is possible to speculate that under certain circumstances, the mercury salts in Precious Pills that appear to be absorbed but rapidly cleared from the blood, could possess some form of bio-activity. Whether this activity is toxic or actually underlies a potentially therapeutic effect remains to be investigated.

**Precious Pills** are complex formulas containing many botanical and mineral ingredients and are traditionally used to treat a wide range of conditions including blood disorders, cancer, neurological problems, allergies, arthritis, chronic wounds as well as use as tonics and antidotes to chemicals and poisons.

Mercury is an important constituent of Precious Pills, however while elemental mercury is considered extremely toxic in Tibetan Medicine, its "detoxified" form, **Tsothel**, produced by a complex process which takes several months, is considered an important therapeutic substance that is safe for oral ingestion.

In view of the growing popularity of Traditional Tibetan medicine in the West and the increasing numbers of patients traveling to Asia for treatment, there is no doubt that further research needs to be performed on these medications.

A much larger prospective, controlled, blinded clinical study should be undertaken in patients taking mercury containing TTM to assess toxicity, with periodic assessments of biochemical and clinical markers, as well as serial documentation of mercury levels in serum, urine, hair and other tissues. In addition, laboratory studies should be performed evaluating the bio-activity of Precious Pills and Tsothel particularly for their anti-inflammatory and anti-cancer activity.

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REFERENCES


### TABLE I

#### Demographic details of patients and controls

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Age (yrs)</th>
<th>Sex</th>
<th>Occupation</th>
<th>Reason for consulting Traditional Tibetan doctor</th>
<th>TTM#</th>
<th>Duration of TTM treatment (mths)</th>
<th>Conventional medical diagnosis</th>
<th>Medication</th>
<th>Conventional</th>
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<tbody>
<tr>
<td>Group I (Mercury containing) (Precious pills)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>28</td>
<td>M</td>
<td>Office worker</td>
<td>Digestive problem</td>
<td>T</td>
<td>30</td>
<td>Past history of typhoid</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>69</td>
<td>M</td>
<td>Retired soldier</td>
<td>Lower back pain Indigestion</td>
<td>T</td>
<td>96</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>67</td>
<td>M</td>
<td>Monk</td>
<td>Arthritis</td>
<td>J,T,R</td>
<td>60</td>
<td>problem Arthritis cervical disc</td>
<td>Analgesics</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>48</td>
<td>M</td>
<td>Security guard</td>
<td>Severe lower back and knee pain</td>
<td>J,T</td>
<td>96</td>
<td>Tuberculosis Sinusitis cervical disc problem</td>
<td>Anti TB analgesics</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>66</td>
<td>M</td>
<td>Monk</td>
<td>headache , Neck pain Gastritis</td>
<td>J,R,M</td>
<td>24</td>
<td>Hypertension Cervical spondylosis</td>
<td>Hypotensive</td>
<td></td>
</tr>
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<td>6</td>
<td>52</td>
<td>M</td>
<td>Office worker</td>
<td>fever , Hypertension Oedema</td>
<td>*J</td>
<td>2</td>
<td>Hypertension</td>
<td>Hypotensive (Nitalapine)</td>
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<tr>
<td>mercury -non)Group II (Tibetan medicine)</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>7</td>
<td>34</td>
<td>F</td>
<td>Office worker</td>
<td>Gastric ulcer</td>
<td>G,Y,T</td>
<td>72</td>
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<td>None</td>
<td></td>
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<td>8</td>
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<td>F</td>
<td>Student</td>
<td>Lower back pain</td>
<td>P,D</td>
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<td>None</td>
<td></td>
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<td>9</td>
<td>29</td>
<td>F</td>
<td>ice worker Off</td>
<td>Indigestion</td>
<td>SH,D,S</td>
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<td>Group III Controls</td>
<td>10</td>
<td>33</td>
<td>M</td>
<td>Office staff</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>11</td>
<td>32</td>
<td>M</td>
<td>administrator</td>
<td></td>
<td></td>
<td>None</td>
<td>None</td>
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</table>

# TTM = Traditional Tibetan Medicine; T=Tso-Tru Dashel, R=Ratna Samphel, J=Jumar 25, M=Mangjor Chemno (Precious Pills containing detoxified mercury (Tsothel))
S=Sedok 5, D=Dhada, P=Padrak, SH=Shiru, T=TKEA8, Y=Yaril 13 G=Ghiuam 9 (Tibetan formulas without added detoxified mercury)
* All Precious pills used by Group I were taken once a week with the exception of Patient 6* who took J (Jumar 25) daily.

### TABLE 2

#### Comparison of non-specific symptoms of mercury toxicity between patient groups

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group I (n=6)*</th>
<th>Group II (n=3)</th>
<th>P</th>
</tr>
</thead>
</table>
## TABLE 3
Chemical Analysis of Precious Pills

<table>
<thead>
<tr>
<th>Precious Pill (mgs)</th>
<th>Mercury Content</th>
<th>Other Substances †</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tso-Tru Dashel (86.3)</td>
<td>2.66% = 2.3 mg</td>
<td>Carbon, 37%, H₂, 6%, N₂, 0.99% Calcium, 6.4%, Sulphur, 0.88%</td>
</tr>
<tr>
<td>2. Mangjor Chemno (131)</td>
<td>1.57% = 2.1 mg</td>
<td>Carbon, 35.5% H₂, 4.7%, Calcium, 3.4% Fe, 1.05%, Phosphorus, 1.06% Sulphur, 0.86%</td>
</tr>
<tr>
<td>3. Ratna Samphel (109.6)</td>
<td>1.33% = 1.5 mg</td>
<td>Carbon, 36% H₂, 5.2% N₂, 1.6% Calcium, 3.2% Sulphur, 0.87% Phosphorus, 1.15% Iron, 0.94%</td>
</tr>
<tr>
<td>4. Jumar 25 (121)</td>
<td>1.15% = 1.4 mg</td>
<td>Carbon, 34.12% H₂, 4.5% N₂, 0.83% Calcium, 5.7% Sulphur, 0.77% Iron, 1.01% Phosphorus, 0.74% Barium, 0.45%</td>
</tr>
</tbody>
</table>

† All samples also contained low levels (ppm) of Al, Mn, Si, Cu and Zn
### TABLE 4
Amount of mercury ingested by Group I patients from Precious Pills and serum and urinary mercury levels

<table>
<thead>
<tr>
<th>Patient</th>
<th>Name of Precious Pill</th>
<th>Amount of mercury/pill (µgs)</th>
<th>Amount of mercury ingested/week (µgs) ‡</th>
<th>Serum mercury levels (µg/L)</th>
<th>Urine * Mercury levels (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tso-Tru Dashel</td>
<td>2300</td>
<td>2300</td>
<td>ND</td>
<td>ND</td>
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<tr>
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<td>Tso-Tru Dashel</td>
<td>2300</td>
<td>2300</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>3</td>
<td>Tso-Tru Dashel Jumar 25 Ratna Sampel</td>
<td>2300 1400 1500</td>
<td>5200</td>
<td>ND</td>
<td>38</td>
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<tr>
<td>4</td>
<td>Tso-Tru Dashel Jumar 25</td>
<td>2300 1400</td>
<td>3700</td>
<td>ND</td>
<td>173</td>
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<tr>
<td>5</td>
<td>Jumar 25 Mangjor Chemno Ratna Sampel</td>
<td>1400 2100 1500</td>
<td>5000</td>
<td>ND</td>
<td>57</td>
</tr>
<tr>
<td>6</td>
<td>Jumar 25</td>
<td>1400</td>
<td>9800</td>
<td>ND</td>
<td>-</td>
</tr>
</tbody>
</table>

ND= Non-detectable
‡ All patients ingested Precious Pills on a once/week basis with the exception of patient 6 who took Jumar 25 daily
* Missing data = 2