BRIEF REPORT

The challenge of cross-cultural collaborative research: lessons learnt from a pilot case–crossover study of severe occupational hand trauma in the People’s Republic of China

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Objective: A pilot epidemiologic study was conducted in the People’s Republic of China to assess the feasibility of applying the study protocol from a US case–crossover study on transient work-related exposures and the risk of an acute occupational hand injury.

Design: Injured workers were recruited from a hand surgery center in Ningbo, Zhejiang, People’s Republic of China. A structured face-to-face interview questionnaire was administered.

Results: 156 workers with hand injury completed the study (73% men). The enrollment rate was 91%. Of those who refused participation, most indicated their reluctance was due to the requirement to sign the written consent form. Considerable variability was found among interviewers in ascertaining responses from participants to important exposure questions (21.3% v 97%).

Conclusions: Recommendations include the following: (1) exploring effective oral-consent protocols that reduce participant concern and still meet human participant protection requirements; (2) using non-physician interviewers; and (3) increasing the intensity and standardization of interviewer training.

In 2002, the People’s Republic of China (PRC) had a reported labor force of 761.3 million.¹ These workers accounted for almost 25% of the global workforce.² During this time, an estimated 20% of the world’s fatal occupational injuries occurred in PRC.³ However, until 1990, there was little peer-reviewed injury research from PRC available in English at the National Library of Medicine (MEDLINE database).

It has been reported that 30% of visits to the emergency departments in China^{4–6} are for hand trauma, of which 41–77% are work related. The most common injuries were laceration (44.9% for work-related and 59.3% for non-work-related injuries) and crush (25.7% and 12.8%, respectively). Common injury sources included sharp objects (36.1% for work-related and 41.9% for non-work-related injuries) and heavy or blunt objects (27.4% and 33.0%, respectively), 33% of work-related injuries involved machines.⁵ In one study on hospitalized patients with hand injuries, the average medical treatment cost was US\$1718,⁷ which exceeded the estimated national average annual income (US\$1698) of PRC in 2003.¹ Workers with hand injury also averaged 171 days off from work.⁷

Lombardi *et al*^{8–9} and Sorock *et al*^{10–13} used the case–crossover method^{14–16} to identify transient risk factors associated with acute traumatic hand injuries in 1166 US workers. The case–crossover design controls for between-person confounders by self-matching. For each case, exposure in the time period

(hazard period) immediately preceding the injury is compared with exposure in a previous time period (control period, estimated during prior work-month). Their results suggested that the relative risk (RR) of hand injury was increased when working with equipment, tools or work pieces not performing as expected (RR 11.0, 95% confidence interval (CI) 9.4 to 12.8), or when using a different work method to do a task (RR 10.5, 95% CI 8.7 to 12.7). Other important transient factors included doing an unusual task, being distracted and being rushed. Additionally, glove use was associated with a lower risk (or was protective) of lacerations and punctures, but not crushes, fractures, amputations and dislocations.¹³

One potential challenge in studying injury in Chinese workers was an expected lesser familiarity with standard participant protection protocols. Although the PRC Ministry of Health released “Provisional guidelines of institutional review for bio-medical research involving human subjects” in 1998, the participant protection practices have been largely limited to pharmaceutical research. The first institutional review board in PRC was established in 1993 after a request by a Sino–US collaborative project.¹⁷

Our pilot study aimed at assessing the feasibility of using the original US study design, protocol and questionnaires, with appropriate translation from English to Chinese, in a hospitalized population of workers with hand injury in PRC. The study features of interest were the acceptance of a standardized US participant protection protocol, evaluation of doctors as the core interviewer group and the degree of success achievable using a structured questionnaire approach.

METHODS

Study population

The Ningbo No 6 Hospital, Ningbo, Zhejiang, PRC, is one of the major centers for hand surgery in Eastern China. An estimated 500 work-related hand traumas are treated every month in this hospital (Dr Hong Chen, Director, Ningbo Hospital, personal communication, 2002). Participants were recruited from the hospital between November 2002 and July 2003. Inclusion required one or more of the following types of work-related injury to the fingers, hand or wrist: laceration, crush, avulsion, puncture, fracture, contusion, amputation or dislocation. The study protocol was reviewed and approved by the Fudan University School of Public Health Institutional Review Board, Shanghai, PRC.

Interview preparation and procedure

The protocol and questionnaire from the US study of acute hand trauma including the interviewer manual^{8–13} were translated

Abbreviation: PRC, People’s Republic of China

Table 1 Characteristics of workers with hand injury and their jobs, Ningbo, East China, November 2002–July 2003 (n = 156)

Characteristics	Value
Age, years mean (SD, median, range)	32.2 (10.4, 31, 17–59)
Sex	n (%)
Male	114 (73.1)
Female	41 (26.3)
Missing	1 (0.6)
Job characteristics	
Industry, n(%)	
Manufacturing	150 (96.2)
Fabrication	41 (26.1)
Machinery	30 (19.1)
Plastics	22 (14.0)
Textiles	10 (6.4)
Electrical	10 (6.4)
Construction	3 (1.9)
Work time, h/week mean (SD, median, range)	
Men	59.8 (18.7, 56, 0.5–98)
Women	58.7 (17.1, 56, 20–112)
Overall	59.4 (18.2, 56, 0.5–112)
Job experience, months mean (SD, median, range)	
Men	31.4 (63.2, 7.0, 0.03–360)
Women	28.2 (36.5, 7.5, 0.03–120)
Overall	30.6 (57.2, 7.5, 0.03–360)
Company size, n(%)	
<50	74 (47.4)
50–99	16 (10.3)
>100	29 (18.6)
Missing	37 (23.7)

into Chinese and then back translated into English for validation. For this pilot study, nine junior doctors or trainees in the hand surgery center were recruited as interviewers. Their training included US human participant protection guidelines, relevant Chinese regulations and face-to-face interview techniques including practice interview exercises.

The prior US study used telephone follow-up interviewing. Considering the low coverage of household telephones in PRC (43%)¹ and the high prevalence of fee-based mobile phones among potential participants, we modified the pilot study design for a face-to-face interview. Participants were enrolled at their first visit and a subsequent interview was scheduled.

Exposure measurement

A case–crossover design was used to quantify the relationship between the following potential transient risk factors and the occurrence of work-related hand injury: using a machine, tool or work material that performed differently than usual (malfunctioning equipment); wearing gloves; performing an unusual task (unusual task); performing a task using unusual work methods (unusual method); being distracted or rushed; working overtime; and feeling ill.

In this design, exposure to these potential risk factors was captured during the 90-min period before the injury. Participants were considered to have been exposed if any measured exposure was reported at the time of the hand injury. The exposure during the control period was estimated as the number of exposed hours per work-month by multiplying the average frequency and duration of exposure to each transient factor in the month (see Sorock *et al*^{10–11} for details). For each transient exposure, unexposed work time was calculated by

Table 2 Injury characteristics of workers with hand injury (n = 156)

Injury characteristic*	n (%)
Injury category	
Crush	87 (47.8)
Laceration	35 (19.2)
Fracture	27 (14.8)
Avulsion	26 (14.3)
Contusion	5 (2.7)
Amputation	2 (1.1)
Laceration length (cm)	
0–2.99	11 (7.1)
3–5.99	38 (24.4)
≥6	23 (14.7)
Sutures (n)	
1–4	29 (18.6)
5–9	18 (11.5)
≥10	20 (12.8)
Damage to	
Tendon	109 (69.9)
Nerve	108 (69.2)
Ligament	78 (50.0)

*182 injuries were reported among the 156 cases.

subtracting the number of exposed hours per work-month from the total time that each participant reported working, including overtime.

Data analysis

Descriptive statistics were estimated for worker demographics, and job and injury characteristics. Interview quality and the responses to questions on transient exposure by study participants before and at the time of injury were summarized and compared between interviewers.

RESULTS

A total of 172 participants were invited to participate in this study, of which 156 signed informed consent and completed the study interview (enrollment rate 91%). Most cases were interviewed within 3–5 days of their hand injury; however, some were interviewed as late as 10 days after their injury (mean (standard deviation (SD)) 5 (2) days). Most participants were men (73%) and the mean (SD) age was 32.2 (10.4) years (table 1).

Participants typically had about 30 months of job experience and worked an average of 59 (18) h/week. Most participants worked in manufacturing (96%), and 57% worked in enterprises with <100 employees.

Almost half of the injuries treated were crushes (48%), followed by lacerations (19%), fractures (15%) and avulsions

Table 3 Participants who did not respond to the questions on transient exposures before and at the time of injury (n = 156)

Transient exposures	Prior work-month n (%)	At the time of injury n (%)
Different work method	143 (91.7)	33 (21.2)
Doing an unusual task	142 (91.0)	32 (20.5)
Being distracted	141 (90.4)	22 (14.1)
Feeling ill	141 (90.4)	23 (14.7)
Being rushed	138 (88.5)	26 (16.7)
Unusually performing equipment or material	136 (87.2)	32 (20.5)
Working overtime	127 (81.4)	20 (12.8)
Wearing gloves	125 (80.1)	76 (48.7)

Table 4 Response percentage to questions on transient exposure among participants with hand injury, by interviewer*

Interviewer	Number of interviews conducted	Percent of questions answered on transient exposures (%)	
		Control period (month or week before the injury)	Hazard period (at the time of the injury)
1	10	0.0	21.3
2	18	2.1	45.1
3	16	2.3	80.5
4	36	4.9	92.7
5	50	28.0	97.0
Total	156	12.9	83.5

*Only those interviewers who conducted ≥ 10 interviews are listed. All interviewers were junior doctors or trainees in the Ningbo No. 6 Hospital, Ningbo, People's Republic of China.

(14%). Most injured workers had either ligament (50%) or tendon or nerve damage (70%; table 2).

In this study, reported exposures ranged from 3% for using a different working method to 48% for wearing gloves. Other reported exposures were being distracted (14.7%), working overtime (14.7%) and being rushed (11.5%).

For most exposures, the average percentage of exposure out of the total person-time at work in the month before the injury was very low, ranging from 0.01% for being rushed to 2.8% for wearing gloves. There was a substantial number of non-responses to the questions on exposure (table 3); therefore, the calculation of the usual frequency of each transient factor was not reliable.

Given the relatively high non-response rates to critical prevalence questions on usual frequency, interviewer performance was assessed. We found substantial between-interviewer variation in the response rates to the questions on transient exposure (table 4). Interviewers who achieved higher response rates to the questions on transient exposure at the time of injury also had correspondingly higher response rates to the same before injury. However, even the highest response rate for questions on transient exposures before injury was only 28%.

DISCUSSION

The pilot study was conducted to assess design feasibility. We expected that the pilot study would identify potential barriers to effective data collection and analysis, which could be considered in future study designs.

Study protocol

The pilot study protocol identified and enrolled participants at their first visit for a subsequent interview. As a second visit to the clinic was needed for ambulatory participants, the mobility of the non-hospitalized population made follow-up difficult. Thus, the most successful approach to participant enrollment was in hospitalized patients.

Interview and interviewer quality

Although a high enrollment rate was achieved (91%), the data quality was generally poor, with the usual frequency of questions on transient exposure often not completed. Potential reasons for problems in data quality may have included the high volume of inpatients for the doctors. Heavy workloads of doctors may have made them less willing to spend time to fully complete the participant interviews. Additionally, although the interviewers were instructed not to skip questions, given the time pressure, some of the participants might not have had sufficient time to generate a response to more challenging items such as the usual frequency of transient exposures. Alternatively, some interviewers may not have clearly understood the importance of the reference period

items. Future studies should consider using non-physicians, supporting healthcare staff or public health workers as interviewers.

Human participant protection protocol

Many patients felt uncomfortable providing their signature to participate in the study. Generally, 15 min were required to explain the consent form and acquire their signature, which was almost half the total time typically required for an entire interview. In the typical scenario, the prospective participant would finish reading the informed consent form and would ask, "could I just start the interview without a signature?"

This reluctance to sign might be due to the following:

1. The practice in China to require a signature only for very formal, major life events (eg, marriage or birth of a child); a similar scenario was reported by Adams *et al.*¹⁸
2. The style of a US human participant protocol being relatively unfamiliar to the patients.
3. The signature being the only identifiable marker left (on the consent form) in writing.
4. The patients' concern about a possible link to their records if information were obtained by their employers, although the human participant protection protocol explicitly guaranteed protection from this possibility.

Dawson and Kass¹⁹ suggested that international collaborative studies should use a flexible approach to informed consent. Therefore, future studies should consider exploring oral-consent approaches to reduce potential participant concerns.

Key points

- A pilot epidemiologic study was conducted to assess the feasibility of applying the study design, protocol and questionnaires from a previously conducted US case-crossover study on transient work-related exposures and the risk of an acute occupational hand injury to workers in China.
- Of workers who refused participation, most indicated that their reluctance was due to the requirement to sign the written consent form. Some technically challenging items had low answer rates. Despite prestudy training, considerable variability was seen among interviewers.
- Recommendations for future studies include use of oral-consent protocols that reduce participants' concern, yet still meet participant protection requirements, using non-physician interviewers and increasing the quality of interviewer training.

Interview process

Participants were generally cooperative with the interviewers regarding the circumstances of their injury. In the US, Brugge *et al*²⁰ also indicated that Chinese-American immigrants were more likely to participate in a survey than non-Chinese immigrants, even without monetary incentives.

However, in some cases, it is possible that the participant neglected to report important details related to the study exposures of interest. The repetitive nature of the questions (ie, collecting information on both exposures at the time of injury and before the injury for each risk factor) may have contributed to participants' failure to provide greater detail. Obviously, the interviewer's ability to administer the questionnaire is a critical factor in encouraging the participant to report all aspects of the injury while providing confidence that participant protection requirements are being followed.

Cultural differences were also noted in responses of participants' to an open-ended question about cause of injury: 27% of participants blamed themselves for not being careful enough while working, which was the second leading cause after machine malfunction (28%). Cheng²¹ suggested that causal factors attributed by continental Chinese workers could be classified into two major types: industrial forces and magical-religious forces. The industrial forces are directed to the work process such as machine defects, piecework, lack of working experience and supervision; the magical-religious forces are related to fate and luck, which are embraced in traditional cultural beliefs commonly found among the Chinese.²¹ The traditional emphasis on harmony and stability may also influence workers to preserve the harmony between themselves and their employer, resulting in a greater self-attribution and focus on intrinsic factors than in other cultures.

CONCLUSION

Our pilot epidemiologic study was conducted to assess the feasibility of applying the study design, protocol and questionnaires from a previously conducted US case-crossover study on transient work-related exposures and the risk of an acute occupational hand injury to workers in PRC. Recommendations for future studies include exploring the potential for effective oral-consent protocols that reduce participant concern and still meet protection requirements, using non-physician interviewers, and increasing the intensity and standardization of interviewer training.

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