

Risks Associated With the Practice of Traditional Chinese Medicine

An Australian Study

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Objective: To investigate the nature and frequency of adverse events that occur as a result of the practice of traditional Chinese medicine (acupuncture and Chinese herbal medicine) in Australia.

Methods: Data on adverse events were obtained as part of a comprehensive survey of all occupational health groups, government-registered and unregistered, who practiced traditional Chinese medicine or 1 of its main modalities.

Results: Practitioners reported numerous adverse events arising from the application of acupuncture (including fainting, nausea and vomiting, and increased pain), or the consumption of Chinese herbal medicines (including direct toxic effects and allergic reactions). Practition-

ers experienced an average of 1 adverse event every 8 to 9 months of full-time practice or 1 adverse event for every 633 consultations. The mean adverse event rate of nonmedical practitioners was less than half the mean adverse event rate of medical practitioners.

Conclusions: The practices of acupuncture and Chinese herbal medicine are not risk-free and fatalities have occurred. Variation in adverse event rates between medical and nonmedical practitioners may reflect differences in relevant education or different reporting behaviors. These data represent the first step in the evaluation of adverse event rates in traditional Chinese medicine.

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IN 1996, 3 state governments in Australia (Victoria, New South Wales, and Queensland) commissioned a review of traditional Chinese medicine (TCM). These states represent 80% to 85% of the Australian population and an estimated 90% of practitioners in Australia who practice TCM. The key objectives of this government review were to determine whether the practice of TCM posed a significant risk of harm to public health and safety and to assess the need for statutory occupational regulation of TCM practitioners.

Traditional Chinese medicine, best known for the practices of acupuncture and Chinese herbal medicine (CHM), has been practiced in Australia for many years and is being used now more than ever before.¹ In 1996 it was estimated there were more than 2.8 million TCM consultations each year in Australia (population, 18 million), representing an annual turn-

over of \$84 million Australian dollars (\$55 million US dollars) from consultations alone.¹ In the 4 years since 1996, the use of CHM in Australia has more than doubled. Increasing numbers of Western health care practitioners, such as medical practitioners, nurses, and physiotherapists, are offering complementary medicine services, particularly acupuncture.² Complementary medicine services in Australia have grown to the extent that consumers now spend approximately twice as much on complementary medicines as their out-of-pocket contributions to pharmaceuticals.³

With the growing use of TCM, regulatory authorities, health professionals, and the public need to understand the risks involved in TCM. This article summarizes data on adverse events that have occurred in clinical practice and have been self-reported by practitioners of TCM, including those who practiced only TCM and

MATERIALS AND METHODS

Data on adverse events were collected through a comprehensive practitioner survey of all occupational groups, government-registered and unregistered, whose members practiced TCM or one of its modalities. In New South Wales, Queensland, and Victoria, an estimated total of 1100 practitioners offered TCM as their primary service and about 2400 (of approximately 16000) medical practitioners offered acupuncture as part of their medical practice. In addition, an estimated 200 practitioners of other health modalities used some form of TCM, usually acupuncture. This group included physiotherapists, chiropractors, osteopaths (osteopaths are not registered medical practitioners in Australia), naturopaths, nurses, and shiatsu therapists. Together these 3700 practitioners comprised approximately 90% of TCM practitioners in Australia.

A comprehensive practitioner survey instrument (110 items, 8 pages) was forwarded to all occupational health groups known to use TCM. Two main questions asked practitioners about adverse events caused by their practice of TCM: 1 question related to acupuncture, and the other to CHM (**Figure**). A list of common adverse events related to the 2 practices followed each question. Practitioners were asked to indicate the number of times particular adverse events had occurred during their TCM practice. This information was subsequently analyzed in the context of years of TCM practice, education, specific herbs and acupuncture techniques used in practice, and concurrent pharmaceutical drugs taken by patients.

During 1996, all professional associations representing nonmedically qualified practitioners of any modality of TCM provided their mailing lists of members under strict confidentiality. These members included practitioners who practiced primarily TCM as well as practitioners from other health professions such as physiotherapy, osteopathy, naturopathy, chiropractic, nursing, and shiatsu therapy. A single mailing list of nonmedically qualified practitioners was formed by combining membership lists from all associations and culling for overlaps from individual lists. It was assumed that practitioners who were not members of any association formed a very small percentage of the total TCM workforce.

The Health Insurance Commission (HIC) of the Australian Federal Government mailed the practitioner surveys to all medical practitioners who practiced TCM. The HIC identified 2408 medical practitioners in Victoria, New South Wales, and Queensland who had made claims in the previous 12 months on a health insurance rebate number (Medicare item) for acupuncture. Distribution through the HIC ensured the most comprehensive identification of medical practitioners practicing acupuncture, given that professional associations representing medically qualified acupuncturists accounted for only one third of claimants on the HIC list. In addition, HIC distribution avoided duplication from overlapping memberships of the 3 medical acupuncture associations.

A bilingual letter (English and Chinese) was distributed with an English copy of the practitioner survey to all practitioners on the 2 mailing lists. Contact names and telephone numbers were provided of bilingual research assistants in each state who would forward a Chinese version of

those whose primary specialty was not TCM. There have been no previous published reports that include adverse events related to both CHM and acupuncture, or that report the experiences of all practitioners that use TCM in their practices.

The adverse events reported here may have been due to the administration of TCM therapy (such as injuries caused by acupuncture and toxic reactions to herbs), the variable quality of medicinal products (such as failure of Good Manufacturing Practice, substitution, or adulteration of herbs), or poor clinical judgement of practitioners (such as misdiagnosis). No attempt has been made to analyze individual adverse events.

Adverse events related to acupuncture and CHM are varied and are reported periodically in the literature.^{1,4-9} In some instances, adverse events related to acupuncture have been the subject of legal examination.¹ Instances of local and systemic infections have been reported in the literature such as endocarditis, septicemia, hepatitis B, human immunodeficiency virus infection, osteomyelitis, myositis, peritonitis, and pleural empyema, allegedly contracted as a result of acu-

puncture.^{1,4} Causality had not been confirmed in many of these cases. Numerous reports of trauma-related injuries from acupuncture have been published in the last 15 years, including pneumothorax, spinal cord injuries, auricular chondritis, fatal and nonfatal cardiac tamponade, pseudoaneurysm, deep-vein thrombosis, nerve damage, burns (from moxa), and severe bruising (from cupping).^{1,4-6} Published reports have also referred to psychiatric changes (such as depression), insomnia, convulsions, hypotension, menstrual disturbance, increased pain, and allergies to certain needle compositions.^{1,4,6}

Adverse events related to the administration of CHM include direct toxic reactions to the herbs, interactions with other medicines, allergic reactions, and idiosyncratic reactions. Direct toxic reactions to certain herbs, including self-poisoning, have been widely reported in the literature.¹ Potential interactions of CHM with pharmaceuticals or other herbs have been reported.^{1,10} There have also been reports of hepatic damage, probably a result of idiosyncratic reactions to CHM.¹¹⁻¹³

the survey if needed. Practitioners were asked to nominate any other Chinese-speaking TCM practitioners who had not yet been contacted. The letter assured participants that the survey was anonymous, and no identifying information was requested. Prepaid envelopes were included for reply.

The practitioner survey was piloted on representatives of the professional associations, and circulated for comment by the Victorian Government TCM Review Committee (18 appointed members). Ethics approval was obtained through the Victorian Department of Human Services Ethics Committee.

Aggregate data were calculated for each adverse event category for acupuncture and CHM separately. Quantification of the frequency of adverse events was performed by calculating 2 ratios: adverse events per year of equivalent full-time TCM practice, and adverse events per number of TCM consultations. Adverse event rates were calculated for the length of time each practitioner had been practicing TCM.

The adverse events per year of equivalent full-time TCM practice were calculated for each practitioner based on his or her responses to the survey. Total adverse events were divided by the number of equivalent full-time years of TCM practice for each practitioner. From these individual rates, the mean rate of adverse events per year of full-time TCM practice was then calculated. Missing values for equivalent full-time years of TCM practice were replaced by calculating a conversion ratio from years of part-time TCM practice based on other respondents in similar categories (medical, nonmedical). When the ratio generated a figure less than 1 equivalent full-time year of TCM practice, 1 year

was inserted. If a respondent failed to indicate years of part-time TCM practice, the missing value for equivalent full-time years of TCM practice was not replaced. This process avoided losing data on adverse events by increasing the number of cases for which adverse events per year of equivalent full-time TCM practice could be calculated. However, this resulted in the lowering of the mean adverse event rate.

The adverse events per number of TCM consultations was derived for each practitioner by dividing the total adverse events reported by a practitioner by an estimation of total TCM consultations for that practitioner. Total consultations were calculated by multiplying average weekly consultations by 48 weeks and then by the total number of years in TCM practice. This calculation assumed that the number of patients practitioners were currently seeing had remained static throughout their practice lifetime, and that the nature of their practice had not shifted significantly between CHM and acupuncture. The mean rate of adverse events per number of TCM consultations could then be calculated. This figure was used as a crude measure of the frequency of adverse events. Missing values for TCM consultations were replaced by calculating the mean number of patients seen by respondents in similar categories (medical, nonmedical) for the TCM clinic hours reported by the individual practitioner.

The Mann-Whitney *U* test for nonparametric data was used to test for significant differences between the adverse event rate per year of full-time TCM practice for medical and nonmedical practitioners. *P* values were 2-tailed, and the level of significance was set at .05. Missing values were not replaced unless indicated.

Despite all of the case reports and summaries of these events, little is understood about the relative risks to the public of the practice of TCM and what measures might be implemented to reduce or minimize these risks. To develop an understanding of the risks it is necessary to establish data on the nature and frequency of such events in clinical practice.

RESULTS

Eleven hundred TCM practitioners responded to the survey, representing conservative response rates of 50% for nonmedical practitioners and 30% for medical practitioners.

NONMEDICAL PRACTITIONERS

Membership lists were collected from the 20 nonmedical professional associations that represented practitioners who practiced TCM. After culling overlapping memberships between associations, the mailing list consisted of 2075 names. Impressions given by asso-

ciation executives indicated, however, that competing associations maintain members on lists even after they had ceased practice. Forty-six surveys were returned by the post office, reducing potential respondents to 2029. One hundred names were then randomly selected from the remaining mailing list (via computerized random-number generation), and efforts were made to make direct telephone contact with these practitioners. During a 2-week period, attempts were made to contact these practitioners through various means, including a minimum of 6 telephone calls made during the day, night, and on weekends. Eighty-three practitioners were contacted, 63 of whom were currently practicing TCM, and 20 of whom were no longer in practice. It was assumed that the practitioners we were not able to contact were no longer in practice. Of 2029 names on aggregated mailing lists it was conservatively calculated that approximately 63% of these practitioners were practicing TCM and 37% were no longer in practice. Six hundred forty-two responses (50%) were received from 1278 potential nonmedical practitioners.

Have you ever in your practice caused any adverse effect in a patient due to acupuncture? Please identify the adverse reaction and the number of times you estimate it to have occurred in all your years of practice (exclude point bleeding and small hematomas).

	No. of Times						Specify
	1	2	3	4	5	>5	
Fainting during treatment	0	0	0	0	0	0	_____
Nausea/vomiting	0	0	0	0	0	0	_____
Increased pain	0	0	0	0	0	0	_____
Pneumothorax	0	0	0	0	0	0	_____
Local skin infection	0	0	0	0	0	0	_____
Psychiatric disturbance	0	0	0	0	0	0	_____
Convulsions	0	0	0	0	0	0	_____

0 Other (Please specify adverse effect and frequency of each)

Have you ever in your practice caused any significant adverse effect in a patient due to the consumption or application of Chinese herbal medicine? Please identify the adverse reaction and the number of times you estimate it to have occurred in all your years of practice.

	No. of Times						Specify
	1	2	3	4	5	>5	
Severe gastrointestinal symptoms (severe or continuous vomiting)	0	0	0	0	0	0	_____
Significant skin reaction	0	0	0	0	0	0	_____
Severe fatigue	0	0	0	0	0	0	_____
Jaundice	0	0	0	0	0	0	_____
Fainting or dizziness	0	0	0	0	0	0	_____
Palpitations	0	0	0	0	0	0	_____
High blood pressure	0	0	0	0	0	0	_____
Psychiatric disturbance	0	0	0	0	0	0	_____
Hepatotoxicity (as identified by blood tests)	0	0	0	0	0	0	_____
Renal toxicity (as identified by blood tests)	0	0	0	0	0	0	_____
Significant respiratory disturbance	0	0	0	0	0	0	_____
Central nervous system effects (eg, numbness, palsy)	0	0	0	0	0	0	_____
Referral to medical practitioner/hospital	0	0	0	0	0	0	_____
Death	0	0	0	0	0	0	_____

0 Other (Please specify adverse effect and frequency of each)

Traditional Chinese medicine practitioner survey questions on adverse events related to acupuncture and Chinese herbal medicine.

MEDICAL PRACTITIONERS

A second mailing list of medical practitioners who provided acupuncture services was maintained by the HIC and consisted of 2408 names. However, not all medical practitioners who were sent survey forms still practiced acupuncture. In fact, 75% of medical practitioners on this mailing list devoted less than 10% of their practice time to TCM¹; there was little motivation for these practitioners to complete a lengthy survey questionnaire. Similar adjustments were applied to the medical practitioner mailing list as were applied to the nonmedical practitioner mailing list, generating a valid list of 1517 names. Four hundred fifty-eight (30%) of 1517 medical practitioners responded. Data provided by the HIC indicated that medical practitioner responses to our survey accounted for 40% of the total acupuncture consultations claimed on Medi-

Table 1. Adverse Events in Acupuncture That Have Occurred During the Practice Lifetimes of the Australian TCM Workforce (N = 1100)*

Adverse Event	Nonmedical	Medical	Total
Fainting during treatment	673	496	1169
Nausea/vomiting	365	169	534
Increased pain	496	573	1069
Pneumothorax	39	25	64
Local skin infection	60	68	128
Psychiatric disturbance	56	36	92
Convulsions	43	37	80
Other events†	65	21	86
Total	1797	1425	3222

*Data are given as number of occurrences. TCM indicates traditional Chinese medicine.

†Includes headaches, diarrhea, sweating, dizziness, severe asthma, and feeling unwell.

care forms. Therefore, a 30% response rate was accepted as a conservative figure.

Sixty-nine of 1100 practitioners chose not to identify their primary form of practice. For the purpose of calculating response rates only, this cohort's responses were grouped with nonmedical and medical mailing lists in a similar proportion to overall responses.

The completed surveys were checked for inconsistencies and fraudulent responses. Subsequent discussions with practitioners, professional associations, and the Victorian Government TCM Review Committee indicated confidence in the data collected. The overall response rates were adequate, and data derived from these surveys were accepted as accurately reflecting the TCM workforce.

ADVERSE EVENTS CAUSED BY ACUPUNCTURE

No significant differences were found in the proportion of practitioners reporting adverse events (63.6% of medical practitioners and 60.1% of nonmedical practitioners). Medical practitioners used predominantly acupuncture, while nonmedical practitioners frequently combined acupuncture and CHM. Aggregate data on the adverse events caused by acupuncture are presented in **Table 1**. Mean length of full-time TCM practice was 7.7 years. Practitioners reported that more than 3000 adverse events occurred during their practice lifetimes. The most common adverse events reported were fainting during treatment (n=1169), increased pain (n=1069), and nausea/vomiting (n=534). Serious adverse events reported included pneumothorax (n=64) and convulsions (n=80).

Not all adverse events reported here occurred in Australia, and data from practitioners who practiced TCM extensively overseas may have confounded these figures. It has been suggested that TCM practiced in China

and other Asian countries carries greater risks. However, removal of the adverse event data submitted by practitioners with more than 1 year of overseas experience did not substantially alter the number or distribution of adverse events.

The majority of acupuncture practitioners stated that they always used single-use disposable needles (93%) and adhered to government skin penetration guidelines (83%). Of the small number (n=69) who did not always use disposable needles, autoclaving was the preferred method of sterilization (68%).

A variety of treatment techniques, many of which fell under the umbrella of acupuncture, were administered to patients. Some of the more traditional techniques such as bleeding, scarring moxibustion, and scraping were used only by nonmedical practitioners, and carried their own distinct risks. It is unknown how many of the adverse events reported by practitioners could be accounted for by any 1 technique.

Adverse events due to acupuncture accounted for 79% of all adverse events reported. This reflects the substantially larger cohort of practitioners who principally use acupuncture.

ADVERSE EVENTS CAUSED BY CHM

Aggregate data on the adverse events caused by CHM are presented in **Table 2**. More than 800 adverse events due to CHM had been reported by practitioners during their practice lifetimes. The most common adverse events reported were severe gastrointestinal symptoms (n=124), fainting and dizziness (n=119), and significant skin reactions (n=110). Serious adverse events reported included central nervous system effects (n=37), hepatotoxicity (n=29), renal toxicity (n=28), and death (n=19). The number of deaths reported is consistent with literature reviews, which cite deaths associated with specific Chinese herbal preparations, notably those containing aconite.¹

Removal of the data submitted by practitioners with more than 1 year of overseas experience resulted in reducing the number of adverse events by 40% (to a total of 514). This was particularly noticeable among nonmedical practitioners (413 events). The difference in the number of CHM adverse events reported by medical compared with nonmedical practitioners reflects the low number of medical practitioners (n=9) who use CHM.

Practitioners were also asked whether they prescribed any of a range of specified Chinese herbs either in raw form or contained in proprietary Chinese medicines. The range included a number of herbal substances prohibited by law. These substances and their frequency of usage are presented in **Table 3**.

Table 2. Reported Adverse Events in CHM That Have Occurred During the Practice Lifetimes of the Australian TCM Workforce (N = 1100)*

Adverse Event	Nonmedical	Medical	Total
Severe gastrointestinal symptoms (severe or continuous vomiting, diarrhea, or pain)	116	14	130
Significant skin reaction	102	16	118
Severe fatigue	60	6	66
Jaundice	29	5	34
Fainting or dizziness	105	15	120
Papitations	72	11	83
High blood pressure	41	6	47
Psychiatric disturbance	33	5	38
Hepatotoxicity	24	5	29
Renal toxicity	23	5	28
Significant respiratory disturbance	23	5	28
CNS effects (eg, numbness, palsy)	29	8	37
Referral to medical practitioner/hospital	31	5	36
Death	15	4	19
Other events†	37	10	47
Total	740	120	860

*Data are given as number of occurrences. CHM indicates Chinese Herbal Medicine; TCM, traditional Chinese medicine; and CNS, central nervous system.

†Includes mild gastrointestinal symptoms, hot flushes, and weakness.

Table 3. Selected Scheduled and Restricted Herbs Illegally Prescribed for Oral Use by the Australian TCM Workforce (N = 1100)*

Chinese Herb (Pharmaceutical Name)	Use in TCM Practice, No. (%)
Ma huang (ephedrae, herba)	126 (11.5)
Ma qian zi (strychni, semen)	22 (2.0)
She xiang (Moschus, secretio)	47 (4.3)
Qing mu xiang (aristolochiae, radix)	100 (9.1)
Fu zi (<i>Aconiti carmichaeli praeparata</i> , radix lateralis)	84 (7.6)
Li lu (veratri, radix et rhizome)	21 (1.9)
Ban bian lian (<i>Lobelia chinensis</i> cum radice, herba)	89 (8.1)
Man tuo luo (<i>datura</i> species)	21 (1.9)

*TCM indicates traditional Chinese medicine.

ADVERSE EVENT RATES ASSOCIATED WITH TCM

We determined that each practitioner had encountered an average of 1.38 adverse events during each year of equivalent full-time TCM practice. Hence, approximately 1 adverse event occurred every 8 to 9 months of full-time practice, or for every 633 consultations (**Table 4**).

The Mann-Whitney *U* test for nonparametric data demonstrated a significant difference between the adverse event rates per year of full-time TCM practice for

Table 4. Adverse Events per Year of Equivalent Full-time TCM Practice (n = 897) and per Consultation (n = 890)*

	Nonmedical	Medical	Total
Adverse events per year of equivalent full-time TCM practice	.88 (0.73-1.02)	2.32 (1.95-2.69)	1.38 (1.21-1.54)
Adverse events per consultation	0.0010 (0.0007-0.0013)	0.0027 (0.0018-0.0036)	0.0016 (0.0012-0.0019)
Conversion to consultations per adverse event	1009 (800-1359)	368 (275-556)	663 (515-820)

*Data are given as number of adverse events (95% confidence interval). TCM indicates traditional Chinese medicine.

medical and nonmedical practitioners ($P < .001$), with medical practitioners reporting more than double the adverse event rate of nonmedical practitioners.

COMMENT

This is the first extensive study of adverse events resulting from TCM that has included representatives of all health occupations that practice TCM. The moderate response rates of 30% to 40% (for medical practitioners) and 50% (for nonmedical practitioners) possibly reflect the length of the survey instrument and the lack of follow-up (anonymity was maintained). Medical practitioners may also have perceived limited relevance of this data to their immediate practice. However, similar response rates to mail surveys sent to physicians are not uncommon.¹⁴

The rate and types of adverse events recorded here are a cause for concern. Practitioners of TCM may encounter a range of adverse events throughout their careers. Those commonly arising from acupuncture treatment include fainting, nausea and vomiting, and increased pain, and those arising from CHM include allergic reactions and toxicity. Both this survey and a Norwegian survey of adverse events caused by acupuncture identify the most common adverse event as fainting during treatment.⁶ However, in contrast with the Norwegian survey in which 3 systemic infections were reported, Australian practitioners reported none. While infections and more serious trauma have been reported in overseas literature, our data indicate they occur less frequently in practices in Australia. While common sense suggests that the use of disposable needles should reduce the risk of infection, there is no published data to confirm this. However, this may account for the relatively low number of infections reported by Australian practitioners.

Chinese herbal medicine caused a variety of less frequent but serious events, including 19 deaths reported by practitioners (an unknown number of which may have occurred outside Australia), which indicate ingestion of potent medicinal substances. At the time of the survey several scheduled substances (including aconite) were still used relatively widely by Australian practitioners of CHM. Either these practitioners were unaware of the legal restrictions or were unwilling to abide by them. Cases

of hepatotoxicity and renal toxicity were also reported, adding evidence to some of the case reports in the international literature.^{11-13, 15-18}

It is uncertain how many of these adverse events (including deaths) were caused by interactions with pharmaceutical drugs. Additional data obtained from a patient survey conducted at the same time found that 35% of patients were taking either raw herbs or proprietary Chinese medicines or both in combination with pharmaceutical drugs (excluding vitamins and nutritional supplements).¹ The potential effect of drug-herb interaction requires extensive investigation.

The adverse event rate based on Australian practitioner reports is approximately 6 times higher than that generated by the Norwegian survey, with the latter reporting 1 event for every 4 to 5 years of practice.⁶ No other published studies have calculated adverse event rates for TCM practice.

There are important distinctions between the Australian and Norwegian studies. The Norwegian survey did not maintain anonymity of responses, which may have been of concern to practitioners in an unregulated area, and may have significantly curbed reports by practitioners. Only acupuncturists listed in the telephone book ($N = 290$) were surveyed out of at least 400 practicing Norwegian acupuncturists. This method of selection may have been biased if the practitioners listed in the telephone book were more "established" and not representative of the profession as a whole. Finally, the Norwegian study calculated the total number of adverse events and divided it by the total number of years of practice, making no allowance for the variation in event rates between practitioners. It was estimated that more than 2400 patients had experienced an acupuncture-related adverse event in Norway, representing a population rate of 0.00055. We counted only acupuncture-related events reported by Australian practitioners and extrapolated this data to the whole Australian population, yielding a slightly higher population rate of 0.00067.

A significant difference was found between the adverse event rates for medical and nonmedical practitioners, with reports from medical practitioners resulting in a higher rate of adverse events. The difference may reflect an increased willingness by medical practitioners to report adverse events. However, no significant differ-

ences were found in the proportion of practitioners reporting adverse events (63.6% of medical practitioners and 60.1% of nonmedical practitioners). One explanation is that a patient suffering an adverse reaction might be more likely to return to the practitioner responsible for the reaction if the practitioner were medically qualified. However, this remains a hypothesis. Underreporting by nonmedical practitioners could also account for the difference in rates, especially among those practitioners who had been involved in practice for many years and may have experienced difficulties in recall. New graduates would be expected to have better recall, and medical practitioners in general were more recent providers of TCM services. In contrast, it is possible that unregistered practitioners may have overreported adverse events to encourage the government to recognize the profession by way of statutory regulation.

Limited training may also have been a contributing factor to the higher adverse event rate among medical practitioners. Medical practitioners reported substantially less training in the practice of acupuncture than nonmedical practitioners.¹ Only 25 of 458 medical practitioners surveyed reported that they had completed more than 12 months of education in TCM, with 72% having completed less than 2 weeks of TCM training or failing to answer the question at all. The reported rate of occurrence of pneumothorax (a highly memorable experience for a practitioner at fault) was almost double that of nonmedical practitioners. Even if this could be explained partly by an increased willingness to report adverse events, it seems imperative that all practitioners receive adequate training on the correct anatomical locations of acupuncture points and surrounding structures.³ This predicates the need to establish a minimum standard of TCM education required for safe practice and corroborates concerns expressed by associations representing TCM practitioners that the education provided by short courses (for both medical and nonmedical practitioners) is inadequate for safe practice. Local trauma and significant predictable adverse events, such as pneumothorax, may be minimized by appropriate training in both anatomy and acupuncture practice.⁵

Case reports alone do not provide an accurate estimate of the risks associated with TCM practice since the total number of patients vs the total number of adverse events is not known. Based on data collected in this survey, there seems to be significant underreporting to government agencies of adverse events associated with TCM, which might be explained by practitioners' lack of awareness of avenues for reporting events related to TCM.¹⁹

This study is a first step in collecting data on adverse events across the breadth of TCM. It is however, limited due to the potential for underreporting by practitioners. The next step would be the examination of this issue in a prospective study.

In a prospective study of hospital admissions during an 8-month period in Hong Kong, adverse events due to CHM accounted for 0.2% of admissions (3 patients in 1701 admissions), and those due to Western pharmaceuticals accounted for 4.4%.²⁰ This study only measured severe adverse events, and the lack of data on the relative use of CHM and Western medicine makes this comparison difficult to interpret. Our study found that 0.16% of all TCM consultations resulted in an adverse event (Table 4). In comparison, independent studies reported that 5.7% of Australian hospital admissions were drug-related²¹ and that 16.6% of Australian hospital admissions resulted in an adverse event caused by health care management.²² Although our data may underestimate the occurrence of adverse events, it would be fair to hypothesize that TCM causes significantly fewer adverse reactions than does Western medicine. Further research needs to be undertaken to provide a more accurate assessment of the comparative risks.

The practices of acupuncture and CHM are however, clearly not risk-free. Avoidance of predictable adverse events in TCM is likely to be minimized by appropriate training. The risks involved in the practice of TCM may increase in the future as a result of the combined use of CHM and pharmaceuticals, the increasing demand placed on TCM practitioners to treat a broader range of serious conditions, the changing demographics of the profession, and the lack of enforced education standards. Diligence needs to be exercised by regulatory authorities to ensure that educational standards minimize these risks.

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