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Research Dissemination Reports

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研究成果報告

Tobacco Control
控煙

Neurology
神經病學

Respiratory Diseases
呼吸系統疾病

Traditional Chinese Medicine
傳統中醫藥

Reproductive System & Childbirth
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Supplement 2

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Editorial

Dissemination reports are concise informative reports of health-related research supported by funds administered by the Food and Health Bureau, for example, the *Health and Health Services Research Fund* (which was consolidated into the *Health and Medical Research Fund* in December 2011). In this edition, 11 dissemination reports of projects related to tobacco control, neurology, respiratory diseases, traditional Chinese medicine, and reproductive system and childbirth are presented. In particular, four projects are highlighted due to their potentially significant findings, impact on healthcare delivery and practice, and/or contribution to health policy formulation in Hong Kong.

Tobacco control in Hong Kong has been carried out since the early 1980s, and control measures in particular the indoor smoking ban have increased in intensity since 2007. There is a sizeable group of smokers who are resistant to giving up. Leung et al¹ aimed to estimate the prevalence of these hardcore smokers and identify demographic, environmental, and smoking-related factors associated with hardcore smoking. They found that the proportion of hardcore smokers increased in the period under study, indicating that a smoking habit is becoming more ingrained. The study also revealed that hardcore smokers are less likely to be aware of existing smoking cessation services. This suggests a need to strengthen the existing cessation services for the whole smoking population, in particular hardcore smokers.

As the global elderly population increases there will be an increase in degenerative changes in cognitive functioning. Lee et al² conducted a study to determine whether a computerised cognitive training programme for the elderly resulted in improved attention and working memory. Among the 383 subjects participating in the 13-week study they found that those who underwent the computerised cognitive training programme demonstrated significant improvement in sustained attention and working memory at both individual and group levels. In elderly individuals with higher computer competency,

adoption of a web-based training programme would allow self-administration at home at any time.

Obstructive sleep apnoea is a form of disordered breathing in which the upper airway closes repeatedly and intermittently during sleep. Continuous positive airway pressure (CPAP) treatment provides effective relief of symptoms and prevents health-related consequences. Effective education is important to enhance CPAP use. Lai et al³ conducted a randomised controlled trial with 100 Chinese subjects with obstructive sleep apnoea and showed that a motivational enhancement programme composed of a single interview and a follow-up phone call at the initiation of CPAP treatment improved treatment adherence, even after 1 year, and led to better health outcome in terms of reducing daytime sleepiness.

Benign prostatic enlargement is a major cause of moderate-to-severe lower urinary tract symptoms among Asian men aged over 40 years. Monopolar transurethral resection of the prostate is the gold standard for surgical management. However, it is associated with the risk of transurethral resection syndrome when glycine solution is used for irrigation. Bipolar surgery of the prostate uses isotonic saline solution for irrigation and thus minimises the risk of transurethral resection syndrome. Ng et al⁴ conducted a randomised controlled trial in 168 eligible subjects comparing the two treatment modalities. They found that bipolar (saline) method achieved a shorter urethral catheter time and hospital stay than the monopolar (glycine) method. After 6 months, both methods achieved similar outcome in terms of symptoms and quality of life.

We hope you will enjoy this selection of research dissemination reports. Electronic copies of these dissemination reports and the corresponding full reports can be downloaded individually from the Research Fund Secretariat website (<http://www.fhb.gov.hk/grants>). Researchers interested in the funds administered by the Food and Health Bureau also may visit the website for detailed information about application procedures.

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Prevalence and characteristics of hardcore smokers in Hong Kong

DYP Leung *, SSC Chan, TH Lam

KEY MESSAGES

1. The proportion of hardcore smokers among male and female smokers increased from 2005 to 2008. This indicates that a smoking habit is becoming more ingrained among smokers in Hong Kong, regardless of gender.
2. A demographic profile of hardcore smokers reveals that they are less likely to be aware of existing smoking cessation services. This suggests a need to strengthen the existing cessation services for the whole smoking population, in particular hardcore smokers.
3. Although the implementation of smoke-free legislation may have provided an environment

to reduce social smoking in the community, it appears that the determination of Hong Kong's smoking population is driven by psychosocial factors.

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Introduction

Tobacco control in Hong Kong has been carried out since the early 1980s, and control measures have increased in intensity since 2007. Although the overall smoking prevalence declined gradually from 15.7% in 1990 to 11.8% in 2008, there were 679 500 daily smokers aged ≥ 15 years in 2008, of whom 55.5% had never tried and did not want to give up smoking, and 92.0% would not try any existing cessation services.¹ There is a sizeable group of smokers who are resistant to giving up or a hardening of the smoking population in Hong Kong.² This study aimed to estimate the prevalence of hardcore smokers in Hong Kong, identify demographic, environmental, and smoking-related factors associated with hardcore smoking by gender, and compare their awareness of current smoking cessation services with that of other smoking subgroups.

Methods

Study design

This study was conducted from December 2010 to May 2011. We conducted a secondary analysis of population data on patterns of smoking from the Thematic Household Survey (THS) in 2005 and 2008. We included 3740 and 2958 current daily smokers aged ≥ 15 years who responded to the THS2005 and THS2008, respectively.

Outcome measures

Based on THS2005 and THS2008, there were two types of hardcore smokers (ie HC2A and HC2B).

HC2A was defined as those who (1) were daily smokers, (2) had a smoking history of at least 6 years, (3) had no history of quit attempts, (4) did not want to give up smoking, (5) smoked ≥ 11 cigarettes per day on average, and (6) were 26 years or older. HC2B was the same as HC2A except that average number of cigarettes smoked per day was ≥ 15 . HC2A was computed for both surveys, whereas HC2B was computed for THS2008 only because daily cigarette consumption was in a categorical format (≤ 10 , 11-20, 21-30, 31+) in THS2005. Smokers who do not meet the criteria for HC2A were considered as non-HC2A. A similar definition was applied to non-HC2B.

Results

Prevalence of hardcore smoking

Using the HC2A definition, 21.8% (in 2005) and 27.4% (in 2008) of daily smokers aged ≥ 15 years were classified as hardcore. From 2005 to 2008, the rate went up from 23.8% to 29.4% in men and from 10.6% to 16.3% in women, increasing in all five age groups (Table 1). The prevalence in 2005 and 2008 increased with age, reaching a peak in the 50-59 age-group and then dropping in the 60+ age-group. Using the more stringent HC2B definition, 25.7% of daily smokers in the THS2008 sample were hardcore. The differences between HC2A and HC2B were within 3%.

Factors associated with hardcore smoking in Hong Kong

Under HC2A, 27 associated factors were identified

TABLE 1. Prevalence of hardcore smoking in Hong Kong by age, gender, and survey year

Parameter	THS2005 (n=3740)		THS2008 (n=2958)		
	No.	% (95% CI) of participants defined as HC2A	No.	% (95% CI) of participants defined as HC2A	% (95% CI) of participants defined as HC2B
Age group (years)					
15-29	691	7.5 (5.8-9.7)	537	12.1 (9.6-15.1)	11.5 (9.1-14.5)
30-39	813	21.8 (19.1-24.7)	627	27.4 (24.1-31.1)	26.5 (23.2-30.1)
40-49	875	25.0 (22.3-28.0)	680	32.1 (28.7-35.7)	30.0 (26.7-33.6)
50-59	654	29.8 (26.4-33.4)	601	34.6 (30.9-38.5)	32.1 (28.5-36.0)
60+	707	24.6 (21.6-27.9)	513	28.7 (24.9-32.7)	26.3 (22.7-30.3)
Gender					
Male	3192	23.8 (22.3-25.3)	2497	29.4 (27.7-31.3)	27.6 (25.9-29.4)
Female	548	10.6 (8.3-13.4)	461	16.3 (13.2-19.9)	15.4 (12.4-19.0)
Total	3740	21.8 (20.6-23.2)	2958	27.4 (25.8-29.0)	25.7 (24.2-27.3)

in the bivariate analysis for the overall sample (Table 2). Among them, three demographic variables (age, marital status, and gender), two smoking-related variables (age started smoking and started smoking 'for refreshment'), seven cessation-related variables (awareness of smoking cessation clinics, and six reasons for not wanting to give up: 'smoking had become a habit', 'not enough determination', 'most friends or colleagues are smokers', 'necessity in social function', 'necessity for killing time', and 'necessity for easing tension'), and three interaction terms with 'year' ('necessity as a refreshment', 'necessity in social function', and 'necessity for killing time') were significant in the logistic regression model.

Slightly different factors associated with hardcore smoking were observed in the male and female sub-samples. Again, the factors identified for HC2A among male smokers were similar to those for the overall sample in the final logistic regression models, except for 'necessity for easing tension'. Among female smokers, only six factors were associated with HC2A (age, educational level, started smoking because of 'social needs', not wanting to give up because 'smoking had become a habit', 'necessity for killing time', and 'necessity for easing tension'), but no interaction term with 'year' was significant.

Both similar and different variables were associated with HC2B when compared with HC2A using THS2008 (Table 3). The significant similar variables included age, gender, age started smoking, awareness of smoking cessation clinics, 'smoking had become a habit', 'not enough determination', 'most friends or colleagues are smokers', 'necessity as a refreshment', and 'necessity for easing tension', whereas the significant different variables were the two reasons for starting to smoke ('to kill time' and

'to make oneself look more mature/stylish') and the two reasons for not wanting to give up ('never thought of quitting' and 'smoking is not harmful to health').

The direction and extent of association of the factors with hardcore smoking, regardless of its definition, were consistent. In particular, smokers in the 15-29 age-group who were married and aware of existing cessation services were less likely to be hardcore, whereas those with reasons for not wanting to give up were more likely to be so. As for the interaction term with 'year', the impact of 'necessity as a refreshment' on the likelihood of being hardcore increased from 2005 to 2008, whereas that of 'necessity in social function' decreased.

Discussion

The prevalence of hardcore smokers in Hong Kong is higher than that in other countries, except for Italy.³⁻⁶ Respectively in 2005 and 2008, 21.8% and 27.4% of Hong Kong smokers aged ≥15 years could be considered hardcore under the HC2A definition, and would have been as high as 25.7% in 2008 under the more stringent definition HC2B. Given that the overall smoking prevalence in Hong Kong decreased from 14.0% in 2005 to 11.8% in 2008, the increase in proportion of hardcore smokers suggests a hardening of the smoking population.³ With an increase in both male (23.8% in 2005 to 29.4% in 2008) and female (10.6% in 2005 to 16.3% in 2008) hardcore smokers under HC2A, the hardening occurred in both populations.

As reported in previous studies,⁴⁻⁷ hardcore smokers differed substantially to their non-hardcore counterparts in the logistic regression models. Overall, age, gender, marital status, and age at which

TABLE 2. Logistic regression of hardcore smoking HC2A for the overall sample and gender subsamples

Parameter	P value and OR (95% CI)*					
	Overall		Male		Female	
	Main effect	Interaction term with 'year'	Main effect	Interaction term with 'year'	Main effect	Interaction term with 'year'
Year	P=0.924	NA	P=0.910	NA	P=0.435	NA
Age group (years)	P<0.001	P=0.222	P<0.001	P=0.280	P=0.003	P=0.063
15-29	0.15 (0.09-0.25)		0.14 (0.08-0.24)		0.66 (0.01-0.35)	
30-39	0.81 (0.56-1.18)		0.84 (0.57-1.25)		0.12 (0.03-0.52)	
40-49	1.09 (0.78-1.52)		1.08 (0.76-1.54)		0.41 (0.11-1.55)	
50-59	1.41 (1.03-1.92)		1.41 (1.02-1.95)		0.87 (0.25-3.00)	
60+	1.00		1.00		1.00	
Marital status	P<0.001	P=0.149	P<0.001	P=0.060	P=0.689	P=0.834
Single	1.00		1.00			
Married	0.55 (0.42-0.72)		0.63 (0.40-0.70)			
Separated/divorced	1.00 (0.61-1.64)		1.14 (0.66-1.97)			
Widowed	0.50 (0.29-0.87)		0.38 (0.20-0.73)			
Gender	P=0.015	P=0.407	NA	NA	NA	NA
Male	1.51 (1.08-2.10)					
Female	1.00					
Educational level	P=0.070	P=0.373	P=0.068	P=0.269	P=0.002	P=0.058
No schooling / kindergarten / primary					0.15 (0.03-0.81)	
Secondary / matriculation					0.76 (0.34-4.38)	
Tertiary					1.00	
Household income level (monthly)	P=0.823	P=0.463	P=0.884	P=0.445	P=0.352	P=0.293
Employment status					P=0.537	P=0.322
Occupation	P=0.159	P=0.106	P=0.571	P=0.152		
Industry engaged in	P=0.949	P=0.792	P=0.867	P=0.563		
Nature of the workplace	P=0.954	P=0.701	P=0.982	P=0.358		
Age starting smoking cigarette (years)	P<0.001	P=0.201	P<0.001	P=0.134	P=0.098	P=0.484
<20	1.97 (1.22-3.17)		2.09 (1.21-3.60)			
20-24	1.40 (0.85-2.28)		1.50 (0.86-2.22)			
25-29	1.26 (0.69-2.30)		1.12 (0.56-2.22)			
30+	1.00		1.00			
Smokers within 3 metres in the workplace	P=0.062	P=0.947	P=0.093	P=0.947	P=0.266	P=0.910
Aware of any smoking cessation clinics or centres in Hong Kong	0.68 (0.55-0.84) P<0.001	P=0.647	0.67 (0.53-0.84) P=0.001	P=0.926	P=0.294	P=0.402
Heard about telephone smoking cessation services	P=0.140	P=0.756	P=0.060	P=0.813		
Reasons for starting to smoke cigarettes						
Influenced by parents/other family members	P=0.992	P=0.400	P=0.724	P=0.656		
Out of curiosity/fun					P=0.103	P=0.920
For refreshment	1.45 (1.02-2.06) P=0.038	P=0.413	1.50 (1.04-1.49) P=0.032	P=0.414		
Social needs					0.19 (0.04-0.94) P=0.042	NA
To kill time	P=0.787	P=0.381	P=0.282	P=0.814		
To ease tension	P=0.966	P=0.820	P=0.991	P=0.883		

* OR (95% CI) for significant variables only

TABLE 2. (cont'd)

Parameter	P value and OR (95% CI)*					
	Overall		Male		Female	
	Main effect	Interaction term with 'year'	Main effect	Interaction term with 'year'	Main effect	Interaction term with 'year'
Reasons for not wanting to give up smoking						
Smoking had become a habit	5.11 (4.18-6.23) P<0.001	P=0.329	5.32 (4.31-6.57) P<0.001	P=0.279	4.71 (2.35-9.43) P<0.001	P=0.804
Not enough determination	1.82 (1.47-2.25) P<0.001	P=0.896	1.93 (1.54-2.41) P<0.001	P=0.868		
Most friends or colleagues are smokers	1.55 (1.22-1.96) P<0.001	P=0.828	1.50 (1.17-1.92) P=0.001	P=0.900	P=0.128	P=0.627
Severe psychological/physical discomfort when quitting smoking	P=0.091	P=0.413	P=0.183	P=0.457	P=0.081	NA
Necessity as a refreshment	P=0.126	2.78 (1.30-5.90) P=0.008	P=0.149	2.84 (1.30-6.23) P=0.009		
Necessity in social functions	1.54 (1.14-2.09) P=0.005	0.50 (0.28-0.89) P=0.018	1.52 (1.11-2.09) P=0.009	0.53 (0.29-0.97) P=0.040		
Necessity for killing time	1.80 (1.34-2.42) P<0.001	0.56 (0.36-0.89) P=0.013	1.74 (1.27-2.40) P=0.001	0.59 (0.36-0.95) P=0.003	2.82 (1.20-6.61) P=0.017	P=0.343
Necessity for easing tension	1.55 (1.09-2.21) P=0.015	P=0.131	P=0.077	P=0.077	2.59 (1.03-6.52) P=0.043	P=0.765
Too easy to get cigarettes or other forms of tobacco product	P=0.786	P=0.792	P=0.876	P=0.705		
Worried about getting sick after quitting smoking	P=0.154	P=0.271	P=0.232	P=0.238		
Worried about getting fat after quitting smoking	P=0.575	P=0.489	P=0.663	P=0.509	P=0.395	P=1.00

they started smoking were associated with hardcore smoking. These results suggest that Hong Kong smokers in the 15-29 age-group who are married are less likely to be hardcore, whereas males who started smoking under 20 years old are more likely to be hardcore. Surprisingly, daily cigarette consumption was consistently a non-significant factor of hardcore smoking in all bivariate analyses in the overall sample and the two gender sub-samples, regardless of definitions. This might be due to the small amount of variation in the individual's daily cigarette consumption: about half the sample smoked 1-10 cigarettes, slightly less than half smoked 11-20, and only about 5% smoked >20 a day, according to THS2005 and THS2008.

Psychological factors might play a key role in hardening of smoking; several reasons for not wanting to give up smoking ('smoking has become a habit', 'not enough determination', 'most friends or colleagues are smokers', 'necessity as a refreshment', 'necessity as a social function', and 'necessity for easing tension') were consistent predictors of hardcore smoking (HC2A and HC2B) in the overall sample. In addition, the impact of 'necessity as refreshment' on

the likelihood of being a hardcore smoker (HC2A) has increased, whereas that of 'necessity in social functions' and 'necessity for killing time' have decreased in both the overall sample and male sub-sample since the implementation of comprehensive smoke-free legislation on 1 January 2007. This may be due to changes in the smoking environment. Smokers are no longer allowed to smoke indoors at their workplace or social functions. Further studies should examine this assertion. Among females, only a few factors were associated with hardcore smoking. This may have been due to the small female sample and many predictors considered in the logistic regression model, leading to a lack of statistical power. Nevertheless, the current findings highlight the important role of psychological factors in hardcore smoking among Hong Kong people. Psychosocial factors, such as attitudes toward second-hand smoke exposure or smoking cessation, perceived health status, perceived stress, and quitting self-efficacy should all be examined in future studies.⁷ In addition, nicotine dependency is consistently reported as a predictor of hardcore smoking but was not measured in THS2005 and

TABLE 3. Logistic regression of hardcore smoking HC2B for the overall sample and gender subsamples

Parameter	P value and OR (95% CI)*		
	Overall	Male	Female
Age-group (years)	P<0.001	P<0.001	P<0.001
15-29	0.34 (0.20-0.56)	0.37 (0.24-0.60)	0.48 (0.10-2.39)
30-39	1.66 (1.10-2.51)	1.87 (1.23-2.83)	1.85 (0.48-7.05)
40-49	1.87 (1.29-2.71)	1.66 (1.13-2.44)	6.74 (1.88-24.20)
50-59	1.85 (1.31-2.63)	1.81 (1.27-2.60)	3.45 (0.88-13.57)
60+	1.00	1.00	1.00
Marital status	P=0.332		P=0.944
Gender	P=0.001	NA	NA
Male	1.82(1.30-2.55)		
Female	1.00		
Educational level	P=0.203	P=0.162	
Household income level (monthly)	P=0.524	P=0.468	
Occupation	P=0.184		
Industry engaged in	P=0.815		
Nature of the workplace	P=0.182	P=0.169	
Age starting smoking cigarette (years)	P<0.001	P<0.001	P=0.051
<20	3.08 (1.57-6.06)	4.61(1.97-10.79)	
20-24	2.21 (1.11-4.41)	3.71(1.57-8.79)	
25-29	1.51 (0.62-3.64)	2.12(0.75-5.95)	
30+	1.00	1.00	
Smokers within 3 metres in the workplace	P=0.150		P=0.053
Aware of any smoking cessation clinics or centres in Hong Kong	0.70 (0.53-0.92) P=0.011	P=0.068	0.35 (0.15-0.81) P=0.015
Heard about telephone smoking cessation services	P=0.427	P=0.252	P=0.281
Reasons for starting to smoke cigarettes			
Influenced by parents/ other family members	P=0.174	P=0.270	
To kill time	0.46(0.23-0.92) P=0.028	P=0.145	
To ease tension	P=0.741	P=0.608	
To make oneself look more mature/ stylish	2.55 (1.21-5.37) P=0.041	2.38 (1.10-5.14) P=0.028	
Reasons for not wanting to give up smoking			
Smoking had become a habit	9.68 (7.50-12.50) P<0.001	9.90 (7.55-13.00) P<0.001	7.86 (3.72-16.63) P<0.001
Not enough determination	2.77 (2.04-3.76) P<0.001	2.91 (2.10-4.02) P<0.001	
Most friends or colleagues are smokers	2.01 (1.42-2.85) P<0.001	1.94 (1.34-2.81) P<0.001	4.15 (1.39-12.32) P=0.011
Necessity as a refreshment	3.75 (1.91-7.36) P<0.001	4.16 (2.08-8.30) P<0.001	
Necessity in social functions	P=0.700	P=0.971	
Necessity for killing time	P=0.599	P=0.655	
Necessity for easing tension	3.79 (2.18-6.58) P<0.001	4.09 (2.22-7.54) P<0.001	
Never thought of quitting smoking	14.34 (10.22-20.12) P<0.001	15.66 (10.89-22.51) P<0.001	10.28 (4.00-26.38) P<0.001
Smoking is not harmful to health	45.29 (4.55-450.42) P=0.001	45.29 (4.57-499.26) P=0.001	

* OR (95% CI) for significant variables only

THS2008. This precluded us from examining the relationship. It is possible that variations in hardcore smoking explained by psychological factors might diminish if nicotine dependency were included in the models.

In the multivariate logistic regression models, awareness of existing cessation services was, in general, negatively associated with hardcore smoking in the overall sample and the two gender sub-samples, regardless of the definition of hardcore smoking used. Although the proportion of smokers aware of existing cessation services increased from 40.8% in 2005 to 60.6% in 2008 over the whole smoking population,¹ our findings suggest that such awareness is limited and insufficient to encourage giving up among hardcore smokers and the *entire* smoking population in Hong Kong. Our findings also suggest that there may be a gender difference in the demographic profile of hardcore smokers. In particular, females were less likely to be economically active than their male counterparts. This result highlights the potential need to strengthen the promotion of smoking cessation among female smokers who are under financial strain. Nonetheless, these results should be interpreted with caution because of unreliable estimates in the logistic regression.

Limitations

The present study has several limitations, and the results should be interpreted with caution. First, since we performed a secondary analysis of an existing data set, and many variables measured in THS2005 were in categorical format, we were unable to match exactly all the criteria of hardcore smoking reported in the literature. In particular, we could only ascertain that certain people had been smoking for 1 to 9 years according to our own calculations; and this group of smokers has not been classified as hardcore. Our results might have underestimated the proportion of hardcore smokers in the smoking population. Second, there were only a few female smokers in the sample and a large number of predictors considered in the models definitely entailed low power statistical tests. As such, the results for female smokers should be interpreted with caution. Third, some previously reported predictors of hardcore smoking, such as nicotine dependency, were not included in the THS2005 and THS2008. This prevented projecting the full picture of factors associated with hardcore smoking and limited the comparability of the current results with those of previous studies from other countries.

Conclusion

Although the implementation of smoke-free legislation may have provided an environment to reduce social smoking in the community, hardening of smoking was driven by psychosocial factors. There may be a need to provide more effective and tailor-made treatments that focus on self-efficacy in resisting smoking. Our findings also shed light on the direction that future cessation services should take. In particular, treatment should focus on breaking the link between smoking and habit, and include a component that tackles external stimuli such as 'smoking is for refreshment and easing tension'.

Acknowledgements

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Results based on a different definition of hardcore smokers from this study have been published in: Leung DY, Chan SS, Chan V, Lam TH. Hardcore smoking after comprehensive smoke-free legislation and health warnings on cigarette packets in Hong Kong. *Public Health* 2016;132:50-6.

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A brief, tailored smoking cessation intervention for smokers with diabetes mellitus in Hong Kong

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KEY MESSAGE

A brief, tailored intervention was not effective in promoting quitting or reducing smoking in smokers with diabetes mellitus. The intervention also did not improve glycaemic control of these patients at 12 months.

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Introduction

Diabetes mellitus (DM) is an epidemic, chronic, non-communicable disease. The number of patients with DM worldwide is expected to reach nearly 552 million by 2030. In Hong Kong, >90% of these patients are diagnosed as having type 2 DM, and 10.4% of them smoke.¹ Continuous smoking increases the risk of cardiovascular disease, diabetic nephropathy, stroke, and amputation. In 2014, the American Diabetes Association strongly recommended to include interventions for smoking cessation as standard medical care for patients with type 2 DM to minimise health risks and control glycaemic levels. The best moment for initiating smoking cessation is at the medical appointment in the DM outpatient clinic. Health care professionals can use this opportunity to encourage smokers with DM to quit smoking. Nonetheless, our recent qualitative study of Hong Kong Chinese smokers with DM showed that these smokers had many misconceptions about the association between smoking and DM.² They were reluctant to quit smoking and did not consider that the risks of continuous smoking could hinder their treatment efficacy and promote DM complications.

We performed a randomised controlled trial to examine the effectiveness of a brief, low-cost, stage-matched smoking cessation intervention to motivate smokers with type 2 DM to quit smoking and minimise their health risks. Subjects in the intervention group received a 20-min face-to-face individualised counselling session, a DM-specific leaflet, and a self-help pamphlet on smoking. Booster talks were given at 1-week and 1-month follow-ups via telephone by nurse counsellors trained in smoking cessation. Subjects in the control group received usual care and a self-help pamphlet as a placebo. Data were collected at 1 week and at 1, 3, 6 and 12 months by the nurse counsellors via

telephone. Biochemical validation was conducted at 12 months on the subjects who claimed that they had quit smoking. We hypothesised that the subjects in the intervention group would have higher rates of self-reported and biochemically validated smoking cessation, higher rates of smoking reduction and better glycaemic control (as measured by haemoglobin A1c [HbA1c] levels) at 12 months, compared with the control group subjects.

Results

From 2012 to 2014, 557 subjects (mean age, 55 years; nearly 90% were men) were recruited from different diabetic clinics of nine major hospitals in Hong Kong and randomised to the intervention (n=283) and control (n=274) group. More than half of them had attained a secondary education and were employed. On average, the subjects had smoked for 38 years and consumed 14 cigarettes daily. Over 70% of them were in the pre-contemplation stage of quitting and perceived themselves to be in good health. The results of an intention-to-treat analysis indicated that the intervention and control group did not differ significantly in the 7-day point-prevalence (9.2% vs 13.9%) or secondary outcomes including a biochemically validated rate of smoking cessation at 12 months, stages of readiness to quit, and number of attempts to quit lasting at least 24 hours. Although the control group had a significantly higher rate of self-reported smoking reduction at 3 months (16.8% vs 10.2%, $p=0.02$), the two groups did not differ significantly at the 6- and 12-month follow-ups.

Discussion

The overall results showed no significant differences between the two groups, as nearly 80% of the patients thought that they were healthy and not in urgent need to quit smoking. This is consistent

with another study in which smokers with DM in the pre-contemplation stage were reluctant to receive smoking cessation intervention.³ In addition, our subjects might have been hardcore smokers, so the brief intervention might not have been sufficient or intensive enough to trigger quitting. Although there are no standard criteria to define hardcore smokers, six characteristics are known for hardcore smokers.⁴ Our subjects fulfilled three of them: regular smoking for 5 years or more, lack of intention to quit, and smoking daily. Besides, our subjects smoked up to 14 cigarettes per day, which also nearly fulfilled another characteristic of smoking 15 cigarettes/day. Our intervention could only point out the association between DM and smoking but not the causation, which might not be strong enough to motivate subjects to quit smoking. In a logistic regression analysis of the predictors of smoking cessation, subjects with higher daily cigarette consumption were more likely to fail to quit (odds ratio [OR]=0.93, 95% confidence interval [CI]=0.89-0.98). This information could be useful for healthcare professionals to estimate the quit rate and thus strengthen the intervention, as there was no association observed between past attempts at quitting and the final rate of quitting.

Quitters and non-quitters did not differ significantly in HbA1c levels at 12 months (7.96% vs 7.99%), but non-quitters had a decreasing trend compared with baseline (OR=0.83, 95% CI=0.71-0.97) after adjusting for confounders such as sex, age, and abstinence at 12 months. One possible explanation is that it is difficult to determine whether HbA1c levels respond to smoking cessation after 12 months. Some studies found that HbA1c levels require 3 years to respond to changes in smoking status, and the reduction in health risk in quitters with DM is only apparent after 5 years of smoking cessation. Thus, a longitudinal study is needed to monitor the HbA1c level among smokers with DM.

Limitations

The results of this study may not be generalisable to all patients with DM, as only those who smoked two or more cigarettes daily were included. We encountered difficulties in recruitment as the prevalence of smoking was low in those who presented to DM outpatient clinics. An early stop to recruitment was recommended by the Independent Data Monitoring Committee after an interim analysis showed that no further benefit could be seen in the intervention group under continuous recruitment. We also had difficulties in collecting data on HbA1c levels from the clinics; this led to non-significant findings due to

missing data.

Recommendations

We suggest the use of stronger warnings on the health risks of smoking to motivate smokers with DM, particularly hardcore smokers, to quit. Patients may see smoking cessation as beneficial to their health in the long run. We also recommend that the causation between smoking and DM complications be emphasised. A longitudinal study would provide more data on the improvement in glycaemic control and the reduction in the complications of DM after smoking cessation.

Conclusions

A brief, tailored intervention was not effective in promoting quitting or reducing smoking in smokers with DM. The intervention also did not improve glycaemic control of these patients at 12 months.

Acknowledgements

This study was supported by the Health and Health Services Research Fund, Food and Health Bureau, Hong Kong SAR Government (#08091061). We thank the diabetic clinics of Caritas Medical Centre, Pok Oi Hospital, Prince of Wales Hospital, Pamela Youde Nethersole Eastern Hospital, Queen Mary Hospital, Ruttonjee Hospital, Tuen Mun Hospital, Tung Wah Eastern Hospital and United Christian Hospital who provided venues and comprehensive support for subject recruitment. We also thank Ms Alice Chung, Ms Anita Chan, Ms Esther Lee, Ms Helen Poon, Ms Kitty Tsui, Ms Lisa Wong, Ms Stella Nap, and Ms Tina Fung for providing professional smoking cessation service to clients; Dr Jing Chen, Dr YN Suen, Mr TK Chau, and Ms Zoe Wan who have participated in the coordination and data analysis of the project; and the student helpers of The University of Hong Kong for their assistance.

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Auditory-based cognitive training programme for attention and memory in older people at risk of progressive cognitive decline: a randomised controlled trial

TMC Lee *, FHW Chan, LW Chu, TCY Kwok, LCW Lam, HMK Tam, J Woo

KEY MESSAGES

1. A computerised cognitive training programme may help slow cognitive decline in the elderly.
2. Participants who underwent a computerised cognitive training programme demonstrated significant improvement in sustained attention and working memory at both individual and group levels.
3. All participants benefited from the cognitive training programme regardless of their pre-morbid general cognitive status or general intelligence.

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Introduction

Medical advances have drastically reduced the mortality rate worldwide. Coupled with a trend for a low fertility rate—particularly in developed countries—the world is ageing rapidly. By 2039 in Hong Kong, the elderly population (age >65 years) will constitute 28% of the total population. There will be more elderly people suffering degenerative changes in cognitive functioning. It is necessary to understand how ageing, whether normal or pathological, affects elderly people's cognitive functioning (eg processing speed, working memory, sustained attention, cognitive inhibition, and task switching ability).

Cognitive ageing may place a burden on the community, particularly on the health care system. Early identification and management of mild cognitive impairment may help prevent further deterioration. According to the frontal ageing/lobe hypothesis,¹ the frontal lobe of the brain is presumed to be most susceptible to deterioration with increasing age, whereas other regions are comparatively spared. Cognitive training based on the concept of neuro-plasticity (experience-induced neuroplastic changes) has been reported to slow cognitive deterioration and enhance cognitive functioning.² Cognitive training programmes have positive effects on processing speed, attention, memory, and reasoning in the elderly population.³ Cognitive functioning improves as a consequence of positive brain changes through repetitive practice.

Attention and working memory are the

building blocks for higher order cognitive functioning, such as executive planning and problem solving. In this study, we examined the efficacy of a computerised cognitive training programme for the elderly. A training paradigm was modelled after the Brain Fitness Programme.³ Based on the concept of neuroplasticity, it was hypothesised that participants who received cognitive training would demonstrate improved attention and working memory.

Methods

Ethics approval was granted by the Institutional Review Board of The University of Hong Kong/Hospital Authority—Hong Kong West Cluster. Informed consent was obtained from each participant during screening.

Of 1159 community-dwelling Chinese adults aged ≥60 years, 533 met the inclusion criteria and were invited to participate of whom 150 declined. The 383 participants were considered at risk of cognitive decline (with a score of 20 to 26 on Montreal Cognitive Assessment) but were of normal general intelligence. They were randomised to one of three groups for 13 weeks: (1) cognitive training, (2) active control, and (3) no-contact control. Of participants, 97 dropped out because of time constraints; 286 who completed a cognitive assessment at time point 2 were analysed (Fig 1).

Results

The participants were comparable in terms of age

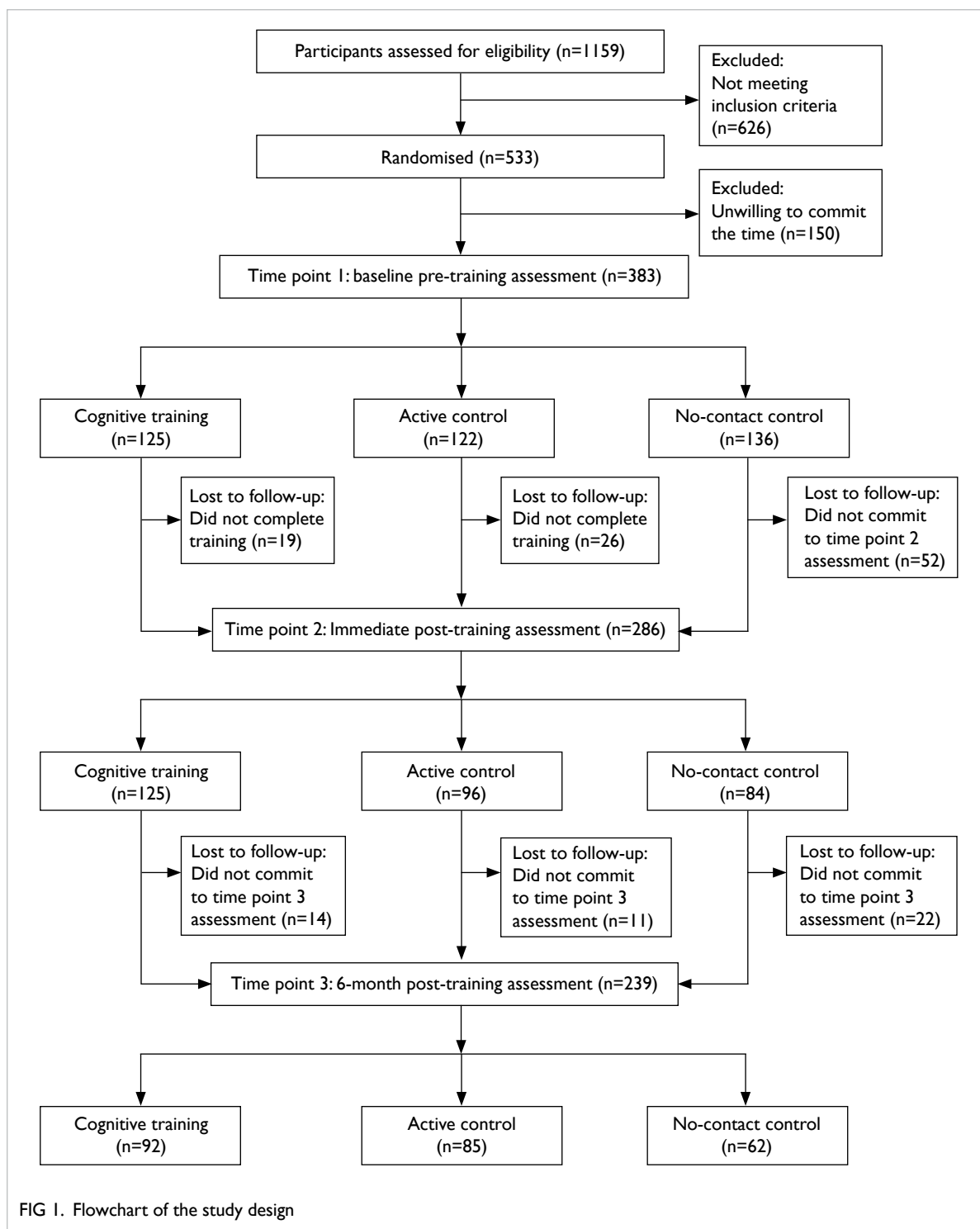


FIG 1. Flowchart of the study design

(mean±standard deviation [SD], 69.72±6.42 years; F=0.45, df=2-283, P=0.64), general cognitive status (mean±SD, 23.75±1.82; F=1.08, df=2-283, P=0.34), general intelligence (mean±SD, 90±9.78; F=1.36, df=2-283, P=0.26), cognitive processing speed status (mean±SD, 71.81±21.65; F=0.44, df=2-283, P=0.64), depression status (mean±SD, 3.98±2.65; F=1.91, df=2-283, P=0.15), and anxiety status (mean±SD,

4.44±2.87; F=2.02, df=2-283, P=0.14). The training groups were matched for gender composition ($X^2(2, n=286)=0.53, P=0.77$).

Auditory sustained attention was measured using the Seashore Rhythm Test. There was a significant main effect in the cognitive training group ($t[106]= -3.63, P<0.001$). Repeated measures ANOVA indicated a trend for significant interaction

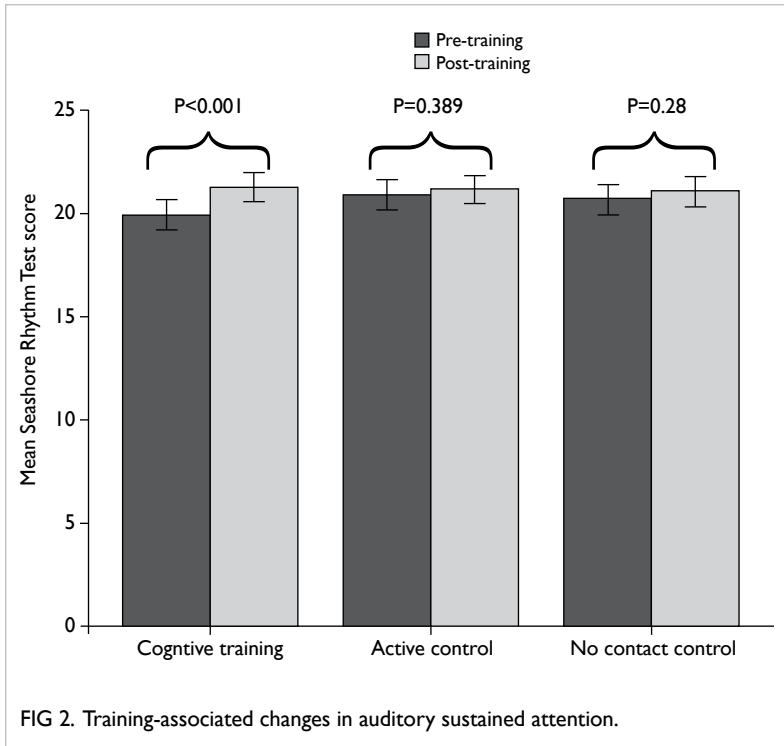


FIG 2. Training-associated changes in auditory sustained attention.

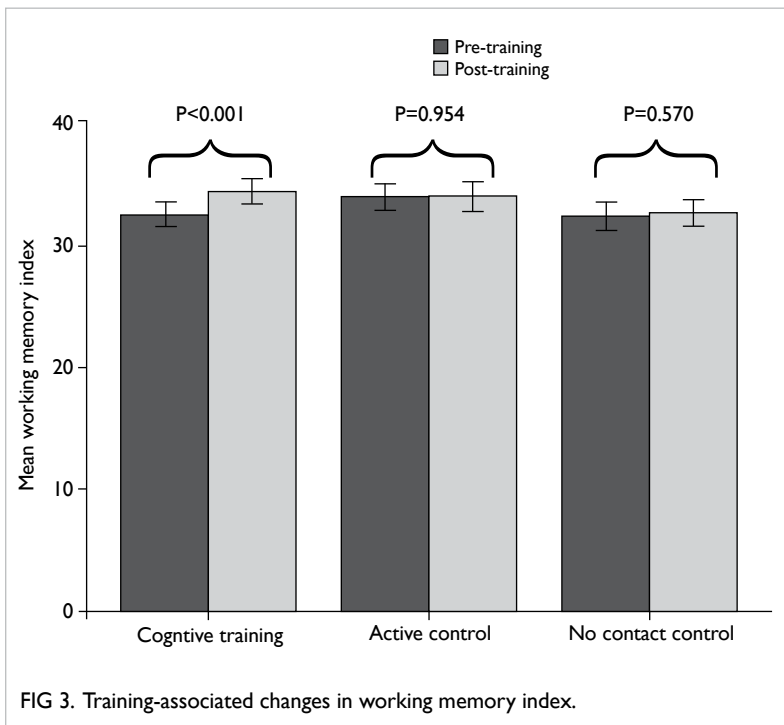


FIG 3. Training-associated changes in working memory index.

effect between the three groups ($F=2.82$, $df=2-283$, $P=0.06$). A post-hoc comparison showed that only the cognitive training group significantly improved after training, not the active control group ($t[96]= -0.87$,

$P=0.39$) or no-contact control group ($t[84]= -1.07$, $P=0.29$) [Fig 2]. The training effect in the cognitive training group was presumed to be sustained at 6 months, as there was no significant difference at time points 2 and 3 ($t[93]=0.24$, $P=0.81$).

Visual sustained attention was measured using the Digit Vigilance Test. There was a significant main effect in all three groups although the post-training interaction effect was not significant among groups in terms of reaction time ($F=0.03$, $df=2-280$, $P=0.97$) or error ($F=1.10$, $df=2-280$, $P=0.34$).

Auditory and visual-spatial working memory was measured using the Digit Span Test and Spatial Span Test. There was a significant main effect in the cognitive training group ($t[106]= -5.61$, $P<0.001$). Repeated measures ANOVA indicated significant interaction effects ($F=8.10$, $df=2-283$, $P<0.001$). A post-hoc comparison showed that only the cognitive training group significantly improved working memory, not the active control group ($t[96]= -0.06$, $P=0.95$) or no-contact control group ($t[84]= -0.57$, $P=0.57$) [Fig 3]. The training effect in the cognitive training group was presumed to be sustained at 6 months, as there was no significant difference at time points 2 and 3 ($t[93]=1.97$, $P=0.052$).

None of the training effects in the cognitive training group correlated with either the baseline general cognitive status or general intelligence (all $P>0.05$). In addition, there was no interaction effect between gender and training effects for auditory sustained attention ($F=0.36$, $df=1-104$, $P=0.55$) or working memory ($F=0.11$, $df=1-104$, $P=0.74$).

Discussion

The findings of this study confirm that cognitive training improves the cognitive domains as indicated by improved working memory and auditory sustained attention. This concurs with the concept of neuroplasticity in which behavioural changes can be induced through manipulation of external experiences, such as structured cognitive training.

Working memory capacity can be expanded through targeted training.⁴ The observed improvement was a near-transfer effect in which training of visual working memory improved both visual and auditory working memory, as reflected by the improved working memory index. A far-transfer effect will be confirmed in future studies.

The significant training effects for auditory sustained attention were only observed in the cognitive training group. No significant across-group difference was detected in visual sustained attention. The present training protocol failed to demonstrate a cross-modality training effect on sustained attention. This may be related to the use of different age cohorts, as the ageing brain is associated with neuronal and synaptic atrophy as well as physiological degeneration,⁵ which may affect

the neuroplastic effect in the elderly.

Baseline general intelligence and general cognitive status were not correlated with training effect. Regardless of pre-morbid cognitive functioning, elderly participants achieved significantly improved sustained attention and working memory. Participants with different levels of pre-morbid functioning may benefit from cognitive training.

Conclusions and implications

The findings of our study support the efficacy of the training programme based on the model of experience-induced neuroplastic change. The computerised cognitive training programme can be used for training elderly people at risk of degenerative cognitive decline. In elderly individuals with higher computer competency, adoption of a web-based training programme would allow self-administration at home at any time. Further studies with longer follow-up of the training effect in preventing Alzheimer's disease or mild cognitive

impairment are warranted.

Acknowledgement

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Transcranial Doppler ultrasonography for detection of cerebral white matter changes in a high-risk population

VCT Mok *, RCW Ma, WWC Chu

KEY MESSAGES

1. In a high-risk population, the pulsatility index of the middle cerebral artery is associated with severity of white matter change (WMC). Nonetheless, its ability to differentiate those with and without significant subclinical WMC is only fair.
2. Using transcranial Doppler ultrasonography as a stand-alone screening instrument is not recommended to detect subclinical WMC.

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Background

Age-related white matter change (WMC) is a manifestation of cerebral small vessel disease and the most common substrate of vascular dementia.¹ Overseas study showed that severe WMC was found in 20% of an elderly population.² Recent longitudinal studies and meta-analysis show that presence of WMC significantly increases the risk of dementia, and more severe WMC is associated with greater risk of cognitive decline.³ WMC frequently coexists with other dementia diseases and aggravates their cognitive severity.⁴ Non-demented elderly persons with WMC should be considered a high-risk group and require early management or monitoring.

Cerebral magnetic resonance imaging (MRI) is the standard imaging method to detect WMC. Nonetheless, it is not cost-effective for large-scale screening for subclinical WMC. Transcranial Doppler ultrasonography (TCD) is more convenient and less costly. It is portable and can be applied at the bedside or in outpatient clinics and community settings. The arterial pulsatility index (PI) is derived from the flow velocity of large arteries and is hypothesised to reflect vascular resistance distal to the examined artery. A study of 55 stroke patients showed that PI of the middle cerebral artery (MCA) correlated with severity of small vessel disease.⁴ Another study in 100 acute stroke patients with WMC and 50 controls without WMC found that the mean PI of bilateral MCAs correlated with WMC volume. The area under the receiver operating curve (ROC) for mean MCA PI to differentiate those with and without WMC was 0.85 (95% confidence interval [CI], 0.78-0.91).⁵ Nonetheless, data from the previous study cannot be generalised to stroke-free subjects as small arteries may dilate during the acute

stroke phase to cause PI fluctuation.

The prevalence of dementia is estimated to increase by more than 300% over the next 30 years and be the greatest contributor to disability among the elderly in China.⁶ WMC-related dementia is potentially preventable due to its vascular nature. We hypothesise that TCD is able to detect non-demented stroke-free subjects who have WMC. TCD can guide selective MRI scanning, enable early detection and management of at-risk subjects, and enhance their recruitment into WMC preventive trials.

Study objectives

This study aimed to validate TCD PI for detecting WMC among non-demented stroke-free elderly subjects with high vascular risk, namely hypertension and/or diabetes mellitus. We hypothesised that MCA PI can significantly differentiate subjects with low and high WMC.

Methodology

Potential subjects were recruited via advertisement at elderly centres. We screened 480 potentially eligible subjects (non-demented, stroke-free community-dwelling Chinese elderly having hypertension and/or diabetes mellitus) using TCD. Only 331 subjects who had at least one viable temporal window were recruited. Demographics were collected, and blood tests and cognitive function tests were performed using a standardised protocol. Brain MRI was arranged and WMC severity was rated according to the Fazekas scale and the age-related WMC scale. WMC volume was quantified automatically on axial FLAIR. By performing TCD through temporal windows on both sides of the brain, the MCA PI was

TABLE. Comparison of subjects with low and high white matter change (WMC)*

Variable	Low WMC	High WMC	P value
Age (years)	70.3±4.5	72.7±5.2	<0.001
Male	77 (50.3)	92 (55.8)	0.322
Education (years)	8.5±4.8	8.1±4.9	0.519
Hypertension	141 (92.2)	156 (94.5)	0.391
Diabetes mellitus	52 (34.0)	59 (36.0)	0.711
Pulsatility index of the middle cerebral artery	1.06±0.18	1.16±0.27	<0.001
Age-related WMC total score	1.9±1.9	4.9±3.0	<0.001
Fazekas score	0.8±0.6	1.7±0.8	<0.001
WMC volume (mm ³)	2161.73±994.65	12076.51±11737.85	<0.001

* Data are presented as mean±SD or No. (%) of subjects

obtained.

Subjects with low (ie 1st and 2nd quartiles) or high (ie 3rd and 4th quartiles) WMC volume were compared for age, sex, education, presence of hypertension and diabetes mellitus, PI, Fazekas and age-related WMC scales, and WMC volumes using independent samples t-test. PI was correlated with continuous WMC volume and WMC quartiles using Spearman correlation analysis. A multivariate binomial logistic regression model was constructed to examine the association between PI and high WMC independent of age, sex, hypertension, and diabetes mellitus. A ROC analysis was conducted to examine the ability of MCA PI to differentiate high and low WMC. Statistical analyses were performed using SPSS version 14. Statistical significance was set at alpha = 0.05.

Results

The mean MCA PI did not differ significantly between 274 subjects with bilateral temporal windows and 57 subjects with left- or right-side temporal window (p=0.531). MCA PI correlated with WMC volume (rho=0.171, P=0.002) and quartiles (rho=0.183, P=0.001). WMC volume was 2088, 3928, and 8080 mm³ at the 25th, 50th, and 75th percentile, respectively. Group comparisons between subjects with high and low WMC are summarised in Table 1.

Compared with subjects with low WMC, those with high WMC were older and had higher MCA PI. In binomial logistic regression analysis, MCA PI was significantly associated with WMC in the upper quartiles (ie 3rd and 4th quartiles), independent of age, sex, and presence of hypertension and/or diabetes mellitus (odds ratio=4.53, 95% CI=1.35-15.24). ROC analysis showed that the area under the curve was 0.60 (95% CI=0.54-0.67, P=0.001, Fig). At an optimal cutoff of ≥0.97, its sensitivity was 82% and specificity was 32% in detecting high WMC. The

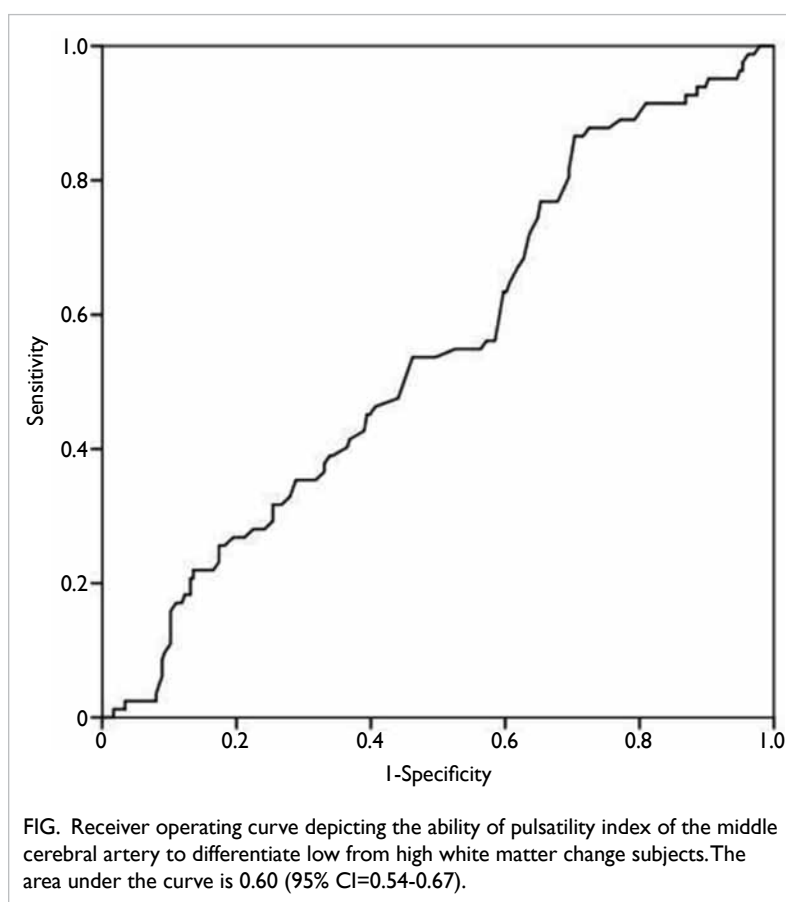


FIG. Receiver operating curve depicting the ability of pulsatility index of the middle cerebral artery to differentiate low from high white matter change subjects. The area under the curve is 0.60 (95% CI=0.54-0.67).

positive and negative predictive values were 56.7% and 68.2%, respectively.

Discussion

Our study shows that MCA PI correlates significantly with WMC volume both continuously and in quartiles. Moreover, the association between PI and high WMC is independent of age, sex, and vascular risk factors. Despite having a relatively high

sensitivity (82%), MCA PI has a low specificity (32%) and only fair area under the curve value and positive and negative predictive values.

The association between WMC and MCA PI can be explained by the pathophysiology of cerebral small vessel disease.^{1,7} As arteriosclerosis narrows the lumen of small arteries and makes the thickened fibrotic vessels lose vasomotor reactivity, the vascular resistance and PI of small vessels increase. A strong association has been reported between mean MCA PI and WMC volume in quartiles among stroke patients with more severe WMC, with a high area under curve of 0.85.⁸ Nonetheless, among community-dwelling stroke-free subjects with vascular risks, the ability of MCA PI to differentiate those with and without significant WMC was only fair (area under curve of 0.60 only).

Although the sample size was large and WMC severity was quantified by a fully automated method, this study had several limitations. First, 31.0% of the 480 potential subjects lacked temporal windows on both sides for TCD. Among the 331 subjects with at least one temporal window, 82.7% had viable temporal windows on both sides, whereas 9.7% and 7.6% had a temporal window on the left or right side only, respectively. The mean MCA PI did not differ significantly in those with bilateral or unilateral temporal windows. This implies that MCA PI obtained from a unilateral temporal window is comparable with that from bilateral temporal windows. Potential TCD limitations should also be considered in the calculation of PI, such as incorrect angle and suboptimal temporal window.⁹ Furthermore, the sampling method was not randomised. As community dwellers were invited by word of mouth and recruited on a voluntary basis, the study subjects may have been more health-conscious and cooperative than an average community dweller with a similar vascular risk profile. The sample bias may partly account for the suboptimal sensitivity and specificity of the cut-off value. Other factors such as intracranial hypertension, respiratory parameters, haemoglobin level, and history of migraine might affect PI but were not investigated. Further studies should consider all these minor but significant factors.

Conclusion

MCA PI is associated with WMC volume in

community dwellers with a high vascular risk profile. Nonetheless, it cannot be recommended as a stand-alone screening tool to detect subclinical WMC among elderly subjects with vascular risk factors. Further research should explore whether a risk index that includes putative biomarkers for WMC (eg age, executive function performance, gait speed) combined with PI measure will be better able to detect significant subclinical WMC in high-risk subjects.

Acknowledgements

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Association of wheeze during the first 18 months of life with indoor nitrogen dioxide, formaldehyde, and family history of asthma: a prospective cohort study

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KEY MESSAGES

1. Indoor exposure to formaldehyde increased the risk of new onset wheezing, and wheezing was more common among infants with a family history of allergy.
2. Indoor exposure to nitrogen dioxide and family history of asthma did not have a significant association with new onset wheezing.
3. Prevention measures to reduce formaldehyde exposure in the home environment should be implemented to reduce the future disease burden of asthma in children.
4. If more subjects were recruited for stratified analyses, the possible interactions between

family history of asthma or allergy and indoor exposure to formaldehyde on the risk of new onset of wheeze could have been better clarified.

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Introduction

The trend of childhood hospital admissions for asthma has increased in Hong Kong.¹ There is limited evidence of the effect of environmental risk factors on the development of childhood asthma. Environmental exposure to formaldehyde and nitrogen dioxide (NO₂) may increase the risk of childhood asthma. Most studies using a case control or cross sectional study design have shown limited epidemiological evidence of the correct temporal relationship between exposures and asthma, and most have not properly examined the role played by family history of asthma or allergy (confounding vs. effect modification). A prospective cohort design would allow proper examination of the temporal relationship between indoor exposure to air pollutants and incident wheezing or asthma. This study aimed to examine: (1) whether exposure to NO₂ and formaldehyde at home will increase the risk of new onset wheezing in the first 18 months of life; (2) if there is any exposure-response relationship between NO₂ or formaldehyde concentrations and the risk of new onset wheezing; and (3) if the relationship(s) is/are modified by a family history of asthma.

Method

This study was conducted from 1 November 2009 to 30 April 2011. Local Hong Kong infants born

between 1 April 2008 and 31 March 2009 who attended any maternal and child health centre, except two on the outlying islands, in Hong Kong were recruited. The sample size was calculated for the birth cohort with NO₂ and formaldehyde as predictor variables and new onset of wheeze as the outcome variable. To facilitate the examination of possible effect modification, eligible subjects were first stratified by family history of asthma or allergy. Roughly equal numbers of infants with a family history of asthma, with a family history of allergy or without any family history of asthma or allergy were recruited. Their parents provided baseline information by completing the validated ISAAC questionnaire before the infants were 4 months old, performed indoor air sampling using standardised passive samplers when the infants were 6 months old, and kept a weekly respiratory health diary and responded to a monthly health telephone survey until the infant was 18 months old. The outcome variable of new onset wheeze was measured between 6 and 18 months of age. We used stepwise Cox-regression models to analyse the associations between exposure to NO₂/formaldehyde and new onset of wheeze (time to event) after controlling for the potential confounders preselected by log rank test. The Cox-regression analysis was repeated in the subgroups of family histories to explore possible effect modifications. Blood samples of subjects with wheeze and a selected sample of subjects without

wheeze were obtained with parental consent to measure eosinophil and immunoglobulin E level to aid in a clinical diagnosis of childhood asthma.

Results

Cohort Subjects

A total of 9321 young infants aged 4 months or younger were screened at 29 maternal and child health centres (excluding two located in the outlying islands with very different living environments). Only 2423 (26%) who fulfilled the inclusion criteria were willing to participate (Fig). A total of 702 subjects were recruited after stratification by family history of asthma and allergy (230 with a family history of asthma, 226 with a family history of allergy, and 246 without any family history of asthma or allergy). 550 subjects completed all observations, but seven subjects who wheezed before the age of 6 months and 15 subjects who provided invalid air samples were excluded. The final cohort included 190

subjects with a family history of asthma, 175 with a family history of allergy, and 163 with no family history of allergy or asthma. During follow-up, 58 (11%) subjects had new onset wheezing at a mean age of 11.4 months.

Nitrogen dioxide in bedrooms

In 544 children's bedrooms, the mean indoor NO₂ level was 42.40 (standard deviation [SD], 30.97) µg/m³. Five samples exceeded the current World Health Organization (WHO) air quality guideline value for 1-hour NO₂ level of 200 µg/m³ and 227 (42%) samples exceeded the annual average standard of 40 µg/m³.² Paired samples t-test indicated that the indoor NO₂ level in 44 subjects' bedroom in September 2009 (summer) was lower (not significantly) than that in February 2010 (winter) by 5.82 (95% CI= -0.53-12.18) µg/m³ (P=0.072).

Formaldehyde in bedrooms

In 541 children's bedrooms, the mean indoor formaldehyde level was 51.09 (SD, 74.94) µg/m³. 94 (17%) samples exceeded the WHO non-industrial indoor formaldehyde exposure standard of 100 µg/m³.³ 33 subjects provided measurement of indoor formaldehyde in both winter (February 2009) and summer (May 2009). Wilcoxon signed rank test indicated that the indoor formaldehyde concentration measured in summer was lower (not significantly) than that in winter (P=0.11).

Medical assessment

A total of 112 medical appointments (for 48 wheezing and 64 non-wheezing subjects) were made when infants were 18 months old. The paediatrician was blinded to the health status of subjects recorded in the health diaries. Of the 48 subjects with wheeze, half were diagnosed with asthma. Of the 64 subjects with no wheeze, eight (12.5%) were diagnosed as likely to have asthma. The overall concordance proportion was 80/112 (71.4%) with a fair kappa of 0.39. Only 95 and 93 blood samples were valid for testing immunoglobulin E and eosinophil, respectively. The mean immunoglobulin E was 94.79 (SD, 166.72; range, 1195) kIU/l. The mean eosinophil count was 4.09 (SD, 3.00; range, 16.00) %. Mann-Whitney *U* test indicated that there was no significant difference in the level of immunoglobulin E and eosinophil count between the wheezing and non-wheezing groups.

Association between socio-demographic home environment factors and new onset wheeze

The associations between 27 socio-demographic or home environment factors and new onset of wheeze were tested by log-rank test (Table 1); 11

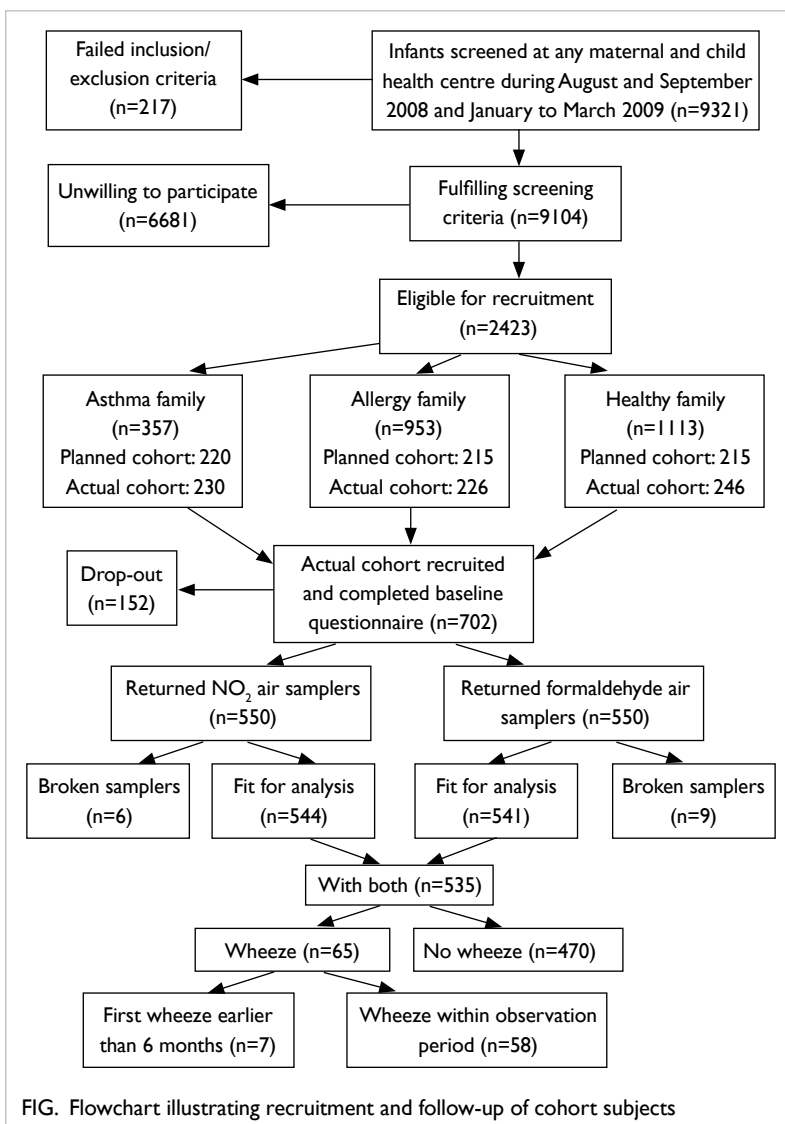


FIG. Flowchart illustrating recruitment and follow-up of cohort subjects

TABLE I. Association between socio-demographic factors and new onset of wheeze in the first 18 months of life

Factor	Count*	No. (%) of wheeze		P value (log rank test)
		No event	event	
All infants	543	484 (89.1)	59 (10.9)	
Gender				0.927
Girl	261	233 (89.3)	28 (10.7)	
Boy	282	251 (89.0)	31 (11.0)	
Breastfeeding				0.228
No	107	92 (86.0)	15 (14.0)	
Yes	436	392 (89.9)	44 (10.1)	
Neo-natal respiratory illness				0.007
No	530	475 (89.6)	55 (10.4)	
Yes	13	9 (69.2)	4 (30.8)	
Sibling				0.044
No	315	288 (91.4)	27 (8.6)	
Yes	228	196 (86.0)	32 (14.0)	
Sibling with asthma				0.573
No	516	459 (89.0)	57 (11.0)	
Yes	27	25 (92.6)	2 (7.4)	
Sibling with allergy				0.064
No	473	426 (90.1)	47 (9.9)	
Yes	70	58 (82.9)	12 (17.1)	
Maternal asthma				0.940
No	453	404 (89.2)	49 (11.8)	
Yes	90	80 (88.9)	10 (11.1)	
Maternal allergy				0.216
No	395	356 (90.1)	39 (9.9)	
Yes	148	128 (86.5)	20 (13.5)	
Father asthma				0.183
No	454	401 (88.3)	53 (11.7)	
Yes	89	83 (93.3)	6 (6.7)	
Father allergy				0.957
No	399	356 (89.2)	43 (10.8)	
Yes	144	128 (88.9)	17 (11.1)	
Family history				0.065
Healthy	164	150 (91.5)	14 (8.5)	
Atopy	184	156 (84.8)	28 (15.2)	
Asthma	195	178 (91.3)	17 (8.7)	
Monthly family income (HK\$)				0.886
<10 000	45	40 (88.9)	5 (11.1)	
10 000-20 000	136	121 (89.0)	16 (11.0)	
>20 000	362	323 (89.2)	39 (10.8)	
Maternal education				0.650
Primary	13	11 (84.6)	2 (15.4)	
Secondary	268	242 (90.3)	26 (9.7)	
College, university or tertiary education	262	231 (88.2)	31 (11.8)	

* Seven subjects with wheezing onset before 6 months were excluded

† Only 18 subjects had wall and floor renovations alone; a positive answer to any of the two questions would be regarded as positive for the final variable

TABLE I. (cont'd)

Factor	Count*	No. (%) of wheeze		P value (log rank test)
		No event	event	
Living area (ft ²)				0.115
<600	298	260 (87.2)	38 (12.8)	
600-1000	216	197 (91.2)	19 (9.8)	
>1000	29	27 (93.1)	2 (6.9)	
Cooking fuel				0.106
Electric	50	48 (96.0)	2 (4.0)	
Gas	493	436 (88.4)	57 (11.6)	
Artificial ventilation during cooking				0.544
No	16	15 (93.8)	1 (6.2)	
Yes	527	469 (89.0)	58 (11.0)	
Provision of air conditioning				0.843
No	31	28 (90.3)	3 (9.7)	
Yes	512	456 (87.9)	56 (12.1)	
Provision of heater				0.646
No	228	205 (89.9)	23 (10.1)	
Yes	315	279 (88.6)	36 (11.4)	
Heating fuel				-
Electric	315	279(88.6)	36 (11.4)	
Gas	0			
Cockroach infestation				0.585
No	343	308 (89.8)	35 (10.2)	
Yes	200	176 (88.0)	24 (12.0)	
Keeping pets (cats & dogs)				0.064
No	473	417 (88.2)	56 (11.8)	
Yes	70	24 (95.7)	3 (4.3)	
Renovation and/or new furniture in past 12 months†				0.224
No	238	208 (87.4)	30 (12.6)	
Yes	305	276 (90.5)	29 (9.5)	
Pregnancy cigarette smoking				0.334
No	535	476 (89.0)	59 (11.0)	
Yes	8	8 (100)	0 (0)	
Maternal or female guardian cigarette smoking				0.954
No	525	468 (89.1)	57 (10.9)	
Yes	18	16 (88.9)	2 (11.1)	
Father or male guardian cigarette smoking				0.481
No	432	383 (88.7)	49 (11.3)	
Yes	111	101 (91.0)	10 (9.0)	
Number of home smokers				0.295
No	442	391 (88.5)	51 (11.5)	
Yes	101	98 (92.1)	8 (7.9)	
Proximity to traffic				0.465
0=never	39	35 (89.7)	4 (10.3)	
1=seldom	274	248 (90.5)	26 (9.5)	
2=often	153	131 (85.6)	22 (14.4)	
3=whole day	77	70 (90.9)	7 (9.1)	

were associated with new onset of wheeze with a P value ≤ 0.25 . They were breastfeeding, neonatal respiratory illness (excluding wheezing and persistent cough), having sibling(s), sibling with allergy, maternal allergy, father with asthma, family history of allergy/asthma, living area, cooking fuel, keeping pets, and renovation and/or new furniture in the past 12 months.

Exposure-response relationship between nitrogen dioxide, formaldehyde, and new onset of wheeze

The correlation between NO₂ and formaldehyde was weak with a Spearman's rho of -0.071 (P=0.1). Therefore both independent variables for NO₂ and formaldehyde were entered simultaneously into the Cox's model. Using a stepwise approach, six possible confounders were adjusted in the final model; indoor exposure to formaldehyde significantly increased the risk of new onset wheeze by 4% (95% CI=1-7%, P=0.02) per 10 units ($\mu\text{g}/\text{m}^3$), as did a family history of allergy (hazard ratio=2.21, 95% CI=1.14-4.25, P=0.02) [Table 2]. Indoor exposure to NO₂ had no

significant effect on risk. Subgroup analyses showed that a family history of asthma did not modify the risk of new onset wheezing associated with exposure to either NO₂ or formaldehyde. Nonetheless, infants with a family history of allergy were marginally more sensitive to the effect of formaldehyde exposure, with an increased risk of 5% (95% CI=1-8%) for new onset wheeze per additional 10 units ($\mu\text{g}/\text{m}^3$) of exposure.

Discussion

Effects of exposure to indoor pollutants

After controlling for confounders, the risk of new onset wheezing in young infants was associated with indoor exposure to formaldehyde, with the risk increased by 4% for every 10-unit increase ($\mu\text{g}/\text{m}^3$). Indoor exposure to NO₂ did not pose a significant risk for new onset wheezing in the first 18 months.

This was the first prospective cohort study to report a significant quantitative association between indoor exposure to formaldehyde and risk of new onset wheeze in young children after adjustment for major potential confounding factors. Our results provide further support of the possible causal relationship between domestic exposure to formaldehyde and the induction of asthma in children.

Indoor exposure to NO₂ at levels between 40 and 45 $\mu\text{g}/\text{m}^3$ has been found to be associated with asthma in asthmatic children,⁴ but this was not confirmed in the present study. It is possible that NO₂ at relatively low levels between 40 and 45 $\mu\text{g}/\text{m}^3$ can exacerbate asthma in children with pre-existing asthma, but not directly induce wheezing/asthma in naïve subjects.

Effect modification by family history of asthma and family history of allergy

A family history of asthma has been established as a risk factor for asthma or wheeze in many studies,⁵ but it was not confirmed in the present study. Infants with a family history of allergy, including parents or a sibling diagnosed with allergy, had an increased risk of new onset wheezing in the present study. The effect of formaldehyde exposure was stronger in infants with a family history of allergy. Effect modification by family history of asthma and family history of allergy was explored, but the inadequate sample size after stratification did not allow proper examination of possible interactions. If more subjects were recruited for the stratified analyses, the possible interactions between family history of asthma or allergy and indoor exposure to formaldehyde and their effect on the risk of new onset of wheeze could have been better clarified.

Limitations

The study subjects might not be representative of all

TABLE 2. Exposure-response relationship between nitrogen dioxide, formaldehyde, and new onset of wheeze

Factor	Adjusted hazard ratio (95% CI)	P value
Formaldehyde	1.004 (1.001-1.007)	0.016
Nitrogen dioxide	0.991 (0.979-1.003)	0.128
Neo-natal respiratory illness (excluding wheezing or persistent cough)		
No	1.000	
Yes	4.133 (1.476-11.576)	0.007
Having sibling(s)		
No	1.000	
Yes	1.871 (1.096-3.193)	0.022
Family history		
Healthy	1.000	
Allergy	2.205 (1.144-4.250)	0.018
Asthma	1.091 (0.533-2.234)	0.812
Living area (ft ²)		
<600	1.000	
600-1000	0.546 (0.304-0.981)	0.043
>1000	0.357 (0.083-1.533)	0.166
Keeping pets		
No	1.000	
Yes	0.423 (0.128-1.395)	0.158
Cooking fuel in household		
Electric	1.000	
Gas	3.235 (0.782-13.388)	0.105

infants born in Hong Kong. Although recruitment from 29 maternal and child health centres (excluding two located in outlying islands with very different living environments) was reasonably representative, the participation rate was <30%, and self-selection bias could have occurred.

The outcome of wheeze was reported by parents and not objectively observed or verified. Over or under reporting was possible. Exposure to NO₂ and formaldehyde was assessed by standard methods, but the one-off measurement might not have been representative of exposure throughout the observation or follow-up period. Subgroups with paired samples during summer and winter months indicated that the seasonal variation in indoor concentrations of NO₂ and formaldehyde was not significant.

Our study had insufficient statistical power for subgroup analyses as a result of overestimation of the occurrence of wheezing (using prevalence in older children to estimate incidence of new onset wheezing in young infants), as well as the lack of full compliance with air sampling.

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Hong Kong SAR Government (#07080591). Results of this study have been presented at the 2010 Joint Conference of International Society of Exposure Science & International Society for Environmental Epidemiology held in Korea, August 2010.

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Long-term efficacy of an education programme in improving adherence with continuous positive airway pressure treatment for obstructive sleep apnoea

A Lai, D Fong, J Lam, M Ip

KEY MESSAGE

This randomised controlled trial demonstrated that a motivational enhancement programme composed of a single interview and a follow-up phone call at the initiation of continuous positive airway pressure treatment can improve treatment adherence in subjects with obstructive sleep apnoea, even after 1 year, and lead to better health outcome in terms of reducing daytime sleepiness.

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Introduction

Obstructive sleep apnoea (OSA) is a form of disordered breathing in which the upper airway closes repeatedly and intermittently during sleep. Continuous positive airway pressure (CPAP) treatment provides effective relief of symptoms and prevents health-related consequences. Effective education is important to enhance CPAP use.

In this randomised controlled trial, we compared the longer term efficacy (1 year) of standard care with or without an additional motivational enhancement programme (using a brief motivational interview and negative message framing communication skills) on CPAP adherence. We hypothesised that subjects in the intervention group who received both standard care and motivational enhancement would have better CPAP adherence and greater improvement in OSA-related health outcome in terms of physiological (blood pressure) and neuropsychological (sleepiness, quality of life, and mood) symptoms, compared with those in the control group who received only standard care, even after 1 year.

Methods

Study design

This study was conducted from May 2011 to February 2013. It was an extension of the 3-month randomised controlled parallel-group study. Subjects were reassessed at 1 year after receiving CPAP education.

Chinese subjects aged ≥ 18 years who attended the Sleep Disorders Centre at Queen Mary Hospital in Hong Kong from May 2010 to October 2011 for OSA (apnoea-hypopnoea index ≥ 5) and were

scheduled for CPAP treatment and in-laboratory auto-CPAP titration for the first time were invited to participate. Subjects were excluded if they had central sleep apnoea, periodic leg movement disorders, coexisting chronic obstructive pulmonary disease, pregnancy, psychiatric illness on treatment, cognitive impairment, illiteracy, unstable health conditions, or dependence in daily care, as were those unable to attend the education session, had been scheduled for OSA follow-up elsewhere, or were participating in another clinical trial. Subjects were randomised to the control group receiving standard care or the intervention group receiving motivational enhancement education and standard care (Table).

Sample size

All 100 subjects recruited in the 3-month trial were invited to participate.¹ The sample size calculation was based on comparison of CPAP adherence between the intervention and control groups. The standard deviation of CPAP adherence at the end of 1 to 6 months ranged from 2 to 3 hours per day.²⁻⁴ Therefore 2.5 hours was taken as the standard deviation. Considering a minimal significant difference of 1.5 hours, 44 subjects in each group were required for a power of 80% and a maximum error of 5% by independent sample *t* test. Assuming a small attrition rate, 50 subjects per group were recruited.

Outcome measures

The primary outcome measure was objective CPAP usage. Secondary outcome measures included daytime sleepiness (Epworth Sleepiness Scale),

TABLE. Standard care with or without motivational enhancement education for continuous positive airway pressure (CPAP) treatment for obstructive sleep apnoea (OSA) [Reproduced from: Lai AY, Fong DY, Lam JC, Weaver TE, Ip MS. The efficacy of a brief motivational enhancement education program on CPAP adherence in OSA: a randomized controlled trial. *Chest* 2014;146:600-10.]

Time	Standard care with or without motivational enhancement
On CPAP titration night	<p>Standard care:</p> <ul style="list-style-type: none"> - Describe titration procedure and provide instructions on how to use the CPAP device - Help patient to choose an appropriate CPAP mask and acclimatise to its use - Demonstrate simple relaxation techniques to help reduce any possible anxiety when using CPAP - Give advice about the care of the CPAP device and mask, and mention the importance of CPAP therapy
On the morning after titration	<p>Motivational enhancement:</p> <p>Part 1: video education with booklet (25 mins)</p> <ul style="list-style-type: none"> - Enhance knowledge on (1) OSA (symptoms, health consequences and treatment options) and (2) CPAP (therapeutic effects, side-effects and suggested solutions to the possible problems and care of the CPAP device) - Share the experience of a current CPAP user for (1) the reasons of using CPAP such as reduced daytime sleepiness and increased daytime energy level, (2) the problems and solutions with CPAP use, and (3) the expected time required to adapt to the CPAP device. <p>Part 2: face-to-face interview (20 mins)</p> <ul style="list-style-type: none"> - Set an agenda and discuss a typical day - Assess the patient's understanding of OSA and CPAP treatment - Review noticeable and less noticeable symptoms - Review subject's pre-treatment sleep and titration reports - Assess readiness for change (use importance and confidence rulers) - Explore the costs and benefits of change (use decisional matrix) and provide a summary statement - Ask permission to provide information - Encourage subject to change and show empathy - Ask evocative questions and end with a summary - Help subject to set realistic goals and develop an action plan
On days 1 to 3 after CPAP use	<p>Part 3: telephone follow-up (10 mins)</p> <ul style="list-style-type: none"> - Ask subject about his/her experience of CPAP use - Help subject to identify any problems in using CPAP for discussion - Encourage subject to seek professional help if needed - Highlight the positive changes to subject; if no positive change, tell subject that positive changes are likely to come with regular use of CPAP over time - Remind subject of the negative consequences that may experience or may not be aware of - Inform subject that things seem to be going as expected - Inform subject that therapist has confident on him/her

health-related quality of life (Calgary Sleep Apnoea Quality of Life Index, Short Form Health Survey), functional outcomes of sleep questionnaire, mood (Depression Anxiety Stress Scale), and blood pressure.

Subjects were assessed at four time-points: baseline, 1 month, 3 months, and 1 year. At 3 months, all subjects had to return their CPAP machine and buy/rent their own for long-term use.

Results

Patient recruitment

100 subjects were randomised to the control (n=51) or intervention (n=49) group. Two subjects withdrew within the first 3 months and four refused to participate; 94 subjects (47 in each group) completed the 1-year assessment. The two groups did not differ significantly at baseline.

Treatment adherence

After adjusting for OSA severity, subjects in the intervention group had higher mean daily CPAP usage by 2.2 (95% confidence interval [CI]=1.2-3.2, P<0.001) hours/day; more subjects bought/rented

the CPAP device (86% vs 52%, P<0.001, Figure 1) and were CPAP compliant (62% vs 28%, P<0.001), compared with those in the control group.

Daytime sleepiness

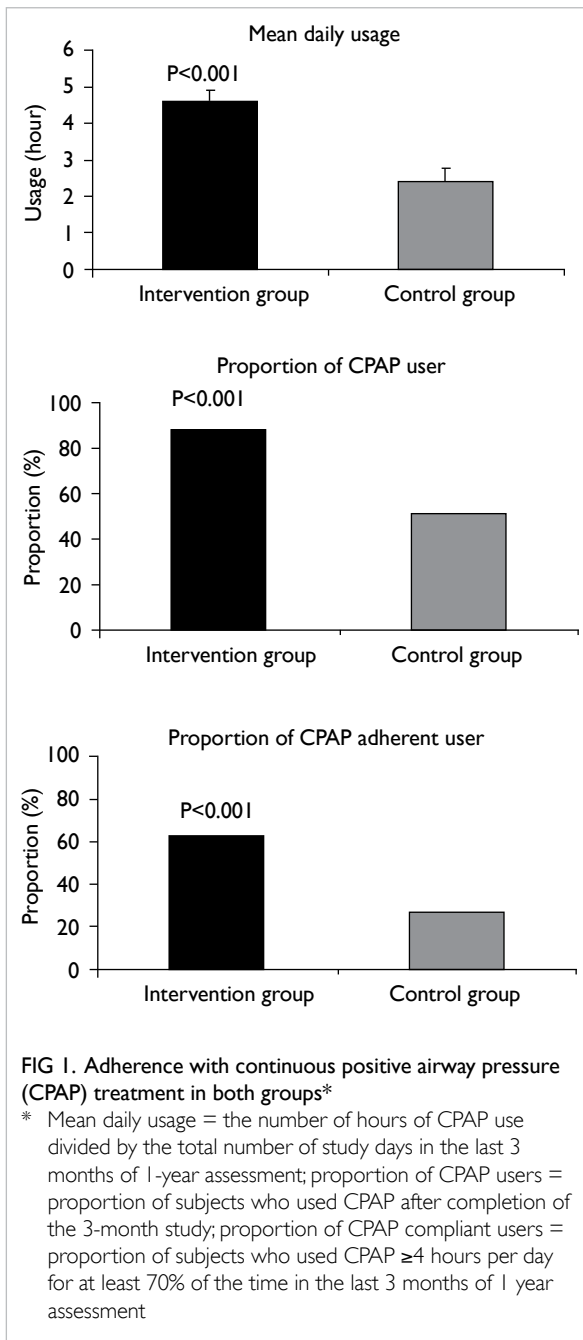
After adjusting for baseline values and OSA severity, subjects in the intervention group had a higher reduction in Epworth Sleepiness Scale score from 9.5±5.8 to 7.3±4.8 (P=0.001) by 2.2 (95% CI=4.2-0.1, P=0.033), compared with those in the control group from 8.9±5.0 to 8.9±4.7 (P=0.913) [Fig 2].

Blood pressure, health-related quality of life, mood

At 1 year, the two groups did not differ significantly in terms of change in blood pressure, health-related quality of life, or mood, after adjusting for baseline values and OSA severity.

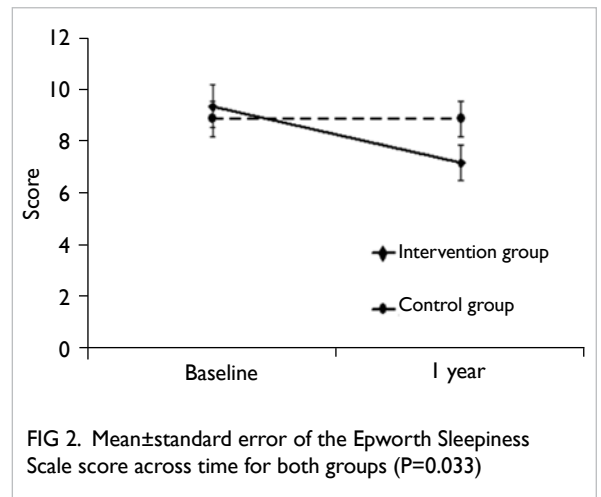
Discussion

The education programme composed of a single session and a follow-up phone call at the initiation of CPAP treatment enhanced treatment adherence with a large effect size (Cohen's d=0.89) even after



one year. The intervention group had 34% more CPAP users and compliant users and achieved a greater reduction in daytime sleepiness.

The motivational enhancement programme was designed to address the psychosocial and behavioural barriers to CPAP use. The interviewer used motivational interviewing skills to help the patient assess the costs and benefits of change by using a decisional matrix to compare use and non-use of CPAP. The interviewer used reflective listening, summarisation, and value exploration to help the subject consider his/her behaviours in a



non-judgemental context and raise his/her intrinsic motivation for CPAP use. We also incorporated video education to enhance knowledge and share the experience of current CPAP users and negative message framing to emphasise the consequence of untreated OSA following failure to use CPAP.

There was significant improvement in daytime sleepiness but not quality of life in the intervention group. Daytime sleepiness is one of the most noticeable complaints of OSA subjects and any improvement can be easily appreciated. The subjects did not have hypertension at baseline, and the effect of CPAP treatment on lowering of blood pressure may not be prominent.

There were some limitations to this study. First, it was not blinded. A double-blind study is difficult to implement in any study of behavioural education. Second, not all bed partners of subjects were invited to participate, as intervention was implemented on the same day of enrolment. Only those who were present at enrolment were invited. The two groups did not differ significantly in the number of family members who participated in the education programme. Third, this was not a time-matched study. The time that health care workers were involved with subjects was approximately 1 hour longer in the intervention group. Fourth, the effectiveness of the education programme may have been affected by the communication skills of the interviewer. The interviewer completed an intensive training course provided by a registered motivational trainer. This may have played a key role in the education programme. CPAP is usually a lifelong therapy; it would be valuable to see if the effects on CPAP adherence will continue for a longer period of time. Our results may not be generalised to subjects who undergo home CPAP titration. It would

be interesting to determine if such a programme is similarly effective.

Conclusion

The motivational enhancement programme was more effective in promoting CPAP adherence and achieved better relief of daytime sleepiness than standard care/advice alone.

Acknowledgements

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Electroacupuncture and wrist splinting for carpal tunnel syndrome: a randomised trial

VCH Chung *, SYS Wong, K Kung, CY Zee, WN Leung, KC Chong, M Wong, C Wong, SM Griffiths

KEY MESSAGES

1. In patients with chronic (≥ 6 months) primary carpal tunnel syndrome (CTS) but no surgical indications, electroacupuncture plus night splinting is more effective than night splinting alone in reducing symptoms and improving function, dexterity, and pinch strength. Nonetheless, the magnitude of improvement in sensation and pain was modest.
2. Electroacupuncture is a useful addition to night splinting for patients with primary CTS, particularly those with chronic mild to moderate

symptoms.

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Introduction

Primary carpal tunnel syndrome (CTS) is a common peripheral entrapment neuropathy with an estimated prevalence of 2.7%. It is a major cause of disability and

incurs considerable limitation in daily activities. As a work-related disorder, CTS has a significant economic impact and often leads to compensation claims. For the management of mild and moderate CTS without median nerve denervation, conservative treatment of night wrist splinting and local steroid injection into the carpal tunnel is commonly used prior to carpal tunnel release surgery. Splinting is often used as first-line treatment. Nonetheless, according to the Cochrane review, splinting only improves CTS symptom score slightly at 4 weeks, whereas steroid injection is superior to placebo injection in improving symptoms at 4 weeks although longer term effect beyond 12 weeks is uncertain. Only one-third of CTS patients who receive steroid injection achieve longer term benefits, and some require two to three further injections to achieve relief. Patients who receive repetitive steroid injections are more likely to develop postoperative CTS symptoms, if they eventually opt for surgery.

Electroacupuncture is a common technique for managing pain and neuropathy. Current clinical evidence of its effectiveness is conflicting and does not clarify its value on top of splinting in a primary care setting. We conducted a randomised trial to compare electroacupuncture plus night splinting with night splinting alone for CTS.

Methods

This study was a prospective, randomised, parallel group trial that compared those with 13 sessions of electroacupuncture plus night splinting with those on the waiting list plus night splinting for idiopathic primary CTS. The duration of the trial was 17 weeks. As recommended by the American Academy of

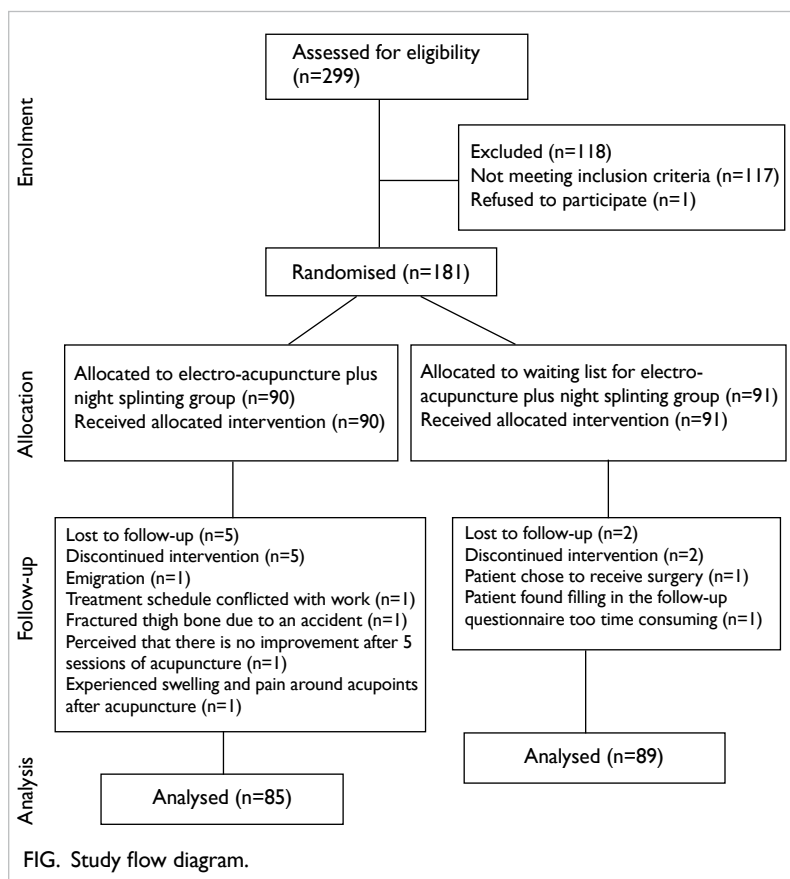


FIG. Study flow diagram.

Orthopaedic Surgeons, the Boston Carpal Tunnel Questionnaire and the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire were used as CTS specific and regional primary outcome measures, respectively. The Boston Carpal Tunnel Questionnaire has two subscales: the Symptom Severity Scale and the Functional Status Scale, with a summary score of 0 to 5; higher score indicates greater severity. The DASH questionnaire includes physical, social, and psychological function domains, with a summary score of 0 (no disability) to 100 (maximum disability).

Pain intensity, strength, sensation, and

dexterity were evaluated as secondary outcomes. For pain intensity, a 0 to 10 point numerical rating scale was used. For sensation, the Semmes-Weinstein monofilament test was used. For dexterity, both blinded and unblinded versions of the Dellon-modified Moberg pick-up test (DMMPUT) were conducted. For strength, maximal tip pinch strength was measured by a hydraulic gauge pinch dynamometer (B&L Engineering PG-30 Pinch Gauge). For the latter two tests, three measurements were made per test and the average was taken as the final value. Adverse events related to electroacupuncture and splinting were monitored.

TABLE I. Improvement in outcome from baseline

Outcome	Mean (95% CI)		Mean difference (95% CI) in score change	P values (linear model adjusted for baseline values)
	Electroacupuncture plus night splinting group	Waiting list plus night splinting group		
Boston Carpal Tunnel Questionnaire				
Symptom Severity Scale				
1st week	0.04 (-0.03, 0.12)	0.01 (-0.08, 0.10)	0.02 (-0.09, 0.13)	0.75
2nd week	-0.01 (-0.09, 0.07)	-0.02 (-0.13, 0.08)	-0.01 (-0.13, 0.11)	0.88
5th week	-0.17 (-0.28, -0.06)	-0.06 (-0.19, 0.07)	-0.15 (-0.29, -0.01)	0.04
17th week	-0.25 (-0.37, -0.12)	-0.09 (-0.25, 0.06)	-0.20 (-0.36, -0.03)	0.02
Functional Status Scale				
1st week	0.14 (0.05, 0.23)	0.09 (0.00, 0.18)	0.05 (-0.08, 0.17)	0.47
2nd week	0.11 (0.00, 0.22)	0.07 (-0.04, 0.17)	0.03 (-0.12, 0.17)	0.71
5th week	-0.01 (-0.12, 0.11)	0.06 (-0.07, 0.18)	-0.09 (-0.24, 0.06)	0.25
17th week	-0.16 (-0.28, -0.04)	0.02 (-0.13, 0.17)	-0.22 (-0.38, -0.05)	0.01
Disabilities of the Arm, Shoulder, and Hand Questionnaire				
1st week	0.09 (-1.65, 1.82)	0.36 (-1.76, 2.48)	-0.44 (-3.09, 2.21)	0.75
2nd week	-1.45 (-3.48, 0.58)	-0.54 (-3.02, 1.94)	-1.11 (-4.19, 1.97)	0.48
5th week	-4.02 (-6.48, -1.56)	-0.87 (-3.92, 2.19)	-3.50 (-7.16, 0.16)	0.06
17th week	-7.75 (-10.55, -4.95)	-1.53 (-5.15, 2.09)	-6.72 (-10.9, -2.57)	<0.01
Numerical rating scale on pain intensity				
1st week	-0.22 (-0.68, 0.23)	-0.43 (-0.89, 0.04)	-0.14 (-0.40, 0.68)	0.61
2nd week	-0.30 (-0.81, 0.21)	-0.50 (-1.01, 0.01)	0.13 (-0.46, 0.72)	0.66
5th week	-0.68 (-1.18, -0.19)	-0.55 (-1.11, 0.02)	-0.22 (-0.81, 0.36)	0.45
17th week	-1.22 (-1.79, -0.65)	-0.61 (-1.22, 0.00)	-0.70 (-1.34, -0.06)	0.03
Sensation diameter at 17th week (mm) using Semmes-Weinstein monofilament test				
Thumb	-0.29 (-0.43, -0.14)	-0.17 (-0.28, -0.06)	-0.05 (-0.21, 0.11)	0.53
First finger	-0.28 (-0.41, -0.15)	-0.12 (-0.22, -0.01)	-0.08 (-0.22, 0.06)	0.26
Middle finger	-0.28 (-0.40, -0.15)	-0.13 (-0.24, -0.01)	-0.11 (-0.26, 0.04)	0.15
Little finger	-0.15 (-0.26, -0.03)	-0.14 (-0.26, -0.03)	-0.02 (-0.16, 0.12)	0.76
Dellon-modified Moberg pick-up test completion time at 17th week (seconds)				
Un-blinded	-2.11 (-4.36, 0.13)	-0.80 (-3.21, 1.61)	-1.87 (-4.61, 0.88)	0.18
Blinded	-6.50 (-9.84, -3.15)	-0.32 (-4.27, 3.63)	-6.13 (-10.6, -1.63)	<0.01
Tip pinch strength at 17th week (lbs)	1.75 (1.27, 2.22)	0.52 (-0.02, 1.06)	1.17 (0.48, 1.86)	<0.01

Results

A total of 181 patients were randomly allocated to electroacupuncture plus night splinting (n=90) or the waiting list plus night splinting (n=91). The two groups were comparable in baseline characteristics, with a mean duration of symptoms of 50 and 51 months, respectively. Patient recruitment flowchart and reasons for drop-out are shown in the Figure.

Boston Carpal Tunnel Questionnaire

Patients in the electroacupuncture group achieved greater improvement in the Symptom Severity Scale score at the 5th (P=0.04) and 17th (P=0.02) week (Table 1), with a higher proportion of patients achieving clinically important improvement (47% vs 36%, Table 2). Patients in the electroacupuncture group also achieved greater improvement in the Functional Status Scale score at the 17th week (P=0.01, Table 1), with a higher proportion of

patients achieving clinically important improvement (35% vs 24%, Table 2).

Disabilities of the Arm, Shoulder, and Hand questionnaire

Patients in the electroacupuncture group achieved greater improvement in DASH score at the 17th week (P<0.01, Table 1), with a higher proportion of patients achieving clinically important improvement (47% vs 29%, Table 2).

Pain intensity

Patients in the electroacupuncture group experienced a greater reduction in pain at the 17th week (P<0.03) although the magnitude of effect was modest (Table 1).

Dexterity, strength, and sensation

Patients in the electroacupuncture group had a

TABLE 2. Proportion of patients achieving clinically important improvement*

Outcome	No. (%) of patients	
	Electroacupuncture plus night splinting group	Waiting list plus night splinting group
Boston Carpal Tunnel Questionnaire		
Symptom Severity Scale		
1st week	11 (12)	19 (21)
2nd week	19 (21)	23 (26)
5th week	33 (39)	27 (31)
17th week	40 (47)	32 (36)
Functional Status Scale		
1st week	7 (8)	17 (19)
2nd week	15 (17)	15 (17)
5th week	19 (22)	18 (20)
17th week	30 (35)	21 (24)
Disabilities of the Arm, Shoulder, and Hand Questionnaire		
1st week	7 (8)	16 (18)
2nd week	17 (19)	19 (22)
5th week	24 (28)	21 (24)
17th week	40 (47)	26 (29)
Pain intensity		
1st week	18 (20)	20 (23)
2nd week	21 (24)	24 (28)
5th week	27 (32)	28 (32)
17th week	34 (40)	31 (35)
Blinded Dellon-modified Moberg pick-up test completion time at 17th week	32 (37)	17 (19)
Tip pinch strength at 17th week	39 (46)	32 (36)

* The minimal threshold is defined as a half of the baseline standard deviation for the Boston Carpal Tunnel Questionnaire, Disabilities of the Arm, Shoulder, and Hand Questionnaire, and Dellon-modified Moberg pick-up test, as well as 1.66 lbs for tip pinch strength and 2 for pain intensity on a numerical rating scale

shorter completion time in the blinded DMMPUT at the 17th week ($P < 0.01$, Table 1), with a higher proportion of patients achieving clinically important improvement (37% vs 19%, Table 2). The two groups did not differ significantly in terms of the un-blinded DMMPUT completion time.

Patients in the electroacupuncture group had stronger tip pinch strength ($P < 0.01$, Table 1), with a higher proportion of patients achieving clinically important improvement (46% vs 36%, Table 2). The two groups did not differ significantly in sensation.

All adverse events were resolved within a week; none was serious.

Discussion

The UK National Institute for Health and Care Excellence (NICE),¹ American Academy of Orthopaedic Surgeons,² and the American College of Occupational and Environmental Medicine³ recommend splinting as the first-line conservative treatment strategy for CTS, and make no recommendation for or against electroacupuncture. In this trial, most patients had chronic symptoms for more than 2 years and moderate severity at enrolment. Splinting alone was inadequate to relieve symptoms and improve function, as none of the outcomes demonstrated a clinically important improvement from baseline in intention-to-treat analyses. The UK NICE guideline recommends the use of steroid injection or surgery if conservative treatment fails to improve symptoms after 3 months. There is no consensus on optimal treatment for patients with chronic (≥ 6 months) mild-to-moderate symptoms.⁴ Results from this trial can provide evidence of the potential benefit of adding electroacupuncture to splinting for CTS patients with chronic mild-to-moderate symptoms as first-line therapy. Future trials may also evaluate the add-on benefit of acupuncture on top of steroid injections.⁵

Acknowledgement

This study was supported by the Health and Health Services Research Fund, Food and Health Bureau, Hong Kong SAR Government (#09100681).

Results of this study have been published in: Chung VC, Ho RS, Liu S, et al. Electroacupuncture and splinting versus splinting alone to treat carpal tunnel syndrome: a randomized controlled trial. *CMAJ* 2016;188:867-75. This work is protected by copyright and the making of this copy was with the permission of the Canadian Medical Association Journal (www.cmaj.ca) and Access Copyright. Any alteration of its content or further copying in any form whatsoever is strictly prohibited unless otherwise permitted by law.

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Bipolar transurethral vapourisation versus monopolar transurethral resection of prostate: a randomised controlled trial

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KEY MESSAGES

1. Transurethral resection in saline bipolar vapourisation of the prostate achieved a shorter urethral catheter time and hospital stay than monopolar transurethral resection of the prostate.
2. At 6-month follow-up, both methods achieved similar outcome in terms of symptoms and quality of life.

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Introduction

Among Asian men, >60% aged 40 years or above experience moderate-to-severe lower urinary tract symptoms, based on the International Prostate Symptom Score.¹ Benign prostatic enlargement is a major culprit. As many as 30% of patients fail to achieve sufficient symptom relief with medical therapy, lifestyle adjustment, and fluid management, and may eventually require more invasive treatment.

Monopolar transurethral resection of the prostate (TURP) remains the gold standard for surgical management. Nonetheless, it is associated with the risk of transurethral resection syndrome when glycine solution is used for irrigation. The absorption of glycine and irrigation fluid from extended resection can lead to glycine toxicity and hyponatraemia.

Bipolar surgery of the prostate uses isotonic saline solution for irrigation and thus minimises the risk of transurethral resection syndrome. Transurethral resection in saline (TURis) bipolar vapourisation is one of the popular modalities. It uses a 'button' electrode instead of a resection-based loop electrode for tissue removal. Bleeding rate is reduced compared with its monopolar counterpart.² This study aimed to determine whether TURis bipolar vapourisation of the prostate results in a shorter hospital stay compared with monopolar TURP, and thus reduction in costs and improvement in effectiveness and outcome. We also aimed to establish the safety and efficacy profiles of TURis bipolar vapourisation.

Methods

This was a two-centre, double-blind, prospective, randomised controlled trial to compare the outcome

of TURis bipolar vapourisation of the prostate versus monopolar TURP. The primary outcome measure was length of hospital stay. The secondary outcome measures included duration of catheter time (hours), dysuria score (0-10, visual analogue scale), and maximal flow (Qmax) on uroflowmetry at 3 and 6 months after surgery.

Men aged 50 to 75 years in whom medical therapy failed to relieve lower urinary tract symptoms or who had urinary retention were recruited. Details of the inclusion/exclusion criteria are listed in Table 1.

Subjects were randomised to undergo either TURis bipolar vapourisation of the prostate or monopolar TURP. Postoperative bladder irrigation was started with 0.9% saline for 6 hours for both treatment arms, unless haematuria was significant according to a standardised colour chart. Bladder irrigation was continued until the urine was sufficiently clear. The catheter was removed and the patient was discharged at the discretion of the managing clinician.

The operating surgeon and theatre staff were informed of the type of surgery one day before. They did not participate in subsequent postoperative clinical care of patients. Both patients and assessors were blinded to the mode of surgery until completion of 6-month follow-up.

The prostate volume was assessed before surgery using transrectal ultrasonography. The dysuria score was assessed using a visual analogue scale when the patient started to self-void following urethral catheter removal. Subjects were followed up in an out-patient clinic at 3 and 6 months for prostate volume, uroflowmetry, International Prostate Symptom Score, and quality of life (QoL) score. Any adverse event was documented.

Descriptive statistics were used for

TABLE 1. Inclusion and exclusion criteria

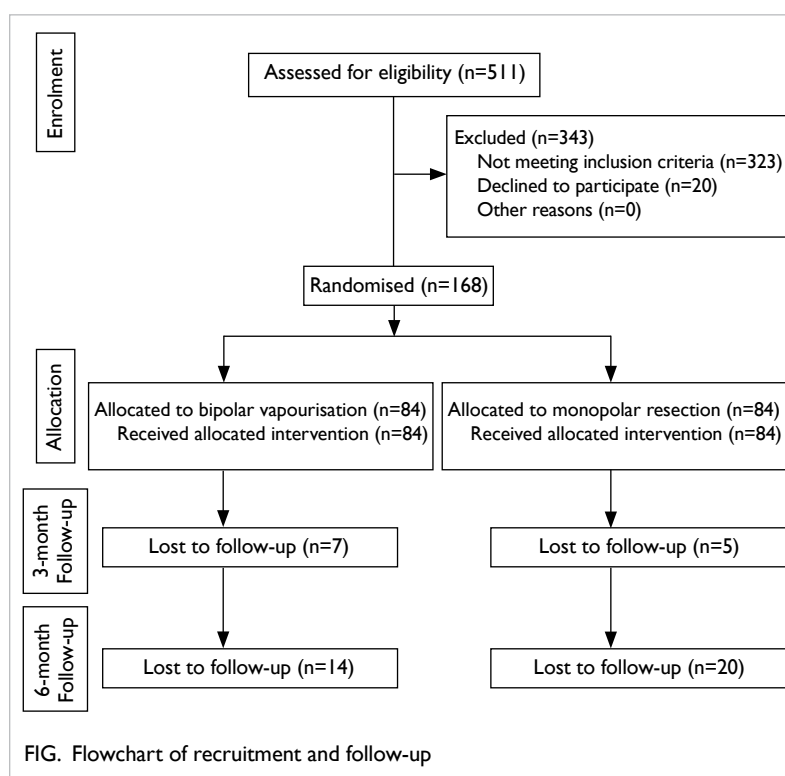
Inclusion criteria	
1.	Men aged 50 to 75 years with benign prostatic enlargement
2.	American Association of Anesthesiology grade ≤ 2
3.	Compliant patients with
i.	Activities of daily living independent or largely independent
ii.	Agreeable to the principle of short stay surgery
iii.	Can have access to hospital care within 15 minutes of travel
And either one of the following conditions:	
4.	Failed medical therapy with alpha-blockers or 5-alpha reductase inhibitors, with International Prostate Symptom Score ≥ 18 and/or maximal flow rate $\leq 15\text{mL/s}$
5.	Urinary retention status
Exclusion criteria	
1.	Previous transurethral resection of prostate or other forms of surgical intervention for benign prostatic enlargement
2.	Patient confirmed to have carcinoma of prostate
3.	Patients with known neurogenic bladder, bladder stone, or urethral stricture

uroflowmetry results, prostate volume, International Prostate Symptom Score, QoL score, peri-operative parameters, and length of stay. Comparison of continuous data between two arms was performed using T test if the data were normally distributed or Mann-Whitney *U* test if the data were ordinal or skewed. Categorical data were analysed using Chi-square test or Fisher's exact test where appropriate. Multivariable logistic regression was performed to determine predictors of length of hospital stay and QoL score. Reference was made to prior randomised controlled trials and systematic review. We assumed that hospitalisation was 60 hours for the monopolar group and 42 hours for the bipolar group, with a pooled standard deviation of 36 hours. It was estimated that at least 84 subjects in each arm were needed to detect a difference of 18 hours at a power of 80% with two-sided test of significance of 5% and an attrition rate of 25%. A P value of <0.05 was considered statistically significant.

Results

Between January 2013 and December 2013, 511 men in whom TURP was indicated were assessed for eligibility. Of them, 168 (mean age, 65.0 ± 5.6 years) were randomised to the TURis bipolar vapourisation group ($n=84$) or monopolar TURP group ($n=84$) [Fig]. The two groups were comparable in terms of patient characteristics.

Compared with the monopolar group, the bipolar group had a longer operative time (51.6 ± 24.5 vs 38.5 ± 20.3 mins, $P < 0.001$), a shorter catheter time (33.6 ± 23.7 vs 40.8 ± 29.4 hours, $P = 0.013$), a shorter length of hospital stay (43.14 ± 18.79 vs 52.33 ± 30.58 hours, $P = 0.013$), and a higher dysuria score (5.1 ± 2.3



vs 3.9 ± 2.4 , $P = 0.005$) [Table 2]. The two groups did not differ significantly in bladder irrigation time or complication and readmission rates (Table 2).

In multivariable logistic regression, the type of surgery was associated with the length of hospital stay (monopolar TURP: odds ratio=3.139, 95% confidence interval=1.548-6.364, $P = 0.002$).

At 3 months, 156 of 168 patients were reviewed.

TABLE 2. Peri- and post-operative outcome

Outcome	Mean±SD		P value	
	Overall	Bipolar group		Monopolar group
Operating time (mins)	45.0±23.3	51.6±24.5	38.5±20.3	<0.001
Haemoglobin drop (g/dL)	0.70±0.87	0.61±0.72	0.78±0.99	0.229
Bladder irrigation (hours)	12.03±7.13	11.0±6.09	13.04±7.94	0.135
Catheter time (hours)	37.2±26.8	33.6±23.7	40.8±29.4	0.013
Dysuria score (0-10)	4.5±2.4	5.1±2.3	3.9±2.4	0.005
Length of hospital stay (hours)	47.74±25.72	43.17±18.79	52.33±30.58	0.014

The two groups did not differ significantly in QoL score or uroflowmetry results. Similar findings were noted at 6-month follow-up.

Discussion

Monopolar TURP is the gold standard for surgical management of benign prostatic enlargement. Nonetheless, TURis bipolar vapourisation is simpler and less costly with comparable clinical benefits to other bipolar techniques. We observed that early severe irritative complications were slightly more frequent in the TURis bipolar vapourisation group than in the monopolar TURP group. Our trial is the first to quantify and compare dysuria severity using a visual analogue scale. The difference in the dysuria symptom score between the two groups could be due to a deeper coagulation depth in TURis bipolar vapourisation. With a larger surface area of the button vapourisation electrode, the extent of thermal injury is accentuated. This may account for a higher dysuria score in the bipolar than monopolar group. Future research should aim to relieve this peri-operative nuisance to improve early operative outcome.

Our current study demonstrated TURis bipolar vapourisation to be superior to monopolar TURP in terms of catheter time and length of hospital stay, with a potentially shorter bladder irrigation time than our current 6-hour protocol. The decreased length of hospital stay is a major contributor to the cost of TURP. The impact of prolonged hospitalisation can be more important than the type of surgery on cost savings. One study reported a cost reduction by 45.6% if the hospital stay for prostate surgery was reduced from 3 to 2 days.³ Our trial demonstrated an almost 10-hour difference in the mean length of stay between the two groups. Such difference could mean an extra night in hospital.

There are limitations to our study. Operations in our series were not performed by a single surgeon. Differences in technique by different surgeons might alter the homogeneity of intervention. Nonetheless, for classic surgery such as TURP, the difference in execution should be minimal. Furthermore,

the follow-up was relatively short. A longer-term comparison would enable more comprehensive appreciation of the outcome of TURis bipolar vapourisation of prostate.

Conclusions

TURis bipolar vapourisation of the prostate is a safe alternative to monopolar TURP, with a reduced length of hospital stay and comparable outcome over a period of 6 months. Nonetheless, longer follow-up would enable a more comprehensive assessment. Shortening hospital stay would contribute to a more efficient use of healthcare resources.

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Effect of weight reduction on severity of lower urinary tract symptoms in obese men with benign prostatic hyperplasia

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KEY MESSAGES

1. A minor change in body mass index does not affect lower urinary tract symptoms, including subjective symptom scores and objective uroflowmetry variables.
2. More effort is needed to optimise the implementation of weight reduction programmes with respect to lower urinary tract symptom improvement in real life.

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Introduction

The aetiology of lower urinary tract symptoms (LUTS) extends beyond prostate enlargement and bladder outlet obstruction. There are multiple pathways that precipitate LUTS onset and progression and make its diagnosis and treatment a challenge. It has been suggested that obese men are more likely to have LUTS and that weight gain worsens LUTS. It is not known whether weight reduction can improve LUTS. The proposed association of obesity with LUTS remains controversial. We conducted a prospective randomised controlled trial to determine whether weight reduction is an effective intervention for LUTS, and assessed the association between obesity and LUTS among patients with benign prostatic hyperplasia.

Materials and methods

This prospective randomised controlled study was approved by the local ethics and research committee. Written informed consent was obtained from each participant. Obese men aged above 50 years who attended our urology clinic for LUTS were enrolled. Details of the inclusion/exclusion criteria are listed in Table 1.

The study duration was 52 weeks. Standardised alpha-adrenergic blocker therapy (tamsulosin 0.4mg oral-controlled absorption system) for benign prostatic hyperplasia / LUTS was provided for run-in. Patient baseline parameters were assessed 4 weeks later. Patients were then randomised to view a video that provided general principles of and advice about weight reduction or enrol in a comprehensive weight reduction programme that included an

integrated assessment, a weight reduction protocol, and medical nutrition therapy.

Patients were assessed at different time points over the course of 48 weeks using uroflowmetry and transrectal ultrasonography. The primary outcome measure was the change in International Prostate Symptom Score (IPSS). Secondary outcome measures included changes in uroflowmetry parameters, nocturia episodes, and prostate volume.

Based on our centre database of >1000 patients with LUTS, the mean total IPSS in patients with moderate to severe symptoms is 19 (standard deviation, 7). A sample size of 65 in each group would have 80% power to detect a four-point difference in means, with a 0.05 two-sided significance level and an attrition rate of 30%.

Descriptive statistics were used for demographic data, uroflowmetry results, prostate volume, IPSS, quality of life (QoL) score, and body mass index (BMI). Comparison of continuous data between the two groups was performed with T test or ANOVA test if the data were normally distributed, and Mann-Whitney *U* test or Kruskal-Wallis test if the data were ordinal or skewed. A P value of <0.05 was considered statistically significant.

Results

Of 180 patients assessed for eligibility, 50 were excluded and 130 were randomised to receive general weight reduction advice (n=65) or comprehensive weight reduction programme (n=65); 117 of them completed the study (Fig). The two groups were comparable at baseline in terms of age, BMI, IPSS, prostate volume, and uroflowmetry parameters (Table 2).

TABLE 1. Inclusion and exclusion criteria

Inclusion criteria	
1.	Men aged ≥ 50 years
2.	Body mass index of 25-35 kg/m ²
3.	Moderate to severe lower urinary tract symptoms (International Prostate Symptom Score >7)
4.	Maximal flow rate of 5-15 mL/s, post-void residuals of <150 mL
5.	Transrectal ultrasonography showing prostate volume >30 cc
Exclusion criteria	
1.	Patients with urethral stricture, neurogenic bladder or structural abnormality
2.	Patients with long-term catheterisation or intermittent self-catheterisation
3.	Patients with prostate cancer or bladder cancer
4.	Patients prescribed 5 α -reductase inhibitors, phytotherapy, or hormonal therapy
5.	Patients who cannot tolerate tamsulosin oral-controlled absorption system
6.	Patients with poor cardiac status (New York Heart Association class III or above) or other medical conditions in whom an intense exercise or weight reduction programme was inappropriate.

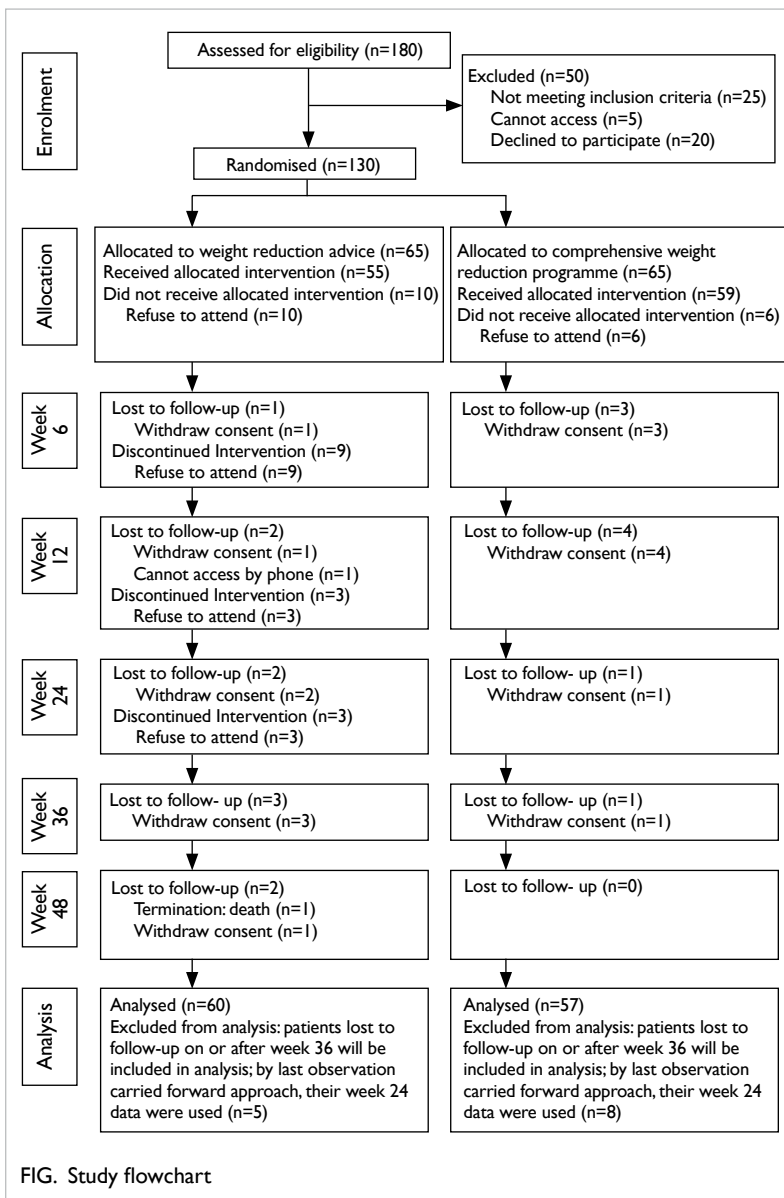


FIG. Study flowchart

After 48 weeks, the mean change in BMI was -0.4 ± 0.9 and -0.4 ± 0.8 kg/m² for the control and active group, respectively. The two groups did not differ significantly in terms of changes in nocturia episodes, total IPSS, IPSS irritative score subset, EuroQol visual analogue scale, maximal flow rate, or post-void residuals. Both groups had an increase in prostate volume although not significantly.

To determine if there was a relationship between obesity and LUTS, patients were categorised as BMI 25 to <30 kg/m² (n=101) or BMI 30-35 kg/m² (n=13) [Table 2]. The two groups did not differ significantly at baseline in terms of nocturia episodes, total IPSS, IPSS irritative score subset, IPSS QoL score, EuroQol visual analogue scale, or uroflowmetry parameters.

Patients who had lost weight during the study period were categorised into four quartiles according to their weight reduction percentage. The four groups did not differ significantly in LUTS parameters or total IPSS.

Discussion

The relationship between obesity and LUTS remains controversial. A positive correlation between obesity and the incidence of LUTS was reported in a western study.¹ Nonetheless, such a relationship was not demonstrated in our study or another.² These contradictory results may be partly due to the different degree of obesity in different studies. In the western study,¹ patients with BMI ≥ 35 kg/m² were compared with those with BMI 23 to <25 kg/m². In Asian populations, there are relatively fewer men who are severely obese (BMI 35 to <40 kg/m²) or morbidly obese (BMI ≥ 40 kg/m²). In our cohort, 101 patients were overweight (BMI 25 to <30 kg/m²) but only 13 patients were obese (BMI 30-35 kg/m²).

TABLE 2. Comparison of patients who received general weight reduction advice (control) or comprehensive weight reduction programme (active) and those with body mass index (BMI) 25 to <30 or 30 to 35 kg/m²

Parameter*	Control (n=57)	Active (n=60)	P value	BMI (kg/m ²)		P value
				25 to <30 (n=101)	30-35 (n=13)	
Age (years)	63.3±7.8	66.5±6.9	0.88	66.9±7.1	62.5±7.7	0.04
Weight (kg)	75.2±6.6	74.3±8.4	0.53	73.7±6.4	84.0±9.3	>0.01
Height (m)	1.66±0.05	1.65±0.07	0.51	1.65±0.06	1.64±0.08	0.39
BMI (kg/m ²)	27.4±1.9	27.3±2.0	0.51	27.0±1.4	31.2±1.5	>0.01
Nocturia episodes	2.5±1.2	2.6±1.2	0.63	2.5±1.2	2.7±1.4	0.61
Total International Prostate Symptom Score (IPSS)	17.6±6.3	17.3±6.9	0.80	17.4±6.6	17.2±6.8	0.93
Irritative score (sum of score of IPSS questions 2, 4, and 7)	7.6±3.3	8.1±2.9	0.44	7.8±3.1	8.0±3.6	0.82
IPSS quality of life score	3.3±0.9	3.2±1.2	0.52	3.3±1.0	2.8±1.5	0.13
EuroQol visual analogue scale	73.8±15.8	74.5±13.8	0.81	75.1±14.1	65.8±18.9	0.11
Maximal flow rate (mL/s)	10.4±4.3	10.2±3.9	0.81	10.0±3.4	12.2±6.9	0.46
Post-void residuals (mL)	57.6±79.2	37.5±48.1	0.27	51.5±68.5	24.8±36.2	0.23
Prostate size (cc)	52.1±23.2	56.6±31.1	0.89	56.8±28.4	40.1±15.3	0.03
Prostate specific antigen (µg/L)	4.21±4.62	5.14±5.17	0.27	5.0±5.1	2.6±2.6	0.07

* Data are presented as mean±SD

Without a significant difference in BMI, a subtle relationship between obesity and LUTS may not be demonstrated.

The degree of weight change with respect to LUTS development has been reported.³ The baseline mean BMI was 26.9 (24.5-29.4) kg/m², and the mean change in BMI after 4 years was 1.4 (0.3-2.5) kg/m². Modest weight loss and weight gain were not associated with changes to the American Urological Association Symptom Index score, and the rate at which the score changed did not vary with the occurrence of a modest weight change. A significant weight change or a significant degree of obesity might be needed to demonstrate such association.

In our study, the control and active groups did not differ significantly in weight reduction percentage. This demonstrates the challenge of getting patients to adhere to a weight loss programme. Most trials are plagued by subsequent weight regain. Even within weight loss trials of continual intervention, weight regain is prominent. To improve the success of a weight reduction programme, more innovative measures are needed.

Conclusion

The association between obesity, weight loss, and LUTS was not demonstrated. This could be due to the less marked weight difference and weight loss in our cohort. Although weight reduction might be an effective measure to improve LUTS, the

implementation of a successful weight reduction programme remains a challenge.

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Quality of life and symptom measurement in Chinese women with pelvic floor disorders: validation study of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire

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KEY MESSAGES

1. Chinese women with pelvic floor disorders, namely pelvic organ prolapse, urinary incontinence, and faecal incontinence, have an impaired quality of life, similar to Caucasian women.
2. The Chinese version of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire are reliable and valid condition-specific health-related quality-of-life questionnaires for women

with pelvic floor disorders.

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Introduction

The prevalence of pelvic floor disorders, namely pelvic organ prolapse, urinary incontinence, and faecal incontinence in women has been reported to be 11.4-39.7%, 25-52%, and 1.4-22% respectively. Caucasian women with pelvic floor disorders have been reported to have significantly impaired quality of life (QOL).¹

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are reliable, valid, and condition-specific symptom and QOL instruments to assess symptoms, their severity, and the impact of different types of pelvic floor disorder on a woman's activities and well-being.² Nonetheless, a Chinese version is not available.

This study aimed to investigate the reliability and validity of a Chinese version of the PFDI and PFIQ in Chinese women with pelvic floor disorders.

Methods

Study design

Approval to use the PFDI and PFIQ was obtained from the original authors. Ethics approval was granted by the local institute. Standard forward translation and back-translation was performed. The back-translated version was sent to the original English speaking authors for review and confirmed no major discrepancy. The Chinese version of the PFDI and PFIQ were finalised.

From July to September 2008, 36 Chinese women who attended the urogynaecology clinic with a pelvic floor disorder were invited to complete and comment on the Chinese version of the PFDI

and PFIQ. They considered the questionnaires comprehensive.

From April 2009 to May 2010, all Chinese women who attended the urogynaecology clinic with a pelvic floor disorder were invited to participate. Exclusion criteria were women aged <18 years or those who were mentally incapacitated. Written consent was obtained. Women completed the Chinese version PFDI and PFIQ and Short Form Health Survey (SF-36).

They were then assessed by a gynaecologist. Both women and gynaecologist graded the overall severity of symptoms on a visual analogue scale (VAS) with a higher score indicating more severe symptoms.

Women then kept a 3-day urinary and faecal diary to quantify the severity of their urinary and bowel symptoms such as urinary frequency and number of incontinence episodes.

Four weeks later, the women recruited in the first 6 months repeated the questionnaires. None had been offered any treatment during this interval; data of those who had stable symptoms were used for analysis in test-retest reliability.

Women who had urinary symptoms were followed up with urodynamic studies. Those who had faecal incontinence underwent anal manometry and anal ultrasonography. The investigators were blinded to PFDI and PFIQ data.

Sample size

The subject-to-item ratio of a given measurement scale should be 5:1 or above, so a sample size >465 (93 items x 5) was needed. A sample size >100 was

required to establish the test-retest reliability.

Study instruments

The PFDI assesses lower urinary tract dysfunction, colorectal-anal dysfunction and pelvic organ prolapse symptom distress. It comprises 46 items in three scales: the Urinary Distress Inventory (UDI), the Pelvic Organ Prolapse Distress Inventory (POPDI), and the Colorectal-anal Distress Inventory (CRADI). Responses range from 1 (not at all) to 4 (quite a bit).

The PFIQ assesses life impact on women with a pelvic floor disorder. It contains three scales: the Urinary Impact Questionnaire (UIQ), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and the Colo-Rectal-Anal Impact Questionnaire (CRAIQ), each with 31 items. Women were asked how symptoms affected their activities and emotions. Responses range from 1 (not at all) to 4 (quite a bit).

The validated Hong Kong Chinese version of the SF-36³ was used to assess the validity of the PFDI and PFIQ.

prolapse, 10.9% had pelvic organ prolapse only, 2.2% had urinary and faecal incontinence, and 0.3% had urinary and faecal incontinence and pelvic organ prolapse.

In those with urinary symptoms, 66.2%, 50.7%, 43.9%, and 25.5% had stress urinary incontinence, urinary urgency, urge urinary incontinence, and urinary retention, respectively. In all, 56.6%, 9.4%, 23.5%, and 10.5% had stage 0, I, II, and III/IV prolapse, respectively. Overall, 71.3% of women completed the 3-day urinary and faecal diary.

A total of 510 (85.4%) women underwent urodynamic studies; 37.0%, 33.2%, 8.9%, 1.8%, and 3.9% were diagnosed with no abnormality, urodynamic stress incontinence (USI), detrusor overactivity (DO), USI and DO, and voiding dysfunction, respectively. In those who complained of faecal incontinence, no pathology was identified after anal manometry or anal ultrasonography.

Of the 270 scheduled for retest, 253 completed the re-test and indicated no change in symptoms or severity of their pelvic floor disorders.

Reliability

Respectively for PFDI and PFIQ, the Cronbach's alpha was 0.92 and 0.98 indicating high internal consistency, and the intraclass correlation coefficient was 0.77 and 0.79 indicating acceptable test-retest reliability (Table 1).⁴

Results

A total of 597 women (mean age, 55.0±11.3 years; mean parity, 2.7±1.5) completed the study. Among them, 54.4% had urinary incontinence only, 32.2% had both urinary incontinence and pelvic organ

TABLE 1. Internal consistency and test-retest reliability of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) and their subscales (Reproduced from: Chan SS, Cheung RY, Yiu AK, et al. Chinese validation of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. *Int Urogynecol J* 2011;22:1305-12.)

PFDI	Internal consistency (Cronbach's α)%	Test-retest reliability (intraclass correlation coefficient) [%]	PFIQ	Internal consistency (Cronbach's α)%	Test-retest reliability (intraclass correlation coefficient) [%]
PFDI	0.93	0.77	PFIQ	0.98	0.79
Pelvic organ prolapse distress inventory	0.87	0.79	Pelvic organ prolapse impact questionnaire	0.97	0.66
General	0.81	0.72	Physical activity	0.93	0.69
Anterior	0.82	0.81	Social relationships	0.92	0.61
Posterior	0.76	0.80	Travel	0.92	0.60
			Emotional health	0.93	0.46
Colo-rectal-anal distress inventory	0.86	0.80	Colo-rectal-anal impact questionnaire	0.98	0.72
Obstructive	0.76	0.80	Physical activity	0.92	0.68
Incontinence	0.77	0.71	Social relationships	0.95	0.66
Pain/irritative	0.76	0.75	Travel	0.92	0.70
Rectal prolapse	0.45	0.68	Emotional health	0.95	0.68
Urinary distress inventory	0.89	0.83	Urinary impact questionnaire	0.97	0.88
Irritative	0.72	0.80	Physical activity	0.83	0.77
Obstructive/discomfort	0.86	0.76	Social relationships	0.91	0.86
Stress	0.80	0.83	Travel	0.84	0.85

Convergent validity

Subscales of PFDI and PFIQ negatively correlated with each subscale of SF-36 (Table 2).⁴ This indicated that the higher the score of PFDI or PFIQ, the greater the negative impact on general health.

The staging of pelvic organ prolapse was positively correlated with POPDI General subscale ($r=0.20, P<0.05$), POPIQ ($r=0.24, P<0.05$), and three subscales. POPDI General subscale score was higher in the stage II or III/IV prolapse group than in the no prolapse group. Anterior subscale was also higher in the stage III/IV group than in the stage II group. The POPIQ score was higher in the stage III/IV group.

The daytime voiding frequency was positively correlated with UDI ($r=0.36, P<0.001$) and UIQ ($r=0.40, P<0.001$). When comparing the UDI score, the no abnormality group scored lower than the USI or DO group. Women diagnosed with USI scored lower than the DO group on the irritative symptom subscale score. The stress symptom subscale score was higher in the USI group than in the no abnormality or voiding dysfunction group. The UIQ score was lower in the no abnormality group than the USI or DO group.

The frequency of faecal incontinence episodes was positively correlated with CRADI ($r=0.27, P<0.001$) and CRAIQ ($r=0.23, P<0.001$). The VAS scores of both women and the gynaecologist were positively correlated with PFDI and PFIQ.

Discussion

PFDI and PFIQ enable a more in-depth assessment of specific concerns critical to different types of pelvic floor disorder and of their treatment outcomes.⁵ Nonetheless, there may be cultural or language concerns, and items may need to be adjusted accordingly. Validating the Chinese version

of PFDI and PFIQ is therefore important for their use in Chinese and in Hong Kong.

Our results showed that the Chinese version of PFDI and PFIQ are reliable for use in women with pelvic floor disorders that include urinary incontinence, pelvic organ prolapse, and faecal incontinence. There was high internal consistency for both PFDI and PFIQ, comparable with the original version.² The test-retest reliability was also acceptable.

The validity of the Chinese version of PFDI and PFIQ was supported by a positive correlation between the women's VAS and their PFDI and PFIQ scores and a negative correlation between SF-36 and PFDI and PFIQ scores, as well as the positive correlation between the UDI and UIQ with the number of urinary incontinence episodes and daytime voiding. This was approximately equal to those demonstrated in the original UDI and the IIQ; and the Chinese version of UDI-6 and IIQ-7.⁶ POPDI and POPIQ also correlated with the staging of pelvic organ prolapse; a higher correlation was found in those with stage II or above. The CRADI and CRAIQ correlated with the number of faecal incontinence episodes.

The differences in the subscale score of POPDI and POPIQ could demonstrate a difference between women with different stages of pelvic organ prolapse. Higher general and anterior subscale scores of POPDI, and POPIQ and emotional and physical activity subscale scores were found in the stage III/IV prolapse group. UDI and UIQ differed in women with different urodynamic diagnoses, with higher UDI and UIQ scores in women diagnosed with USI or DO, a higher irritative symptom subscale score in those with DO, and a higher stress symptom subscale score in those with USI than those with no abnormality. Finally, CRADI and CRAIQ were

TABLE 2. Correlation between subscales of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) and subscales of SF-36* (Reproduced from: Chan SS, Cheung RY, Yiu AK, et al. Chinese validation of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Int Urogynecol J 2011;22:1305-12.)

Subscales of SF-36	Correlation with subscales of PFDI			Correlation with subscales of PFIQ		
	Pelvic organ prolapse distress inventory	Colo-rectal-anal distress inventory	Urinary distress inventory	Pelvic organ prolapse impact questionnaire	Colo-rectal-anal impact questionnaire	Urinary impact questionnaire
Physical functioning	-0.33	-0.33	-0.38	-0.39	-0.34	-0.46
Role-physical	-0.36	-0.33	-0.36	-0.36	-0.30	-0.43
Bodily pain	-0.39	-0.42	-0.39	-0.33	-0.33	-0.43
General health	-0.29	-0.32	-0.29	-0.24	-0.30	-0.38
Vitality	-0.29	-0.32	-0.35	-0.28	-0.25	-0.42
Social functioning	-0.30	-0.34	-0.37	-0.37	-0.35	-0.51
Role-emotional	-0.32	-0.32	-0.36	-0.32	-0.29	-0.46
Mental health	-0.32	-0.38	-0.39	-0.32	-0.34	-0.53

* P<0.001 for all

higher in women with faecal incontinence. All these findings confirm the validity of both PFDI and PFIQ.

The Chinese version of PFDI and PFIQ may help healthcare providers, especially gynaecologists, when exploring symptoms and their impact on QOL in women with pelvic floor disorders, especially urinary incontinence and pelvic organ prolapse. These instruments are comprehensive and should encompass most urinary and prolapse symptoms. Gynaecologists may also use them to assess treatment outcome, both conservative and surgical, after the responsiveness of these tools has also been assessed.

The Chinese version of PFDI and PFIQ can be downloaded from the website of the Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong (<http://www.obg.cuhk.edu.hk/urogynaecology/urogynaecology-resources/>).

Conclusions

The Chinese version of PFDI and PFIQ are reliable and valid condition-specific health-related QOL questionnaires for women with pelvic floor disorders.

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Results of this study have been published in: Chan SS, Cheung RY, Yiu AK, et al. Chinese validation of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. *Int Urogynecol J* 2011;22:1305-12.

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Pelvic floor disorders related to pregnancy: a prospective observational study

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KEY MESSAGES

1. Pelvic floor changes and disorders may occur during pregnancy. Symptoms are prevalent after delivery.
2. Levator ani muscle injury occurs following vaginal delivery. Pelvic floor changes occur regardless of mode of delivery.
3. Antenatal symptoms of pelvic floor disorders increase with maternal age and body mass index; pelvic floor changes are a risk factor for postnatal

pelvic floor disorders.

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Introduction

Pelvic floor disorders (urinary incontinence, pelvic organ prolapse, and faecal incontinence) are an important public health issue because of their high prevalence, deleterious effects on quality of life, and impact on the healthcare system.¹ The number of surgeries performed for urinary incontinence and pelvic organ prolapse has increased in Hong Kong women.¹

The prevalence of urinary incontinence has been reported to be 16-60% during pregnancy and 16-34% following delivery. Faecal incontinence and pelvic organ prolapse have been reported by 5-22% and >80% of women after delivery, respectively. There is evidence of pelvic floor changes after delivery. Most studies have focused largely on the effect of delivery in Caucasian women with evaluation commenced in late pregnancy and continued until shortly after delivery. Antenatal information is limited, as is that related to ethnic differences.

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) can be used to assess different types of pelvic floor disorder and their impact on a woman's quality of life. Chinese validated versions are available and their responsiveness has been validated.^{2,3} Translabial ultrasonography has been established to assess pelvic floor biometry and levator hiatus.

This prospective observational study aimed to assess the prevalence and types of pelvic floor disorder that occur during pregnancy until one year after delivery.⁴⁻⁸ The relationship of pelvic floor anatomy and pelvic floor disorders during and after pregnancy, and risk factors were explored. These might have an impact on the management of pregnancy and delivery.

Methods

Ethics approval and informed consent were obtained. All Chinese nulliparous women who reported no pelvic floor disorders prior to pregnancy at their first trimester visit (10-13 weeks of gestation) were recruited and assessed at the second (24-28 week) and third (35-38 week) trimesters. They completed the Chinese PFDI and PFIQ,² and underwent standard translabial three-dimensional ultrasonography at rest, during a Valsalva manoeuvre, and during pelvic floor muscle contraction.

Time and mode of delivery were determined by obstetric indications and included vaginal delivery (VD), operative vaginal delivery involving ventouse extraction or forceps delivery and elective or emergency Caesarean section (CS).

Women were followed up at 8 weeks, 6 and 12 months postpartum. Pelvic floor disorder symptoms were again assessed by PFDI and PFIQ. Gynaecological examination was performed to determine any POP according to the Pelvic Organ Prolapse-Quantification System. Translabial ultrasonography was performed to determine the position of the bladder neck (BN), cervix, and ano-rectal junction relative to the level of the reference point (postero-inferior edge of the pubic symphysis), the hiatal area (HA) and presence of any levator ani muscle (LAM) injury.

Results

In all, 442 women were recruited; their mean age was 30.6±3.8 years and mean body mass index (BMI) was 21.0±2.8 kg/m² in the first trimester. Of them, 405 (91.6%) completed all antenatal assessments,⁶ and 328 (74.2%) completed the whole study (12 months after delivery).^{5,7,8}

The prevalence of stress urinary incontinence (SUI), urge urinary incontinence (UUI), and prolapse symptoms significantly increased with advancing gestation (Table 1).⁵ Higher maternal age was associated with antenatal SUI and UUI; higher maternal BMI was associated with faecal incontinence.⁵

As pregnancy advanced, the BN, cervix, and the ano-rectal junction descent increased significantly; and the HA enlarged significantly (Table 2).^{6,7}

Antenatal SUI and UUI were associated with a more distal position of the BN; third trimester prolapse symptoms were associated with a significantly larger HA and greater descent of the ano-rectal junction, whereas second trimester faecal incontinence was associated with a larger HA.⁶

The mean gestation at delivery was 39.2±1.9 weeks and mean birth weight was 3.07±0.46 kg. For women who underwent VD, 26 (9.9%) was given intrapartum epidural analgesia and 191 (95.0%) required episiotomy.

LAM injury was not detected in any women antenatally. After delivery, 57/263 (21.7%, 95% confidence interval [CI]=16.7-26.7%) women who underwent VD sustained injury to the LAM and included spontaneous VD (n=31, 15.4%), ventouse extraction (n=16, 33.3%), and forceps delivery (n=10, 71.4%).⁴ None who underwent CS had LAM injury; only operative VD increased the risk of LAM (odds ratio [OR]=3.09).⁴ Indication for operative VD was not associated with LAM injury.

At 12 months, the prevalence of SUI and UUI was 25.9% (95% CI=21.5-30.6) and 8.2% (95% CI=5.2-11.2), respectively.⁵ After VD, the respective prevalence was 29.7% and 9.1% (Table 1).⁵ The

prevalence of faecal incontinence of solid/loose stool was 4.0% (95% CI=1.9-6.1); risk factors for SUI were VD (OR=3.6), antenatal SUI (OR=2.8), and UUI (OR=2.4); and predictors of UUI were antenatal UUI (OR=6.4) and maternal BMI during the first trimester (OR=1.2), whereas the risk factor for faecal incontinence at 12 months was antenatal faecal incontinence (OR=6.1) [Table 3].⁵

Generally, the BN and cervix were at a lower position at 8 weeks. As time following VD increased, the BN returned to an upper position, and HA reduced (Table 2).⁷ By 12 months, the BN was more distal during Valsalva manoeuvre and displacement had increased; the cervix remained at a lower position.⁷ Subgroup analysis of spontaneous and operative VD groups revealed no significant difference in any pelvic floor biometry.

After CS delivery, the BN and ano-rectal junction were lower during Valsalva manoeuvre only, compared with the first trimester.⁷ The cervix was lower in all postures; the HA remained increased.⁷ Subgroup analysis showed no difference in pelvic floor biometry between the elective and emergency CS groups. The cervix was lower at 12 months than during the first trimester in the 22 women who had no labour.⁷

The BN was lower in the VD than CS group at 8 weeks but not at 6 or 12 months after delivery. Nonetheless, HA remained significantly increased.⁷

At 12 months, during Valsalva manoeuvre, 90 (35.6%) women in the VD group and 24 (31.4%) women in the CS group had irreversible over-distension (HA at 12 months was >20% increase than at first trimester).⁷ Presence of LAM injury increased the risk of irreversible over-distension. If

TABLE 1. Prevalence of urinary incontinence (UI) and faecal incontinence during pregnancy and after first delivery, and comparison between vaginal delivery (VD) and Caesarean section (CS) groups at 12 months after delivery (Reproduced with permission from: Chan SS, Cheung RY, Yiu KW, Lee LL, Chung TK. Prevalence of urinary and fecal incontinence in Chinese women during and after first pregnancy. *Int Urogynecol J* 2013;24:1473-9.)

Symptoms	No. (%) of subjects								
	Trimester of pregnancy (n=328)			Postnatal (n=328)			At 12 months		
	First	Second	Third	8 weeks	6 months	12 months	VD (n=252)	CS (n=78)	P value
Stress UI	30 (9.1)	106 (32.35)*	124 (37.8)*†	61 (18.6)*‡	72 (22.0)*‡	85 (25.9)*‡	74 (29.4)	11 (14.1)	0.009
Urgency UI	16 (4.9)	17 (5.2)	47 (14.3)*†	29 (8.8)*‡	18 (5.5)‡	27 (8.2)*‡	23 (9.1)	4 (5.2)	0.28
Mixed urinary incontinence	8 (2.4)	11 (3.3)	34 (10.4)*†	16 (4.9)‡	14 (4.3)‡	22 (6.7)	18 (7.1)	4 (5.3)	0.57
Any urinary incontinence	38 (11.5)	112 (34.1)*	134 (41.8)*†	74 (22.6)*‡	76 (23.2)*‡	90 (27.7)*‡	79 (31.3)	11 (14.5)	0.004
Faecal incontinence with normal stool	2 (0.6)	6 (1.8)	3 (0.9)	3 (0.9)	1 (0.3)	1 (0.3)	1 (0.4)	0	--
Faecal incontinence with liquid/loose stool	9 (2.7)	11 (3.4)	10 (3.0)	17 (5.2)	12 (3.7)	13 (4.0)	11 (4.4)	2 (2.6)	0.74
Flatus incontinence	124 (37.8)	137 (41.8)	120 (40.9)	100 (30.5)	79 (24.1)	60 (18.3)	45 (17.9)	15 (19.2)	0.78
Any faecal incontinence (excluding flatus incontinence)	10 (3.0)	15 (4.6)	11 (3.4)	17 (5.2)	12 (3.7)	13 (4.0)	11 (4.4)	2 (2.6)	0.74

* P<0.05 as compared to first trimester

† P<0.05 as compared to second trimester

‡ P<0.05 as compared to third trimester

TABLE 2. Comparison of pelvic floor biometry before and after delivery in vaginal delivery and Caesarean delivery groups (Reproduced with permission from: Chan SS, Cheung RY, Yiu KW, Lee LL, Chung TK. Pelvic floor biometry of Chinese primiparous women 1 year after delivery: a prospective observational study. *Ultrasound Obstet Gynecol* 2014;43:466-74.)

Variable	Trimester			Postnatal			P value (ANOVA to compare the pelvic floor biometry at postnatal 8 weeks, 6 months, and 12 months)	Partial Eta squared (≤0.01=small, 0.06=moderate, ≥0.14=large effect)
	First	Second	Third	8 weeks	6 months	12 months		
Vaginal delivery group								
At rest								
Bladder neck (BN) position (cm)	-2.89±0.37	-2.82±0.44	-2.59±0.60	-2.78±0.38*†‡	-2.89±0.36†‡	-2.83±0.64 ‡	<0.05	0.10
Cervix (cm)	-5.36±1.48	-4.84±0.99	-4.60±0.98	-4.51±1.15*†	-4.55±1.00*†	-4.54±1.11*†	0.71	0.003
Ano-rectal junction (cm)	-2.0±0.79	-1.68±0.91	-1.36±0.99	-2.13±0.93†‡	-2.17±0.78*†‡	-2.12±0.82 ‡‡	0.68	0.003
Hiatal area (cm ²)	11.3 6±2.40	12.27±2.62	12.92±3.21	12.30±2.71*†	12.02±2.66*†	11.95±2.37 *†‡§	0.12	0.02
At Valsalva								
BN position (cm)	-2.55±0.51	-2.20±0.61	-2.03±0.66	-1.95±0.73*†	-2.11±0.69*	-2.10±0.78*	0.01	0.04
BN displacement from rest (cm)	0.82±0.56	1.17±0.67	1.08±0.67	1.46±0.81*†‡	1.38±0.83*†‡	1.42±0.90*†‡	0.23	0.01
Cervix (cm)	-4.80±1.63	-4.42±1.30	-4.09±1.31	-3.81±1.29*†‡	-3.75±1.21*†‡	-3.86±1.14*†‡	0.33	0.01
Ano-rectal junction (cm)	-1.35±0.90	-0.86±0.99	-0.65±1.16	-1.09±1.11*†‡	-1.12±0.97*†‡	-1.04±1.05*†‡	0.53	0.01
Hiatal area (cm ²)	12.63±2.17	13.86±3.71	15.02±4.65	15.13±4.04*†	14.31±4.5*†	14.20±4.21*†	<0.05	0.07
At pelvic floor contraction								
BN position (cm)	-2.96±0.40	-2.94±0.54	-2.83±0.41	-2.79±0.56*†	-2.90±0.38*†‡	-2.91±0.41*	0.001	0.06
BN displacement from rest (cm)	0.42±0.30	0.57±0.59	0.61±0.42	0.56±0.56*	0.54±0.39*	0.58±0.64*	0.63	<0.01
Cervix (cm)	-5.32±1.39	-4.99±1.20	-4.73±0.94	-4.64±1.05*†	-4.63±1.07*†	-4.73±0.92*†	0.29	0.01
Ano-rectal junction (cm)	-1.97±0.76	-1.71±0.86	-1.52±0.89	-2.14±0.80*†‡	-2.12±0.81*†‡	-2.08±0.73†‡	0.51	0.01
Hiatal area (cm ²)	9.63±2.17	10.14±1.97	10.62±2.21	10.76±2.28*†	10.04±2.17*†	9.99±2.11*†	<0.05	0.16
Caesarean delivery group								
At rest								
BN position (cm)	-2.94±0.36	-2.81±0.49	-2.46±0.89	-2.87±0.31‡	-2.83±0.30*†	-2.83±0.30*†	0.60	0.02
Cervix (cm)	-5.40±1.06	-4.78±1.01	-4.60±1.09	-4.56±0.97*	-4.39±0.82*†	-4.54±0.97*	0.35	0.03
Ano-rectal junction (cm)	-1.8±0.89	-1.64±0.90	-1.23±1.03	-1.99±1.04†‡	-2.00±0.82†‡	-1.90±0.85†‡	0.64	0.01
Hiatal area (cm ²)	11.06±2.38	11.99±2.56	12.72±3.04	10.62±2.05†‡	10.26±2.27*†‡	10.91±1.98†‡§	0.02	0.11
At Valsalva								
BN position (cm)	-2.57±0.47	-2.26±0.55	-2.11±0.53	-2.31±0.44*†	-2.22±0.54*	-2.14±0.64*	0.05	0.09
BN displacement from rest (cm)	0.81±0.53	1.09±0.64	1.10±0.67	1.00±0.61*	1.15±0.72*	1.26±0.77*	0.01	0.13
Cervix (cm)	-4.98±1.02	-4.43±1.05	-4.13±1.56	-3.93±1.16*†	-3.61±1.08*†‡	-3.64±1.16*†‡	0.05	0.09
Ano-rectal junction (cm)	-1.29±0.94	-0.89±0.97	-0.74±1.05	-1.00±0.97*	-0.96±0.92*†	-0.80±0.97*	0.18	0.05
Hiatal area (cm ²)	11.80±2.78	13.63±3.26	14.62±3.72	12.47±3.11†‡	12.34±3.60†‡	12.94±3.02*†‡	0.07	0.08
At pelvic floor contraction								
BN position (cm)	-2.93±0.36	-2.96±0.38	-2.86±0.45	-2.89±0.39	-2.82±0.37*†	-2.85±0.38†	0.45	0.02
BN displacement from rest (cm)	0.39±0.30	0.54±0.30	0.61±0.37	0.57±0.36*	0.52±0.39*	0.47±0.33‡	0.20	0.05
Cervix (cm)	-5.45±0.97	-5.17±0.94	-4.84±0.90	-4.68±1.38*†	-4.55±0.89*†	-4.66±0.95*†	0.52	0.02
Ano-rectal junction (cm)	-1.92±0.92	-1.79±0.83	-1.45±0.90	-2.0±0.79‡	-2.08±0.80†‡	-1.91±0.64‡	0.15	0.05
Hiatal area (cm ²)	9.46±2.12	10.11±1.99	10.33±2.21	8.95±1.74*†‡	8.83±1.86*†‡	9.22±1.67†‡	0.06	0.08

* P<0.05 as compared to first trimester
† P<0.05 as compared to second trimester
‡ P<0.05 as compared to third trimester
§ P<0.05 between vaginal delivery and caesarean delivery at rest
|| P<0.05 between vaginal delivery and caesarean delivery at pelvic floor muscle contraction

TABLE 3. Multivariable logistic regression for risk factors of urinary incontinence (UI) and faecal incontinence in women at 12 months after first delivery (Reproduced with permission from: Chan SS, Cheung RY, Yiu KW, Lee LL, Chung TK. Prevalence of urinary and faecal incontinence in Chinese women during and after first pregnancy. *Int Urogynecol J* 2013;24:1473-9.)

Variable	OR (95% CI)	P value
Stress UI (n=328, χ^2 (6)=53.3, P<0.005)		
Vaginal delivery	3.58 (1.57-8.14)	0.002
Antenatal stress UI	2.81 (1.48-5.32)	0.002
Antenatal urgency UI	2.35 (1.13-4.92)	0.023
Maternal age	1.10 (1.0-1.19)	0.05
Maternal body mass index (BMI) at 12 months after delivery	1.11 (0.94-1.33)	0.20
Maternal BMI at first trimester	1.05 (0.84-1.30)	0.68
Urgency UI (n=328, χ^2 (4)=31.7, P<0.005)		
Antenatal urgency UI	6.44 (2.52-16.43)	<0.005
Maternal BMI at first trimester	1.21 (1.06-1.38)	0.006
Antenatal stress UI	2.00 (0.74-5.40)	0.17
Maternal age	1.05 (0.93-1.18)	0.47
Faecal incontinence (n=328, χ^2 (2)=9.2, P<0.01)		
Antenatal faecal incontinence	6.1 (1.75-21.5)	0.005
Maternal BMI at first trimesters	1.18 (0.99-1.39)	0.06

women with LAM injury were excluded, 41 (14.1%), 86 (29.7%), and 36 (12.4%) women had irreversible over-distension at rest, and during Valsalva manoeuvre and pelvic floor muscle contraction, respectively.⁷ Only maternal age in the first trimester was a significant risk factor for irreversible over-distension at rest (OR=1.12).⁷

Compared with women in the no injury group, more women who sustained injury to the LAM had descent of the BN (by Pelvic Organ Prolapse-Quantification System) at both 8 weeks and 12 months, and had prolapse symptoms at 8 weeks but not at 12 months.⁸ Pelvic Organ Prolapse Distress Inventory general and Urinary Distress Inventory obstructive subscale scores were higher at 8 weeks although no differences in PFDI and PFIQ were evident by 12 months.⁸

Discussion

In our study, the prevalence of antenatal SUI, UUI, and faecal incontinence during different trimesters was similar to that in previous Caucasian studies. About 50% of women remained continent. Higher maternal age was a risk factor for antenatal SUI; higher maternal BMI was a risk factor for faecal incontinence.

There was a 15 to 25% increase of HA during the third trimester compared with the first trimester. There was a 27 to 41% increase of HA in women during the third trimester compared with non-pregnant nulliparous women. There was significant descent of the BN, cervix, and ano-rectal junction as gestation advanced. Nonetheless, BN mobility

tended to be less compared with Caucasians. There are no longitudinal data to enable comparison of cervix and ano-rectal junction position during pregnancy.

Antenatal SUI was associated with a more caudal position of the BN and a larger HA. HA at rest was associated with prolapse symptoms and third trimester faecal incontinence.

After the first VD, 21.7% of Chinese women sustained LAM injury. This is comparable with previous studies although obstetric practices differed. Only operative VD was a risk factor. Forceps delivery has been reported to result in more trauma to the vagina compared with ventouse extraction. It appears that the same is true for the pelvic floor.

The prevalence of urinary incontinence after the first delivery was similar to the pooled prevalence of urinary incontinence (25.5%), SUI (12%), and UUI (3%) in previous Caucasian studies. At 12 months, VD (including operative VD) and antenatal SUI and UUI were risk factors for SUI; antenatal UUI and higher maternal BMI during the first trimester were risk factors for UUI. This suggests that the pathophysiology of urinary incontinence begins during pregnancy, before the onset of labour or delivery. Our study identified only greater maternal age to be associated with antenatal SUI and UUI. The prevalence of postnatal faecal incontinence (4%) was similar to previous reports, with its antenatal presence being the only risk factor. The effect of episiotomy on postnatal faecal incontinence remains controversial.

The BN position became lower during

pregnancy and at 8 weeks, but thereafter tended to revert to its position of the first trimester. Nonetheless, it remained significantly lower at 12 months. There were also more instances of BN displacement. At 8 weeks, there was more displacement in the VD group, but no difference between the VD and CS groups by 12 months.

Descent of the cervix remained significant in both VD and CS groups even at one year. In the 22 women who had no labour, the cervix was at a lower position. This suggests that descent of the cervix and hence the uterus occurs in women who carry a pregnancy beyond 35 weeks of gestation, and that the changes persist until at least one year after delivery. A pregnancy that reaches the third trimester, regardless of mode of delivery, has an effect on the pelvic floor postnatally. Further study is required to confirm if the changes persist after one year.

There was significant distal movement of the ano-rectal junction in both the VD and CS groups at 12 months. Episiotomy may not confer any protection against posterior compartment descent after delivery.

HA was persistently larger in the VD group than the CS group. The most important factor related to irreversible hiatal distension was LAM injury, followed by greater maternal age.

Partial or complete recovery of LAM was evident in 20.8% of women. This is similar to previous reports. By 12 months, the pelvic floor partially 'recovered'; the BN returned to a more proximal position from 8 weeks, although it remained significantly lower compared with its position during the first trimester.

More women in the LAM injury group had BN and anterior compartment descent at 8 weeks. This was compatible with a higher Pelvic Organ Prolapse Distress Inventory general subscale score (meaning more severe symptoms) at 8 weeks. Nonetheless, the overall PFDI and subscale scores in women with LAM injury were much lower, compared with another cohort of Chinese women with mild POP.⁹ Childbirth and LAM injury are important contributing factors to pelvic floor disorders, despite not related to symptoms at 12 months. This suggests that other factors contribute to the onset of pelvic floor disorders after delivery, eg antenatal SUI, UII, and faecal incontinence. Other pelvic floor changes or injury may also contribute to pelvic floor disorders, eg BN mobility, HA, concomitant anal sphincter injury.

Conclusions

Some symptoms of pelvic floor disorders begin during pregnancy. In our study, the prevalence of SUI, UII, faecal incontinence, and prolapse symptoms was 25.9%, 8.2%, 4%, and 7.6%, respectively, 12 months

after delivery. Pelvic floor anatomical changes were observed by translabial ultrasonography during pregnancy and until 12 months following delivery. There was increased pelvic organ mobility and increased HA after delivery. Irrespective of the mode of delivery, sustained pelvic floor anatomical changes were detected. Some symptoms of antenatal pelvic floor disorders and pelvic floor anatomical changes are related to symptoms of postnatal pelvic floor disorders. It may be beneficial to teach women pelvic floor exercises to reduce symptoms.¹⁰

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Results of this study have been published in References 4 to 8.

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