SUPPLEMENT 3

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Health and Medical Research Fund

Research Dissemination Reports

醫療衞生研究基金

研究成果報告

Cardiovascular disease
心血管疾病

Mental health
精神健康

Neurology
神經病學

Children's health
兒童健康

Reproductive health
生殖健康

Renal system
腎系統

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Supplement 3

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Health and Medical Research Fund

Research Dissemination Reports

CARDIOVASCULAR DISEASE

MENTAL HEALTH

NEUROLOGY

CHILDREN'S HEALTH

REPRODUCTIVE HEALTH

RENAL SYSTEM

Implementing evidence-based research in the era of COVID-19 and other global health challenges

RA Collins, TN Wei, AMY Tang, AOK Fan, AYK Fung

Research Office, Food and Health Bureau, Government of the Hong Kong Special Administrative Region

The Health Research Symposium 2021 (https://rfs.fhb.gov.hk/english/events/health_research_symposium_2021.html), organised by the Research Office of the Food and Health Bureau (FHB), was held on 23 November 2021 at the Hong Kong Academy of Medicine Jockey Club Building. The event, which marked the 10th anniversary of the establishment of the Health and Medical Research Fund (HMRF), provided a valuable platform to facilitate academic exchange, bringing together researchers, health service providers, and policy makers to share with a view to advancing science in health. This year's Symposium, for the first time, was held in hybrid mode with presentations being made both virtually and in person. The Symposium was attended by some 690 delegates (online and on-site). A total of 207 abstracts were published and 185 electronic posters were exhibited on the online platform, including 30 physical posters of COVID-19 studies, which were also exhibited on-site.

The Symposium opened with a short video clip describing the role and impact of the HMRF since its establishment in 2009 (https://www.youtube.com/watch?v=aY7ar21i_TA). In the video, many renowned local researchers highlighted the impact of HMRF in translating research findings into evidence-based policies and practices as well as in building up capacity in the research community.

Prof Sophia Chan Siu-chee, JP, the Secretary for Food and Health, officiated at the Opening Ceremony and warmly welcomed the keynote speakers, distinguished guests, and other participants to the Symposium. She noted the continuous growth and development of health and medical research in Hong Kong from 1994 to the present day and the unique position of the HMRF as the only local funding platform bridging the gap between benchtop research and clinical translation of research findings. Reflecting on the Symposium's theme of "Implementing evidence-based research in the era of COVID-19 and other global health challenges", Prof Chan stated that it aimed to understand how the challenges to the healthcare system resulting from the global COVID-19 pandemic could be mitigated through application of evidence-based research findings, which well reflected the HMRF's objectives.

FHB and HMRF have awarded a total of $513 million to support 67 COVID-19 research studies in the period April 2020 to August 2021. Many of these studies applied cutting-edge technologies to fill the knowledge gaps from bench to bedside to the community and to better prepare Hong Kong for the recovery stage of the COVID-19 epidemic. Prof Chan expressed her sincere thanks to each and every project team joining the fight against COVID-19.

FHB has committed extensive resources via the HMRF to support research on primary healthcare and non-communicable diseases, and many of these studies were being showcased at the Symposium. Several studies, for example, those on tobacco control and cancer screening, have had a positive impact on the quality of life and overall population health through informing health policy and decision-making as well as enhancing clinical practice and health services. The significant reduction in smoking and tobacco use in Hong Kong in recent years and the implementation of the Breast Cancer Screening Pilot Programme were just two examples of the application of findings from HMRF-funded research projects.

In closing, Prof Chan thanked the four keynote speakers, 24 local speakers, as well as Members of the Organising Committee and Review Panel of the Symposium, the Moderators of the Keynote and Parallel Sessions, and the notable experts who had participated in the HMRF video clip.

The following is a summary of the four keynote lectures:

Keynote lecture 1:
Innovation in design and implementation of primary care clinical trials to generate evidence for community therapeutics for COVID-19: The UK National Urgent Public Health PRINCIPLE Trial example

Prof Chris BUTLER
Professor of Primary Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, United Kingdom

Moderator: Prof Gabriel LEUNG, LKS Faculty of Medicine, The University of Hong Kong

Prof Butler presented a lecture that focused on an example of the rapid initiation and implementation of a novel clinical trial in the community, with

findings generated rapidly enough to be implemented during the COVID-19 pandemic. The platform randomised trial of treatments in the community for epidemic and pandemic illnesses (PRINCIPLE) was a multicentre, open-label, multi-arm, response-adaptive platform randomised controlled trial of community treatments for COVID-19. Prof Butler explained that PRINCIPLE operated under a master protocol that allowed the addition of further interventions into the trial while the trial was already in progress, so a new trial did not need to be started afresh each time an additional suitable intervention became available. This meant that existing controls could be used efficiently to give rapid answers about the effectiveness of new interventions. Response adaptive randomisation allowed the proportion of participants allocated to each intervention to be adjusted, based on emerging data from the trial to increase efficiency and shorten time to results. Apart from innovations in trial design, PRINCIPLE also resulted in innovation in trial implementation such as recruiting subjects through online methods as well as stimulating innovation in the evidence base where clinical alerts could be rapidly disseminated to clinicians to facilitate uptake of the latest findings.

Keynote lecture 2:
Infectious disease dynamics as a tool for decision makers during pandemics
Prof Steven RILEY
Professor of Infectious Disease Dynamics, School of Public Health, Faculty of Medicine, Imperial College London, United Kingdom

Moderator: Prof Gabriel LEUNG, LKS Faculty of Medicine, The University of Hong Kong

Many infectious diseases spread quickly from person to person. This makes them fundamentally different to other health threats because the amplitude of the threat they pose can accelerate exponentially, forcing leaders to make very difficult decisions in a short space of time with imperfect information. The emergence of SARS-CoV-2 illustrated clearly how leaders can reach very different conclusions. In his keynote presentation, Prof Riley gave examples of how the science of infectious disease dynamics could help reduce uncertainty when used to inform planning, responding, and learning from pandemics. As the world transitions from low to high immunity against SARS-CoV-2 with as little health impact as possible, Prof Riley noted that we have the opportunity to revise our plans to reduce greatly the impact of the next similar emergent virus.

Keynote lecture 3:
Introducing Implementation Science – Linking Research and Practice
Prof Per NILSEN
Professor of Health Medicine and Caring Science, Linkoping University, Sweden

Moderator: Prof YEOH Eng-kiong, The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong

Prof Nilsen provided an overview of the implementation science field and summarised knowledge about barriers to implementation and facilitators and strategies to overcome challenges to achieve a more evidence-based healthcare practice. Prof Nilsen explained that the word 'implement' was derived from the Latin 'implere', meaning 'to fulfil' or 'carry into effect'. This provided a basis for a broad definition of implementation science as the scientific inquiry into questions concerning how to carry intentions into effect. The intentions might be formulated in policies, clinical guidelines or other recommendations; they could be manifested in specific interventions; and they could relate to the use of research in decisions by individuals and organisations. The birth of implementation science was usually linked to the emergence of the evidence-based movement in the 1990s, which popularised the notion that research findings and empirically supported ('evidence-based') interventions should be more widely implemented in healthcare and other settings for improved health and welfare of populations. The field of implementation science has identified many challenges that exist when translating research into practice and investigated strategies to address these obstacles.

Keynote lecture 4:
Better Research and Better Uptake: Lessons from the Pandemic
Prof Paul GLASZIOU
Director, Institute for Evidence-Based Healthcare, Faculty of Health Sciences & Medicine, Bond University, Australia

Moderator: Prof YEOH Eng-kiong, The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong

In his presentation, Prof Glasziou pointed out that in previous pandemics, large-scale randomised trials were generally not set up in time. For the >2000 planned drug studies examining COVID-19 treatments, most had delivered little or no directly useful information. However, there were some important exceptions, with trials such as RECOVERY, REMAP-CAPS, and SOLIDARITY setting new standards and showing that a combination of old-fashioned randomisation, established clinical-trials networks and imaginative use of modern information technology could provide many rapid and reliable therapeutic answers. The speed of the RECOVERY trial was record-breaking: the period from protocol

to first patient recruitment was 9 days, with the 176 UK hospitals recruiting >12 000 hospitalised patients (15% of the UK COVID-19 cases at the time), and it provided clear answers within a few months on the effectiveness of dexamethasone and the ineffectiveness of hydroxychloroquine and lopinavir-ritonavir. Although the pandemic had seen remarkable trials for vaccines and drug treatments, much less had been done to evaluate the effects of public health and social measures (also known as non-pharmaceutical interventions). Only a handful of trials had been registered and few completed in time to influence practice and policy. Important lessons could be learned from examining both the successes and failures of research during this pandemic, both in research and in its implementation.

Sharing session on Research Fellowship Scheme

Four researchers supported by the Research Fellowship Scheme of the HMRF shared what they had learnt from their training programmes and how they had applied the skills acquired in their research projects. Dr KWOK Man-ki (School of Public Health, The University of Hong Kong) presented her work on "Income inequality and cardiovascular health in China". Dr Wendy HUANG Yajun (Department of Sport, Hong Kong Baptist University) presented her work on "Evaluation of uptake and impact of Physical Activity Guidelines for preschool children in Hong Kong". Dr Jessie LIANG Qiaoyi (Department of Medicine and Therapeutics, The Chinese University of Hong Kong) presented her work on "Establishing a best panel of stool-based detection for non-invasive colorectal neoplasm screening". Dr Jeremy TEOH Yuen-chun (The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong) presented his work on "The cost-effectiveness of Prostate Health Index for prostate cancer detection in Chinese men".

Award ceremony

The Symposium ended with an award ceremony to acknowledge outstanding research whose outcome has influenced health policy and practice in Hong Kong. The award recipients were as follows:

Outstanding project team on COVID-19 Research Awards

Principal applicant	Project title
Prof Benjamin John COWLING The University of Hong Kong	Nowcasting COVID-19 transmission dynamics, severity, and the effectiveness of control measures
Prof NG Siew-chien The Chinese University of Hong Kong	Role of gastrointestinal tract and gut microbiota in pathogenesis of coronavirus disease 2019 (COVID-19): a missing site for viral replication and transmission
Prof Leo POON Lit-man The University of Hong Kong	Molecular epidemiological study of COVID-19 cases in Hong Kong
Dr Gilman SIU Kit-hang The Hong Kong Polytechnic University	Whole-genome sequencing of COVID-19 cases in Hong Kong: development of a geo-phylogenetic database and characterisation of SARS-CoV-2 variants circulating in the community
Prof ZHANG Tong The University of Hong Kong	Grid monitoring of SARS-CoV-2 in sewage for an early-warning sign of community outbreak

The 10th HMRF Anniversary Awards

Breakthrough research

Principal applicant	Project title
Prof Alfred CHENG Sze-lok The Chinese University of Hong Kong	Elucidating gene regulatory networks of HBx isolated from novel HBV subgenotype/ mutants associated with increased risk of hepatocellular carcinoma
Prof Richard CHOY Kwong-wai The Chinese University of Hong Kong	Clinical application of an established target-enrichment massively parallel sequencing method for genetic screening and diagnosis of hereditary hearing loss patients with normal arrayCGH result
Prof JIN Dong-yan The University of Hong Kong	Roles of Epstein-Barr virus-encoded miR-BART microRNAs in viral persistence and transformation of epithelial cells

Public health, clinical and health services research

Principal applicant	Project title
Prof Cindy LAM Lo-kuen The University of Hong Kong	A study on health-related quality of life of patients with colorectal neoplasm and cost-effectiveness analysis of colorectal cancer screening in Hong Kong
Dr Wendy LAM Wing-tak The University of Hong Kong	A longitudinal study of psychosocial needs, physical symptom distress, and psychological distress of Chinese patients with colorectal cancer
Prof Vincent MOK Chung-tong The Chinese University of Hong Kong	Amyloid burden in poststroke dementia

Health promotion

Principal applicant	Project title
Prof LAM Tai-hing The University of Hong Kong	Youth Quitline: an accessible telephone-based smoking cessation hotline for youth
Prof Albert LEE The Chinese University of Hong Kong	Community development approach to create better health of our young generation within the settings of their daily life
Prof Vivian LEE Wing-yan The Chinese University of Hong Kong	Joint nursing-pharmacy health promotion programme for hidden elders in the community
Prof Agnes TIWARI Fung-yee The University of Hong Kong	Becoming parents: a hospital-community partnership to enhance transition to parenthood

Excellent Research Awards

Principal applicant	Project title
Prof Richard CHOY Kwong-wai The Chinese University of Hong Kong	Whole genome sequencing analysis of genetically undiagnosed euploid fetuses with increased nuchal translucency
Prof Ava KWONG The University of Hong Kong	Screening of founder and recurrent BRCA mutations in Hong Kong and US Chinese populations
Prof LAU Chak-sing The University of Hong Kong	Validation of a new definition of lupus low disease activity state (LLDAS): clinical and management implications
Prof LI Miao-xin Administering institution: The University of Hong Kong	Development of multivariate gene-based association analysis approaches for endophenotypes of complex diseases and their application to genetic mapping in a Chinese schizophrenia sample
Prof Winnie MAK Wing-sze The Chinese University of Hong Kong	Mobile self-compassionate programme for the promotion of public mental health: randomised controlled trial
Prof NG Ho-keung The Chinese University of Hong Kong	Molecular stratification of lower grade gliomas in routine practice in Hong Kong

Excellent Health Promotion Project Awards

Principal applicant	Project title
Ms Vicky CHUNG Wai-yin Life Education Activity Programme	"A Healthy Me Is Alcohol Free"- Helping students to avoid alcohol and develop a healthy life (健康不要「酒」)
Prof Angela LEUNG Yee-man The Hong Kong Polytechnic University	Changing the way we prevent diabetes: the use of mobile application

The Most Promising Young Researcher Awards

Principal applicant	Project title
Dr CHEUNG Ching-lung The University of Hong Kong	The role of vitamin D and bone metabolism in cardiovascular events risk, an interaction or mediation? An 11-year follow-up study
Prof LI Miao-xin Administering institution: The University of Hong Kong	Development of multivariate gene-based association analysis approaches for endophenotypes of complex diseases and their application to genetic mapping in a Chinese schizophrenia sample

Best Poster Awards

Principal applicant	Project title
Prof David HUI Shu-cheong The Chinese University of Hong Kong	Comparisons of exhaled air dispersion during high flow nasal cannula oxygen therapy and CPAP
Prof JIN Dong-yan The University of Hong Kong	Development and test of candidate attenuated vaccines for SARS-CoV-2
Prof Maria LUNG The University of Hong Kong	Clinical application of enumeration and genomic characterization for non-invasive detection and real-time monitoring of circulating tumor cells for esophageal carcinoma
Prof Joyce YOU Hoi-sze The Chinese University of Hong Kong	EGFR mutation-guided first-line target therapies of advanced non-small-cell lung cancer: a health economic analysis
Dr Derek CHEUNG Yee-tak The University of Hong Kong	Use of nicotine replacement therapy sample and brief smoking cessation advice for recruiting smokers to smoking cessation services and motivating quit attempts

To celebrate the 10th anniversary of the establishment of the HMRF and the 25th anniversary of the establishment of the Hong Kong Special Administrative Region, the recipients of the 10th HMRF Anniversary Award were invited to give a presentation at a series of Journal Clubs (https://rfs2.fhb.gov.hk/english/events/events.html) organised by the Research Office of FHB from January to May 2022. The talks focused on the new findings and their implementation into practices in clinical and community settings.

Dr Chui Tak-yi, JP, Under Secretary for Food and Health, thanked the keynote speakers, moderators, judges, speakers in the parallel sessions, and all those who had prepared posters about their work. He also congratulated all the awardees who had conducted world-class studies and proved themselves as leading experts in their own research area. Finally, Dr Chui thanked the Organising Committee and all the delegates for attending and looked forward to meeting them again at the next Health Research Symposium.

Reversibility of liver stiffness after tricuspid annuloplasty: a case-control study (abridged secondary publication)

KH Yiu *, WK Seto, MF Yuen, HF Tse

KEY MESSAGES

1. Patients who underwent combined tricuspid annuloplasty (TA) and left-sided heart valve surgery had higher baseline liver stiffness scores than those who underwent only left-sided heart valve surgery.
2. Liver stiffness significantly improved after TA.
3. Liver stiffness was associated with adverse outcomes in patients who underwent combined TA and left-sided valve surgery. Liver stiffness score of ≥15.5 kPa predicted the 1-year adverse outcome, with sensitivity of 72% and specificity of 62%.

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Introduction

Tricuspid regurgitation (TR) can cause irreversible liver damage. Nonetheless, the reversibility of liver stiffness is unknown after valve surgery, especially after combined tricuspid annuloplasty (TA). The aim of the present study was to evaluate the reversibility of liver stiffness after patients underwent valve surgery and to determine the prognostic role of liver stiffness in patients who underwent combined TA and left-sided heart valve surgery.

Methods

This was a prospective, observational, non-randomised study. Of 369 patients with moderate-to-severe valvular heart disease evaluated, 80 did not undergo surgery, 132 underwent left-sided heart valve surgery, and 157 underwent combined TA and left-sided heart valve surgery (Table 1). Baseline clinical, echocardiographic parameters and liver stiffness were recorded. Adverse outcome after valvular surgery was defined as the occurrence of heart failure requiring admission or all-cause mortality.

Results

Patients who underwent combined TA and left-sided heart valve surgery had the highest liver stiffness score, followed by patients who did not undergo surgery. Patients who underwent TA had higher percentage of combined mitral valve replacement and dual valvular surgery. However, nearly half of those who underwent only left-sided heart valve surgery underwent aortic valve replacement. Of 48 patients who died before 1-year follow-up liver stiffness examination, 21 (43.7%) did not undergo surgery, seven (14.6%) underwent only left-sided heart valve surgery, and 20 (41.7%) underwent combined TA and left-sided heart valve surgery.

Of 321 patients who had fibroscan test, 59 did not undergo surgery, 125 underwent only left-sided heart valve surgery, and 137 underwent combined TA and left-sided heart valve surgery. Liver stiffness improved significantly in patients who underwent combined TA and left-sided heart valve surgery but not in patients who underwent only left-sided heart valve surgery (Table 2). Liver stiffness tended to deteriorate in patients who did not undergo surgery. Improvement in liver stiffness indicated the reversibility of liver stiffness after TA.

After a median follow-up duration of 28 months in patients who underwent combined TA and left-sided heart valve surgery, 25 patients died and 25 patients developed heart failure that required hospital admission. Univariate Cox regression analysis demonstrated that adverse events were associated with age, diabetes mellitus, hypertension, New York Heart Association class III/IV, aortic valve replacement, and liver stiffness score (Table 3). Multivariable Cox regression analysis demonstrated that only age and liver stiffness score were independent predictors of adverse events (Table 3).

Receiver operating characteristic curve was generated to determine the discriminative ability of liver stiffness score in predicting adverse events at 1-year follow-up in patients who underwent combined TA and left-sided heart valve surgery. Liver stiffness score (area under the curve=0.69, P<0.01, Fig) was associated with adverse events and

TABLE 1. Baseline characteristics of patients

Variable	Patients without surgery (n= 80)*	Patients with only left-sided heart valve surgery (n=132)*	Patients with combined TA and left-sided heart valve surgery (n=157)*	P value (one-way ANOVA)
Age, y	65.6±11.3	62.2±8.7†	63.4±8.6	0.03
Male	26 (32.5)	65 (49.2)†	56 (35.7)‡	0.02
Diabetes mellitus	14 (17.5)	27 (20.5)	31 (19.7)	0.87
Hypertension	21 (26.3)	51 (38.6)	33 (21.0)‡	<0.01
Hyperlipidaemia	9 (11.3)	39 (29.5)†	26 (16.6)‡	0.02
Smoking	10 (12.5)	23 (17.4)	21 (13.4)	0.52
Atrial fibrillation	48 (60.0)	37 (28.0)†	128 (81.5)‡	<0.01
Chronic rheumatic heart disease	46 (57.5)	42 (31.8)†	118 (75.2)‡	<0.01
New York Heart Association class III/IV	21 (26.3)	43 (32.6)	77 (49.0)‡	<0.01
Left ventricular ejection fraction, %	59.7±10.2	56.8±9.1	56.3±8.7‡	0.02
Pulmonary artery systolic pressure, mmHg	43.0±12.7	36.0±11.5†	48.6±13.1‡	<0.01
Moderate-to-severe tricuspid regurgitation	49 (61.3)	17 (12.9)†	138 (87.9)‡	<0.01
Residual moderate-to-severe tricuspid regurgitation after surgery	-	4 (3.0)	13 (8.3)	0.06
Concomitant coronary artery bypass graft	-	21 (15.9)	12 (7.6)	0.03
Valvular surgery detail				<0.01
Mitral valve repair	-	36 (27.3)	28 (17.8)	
Mitral valve replacement	-	16 (12.1)	61 (38.9)	
Aortic valve replacement	-	61 (46.2)	13 (8.3)	
Dual valvular surgery	-	19 (14.4)	55 (35.0)	
Liver stiffness score, kPa	16.1±15.1	8.4±8.2†	18.2±14.5#	<0.01

* Data are presented as mean ± standard deviation or No. (%).
† P<0.05 compared with patients without surgery
‡ P<0.05 compared with patients with the other valve surgery or with TA

TABLE 2. Liver stiffness progression at 1-year follow-up

	Patients without surgery (n=59)	Patients with only left-sided heart valve surgery (n=125)	Patients with combined tricuspid annuloplasty and left-sided heart valve surgery (n=137)
Liver stiffness at baseline, kPa	11.9±9.5	7.7±6.5	17.1±13.3
Liver stiffness at follow-up, kPa	13.3±13.6	8.0±5.9	10.9±8.6
P value	0.25	0.59	<0.01

thus was used to calculate the optimal cutoff value for prediction of outcome. The cutoff value of ≥15.5 kPa predicted the 1-year adverse outcome, with sensitivity of 72% and specificity of 62%.

Discussion

Transient elastography is a reliable and non-invasive ultrasound-based technique for evaluating liver fibrosis according to the European Association for the Study of the Liver guidelines.[1,2] Patients with heart failure have increased liver stiffness as measured by transient elastography.[3] The degree of TR is associated with the degree of liver stiffness.[4] In the present study, baseline liver stiffness was higher in patients who underwent combined TA surgery than those who underwent only left-sided heart valve surgery. This finding indicates that the presence of moderate-to-severe TR may lead to liver function disorder and consequently increasing liver stiffness. Nonetheless, there was reversibility change and significant improvement in liver stiffness after combined TA surgery in those who underwent combined TA and left-sided heart valve

TABLE 3. Factors associated with long-term adverse events in patients who underwent combined tricuspid annuloplasty and left-sided heart valve surgery

Variable	Univariate		Multivariable	
	Hazard ratio (95% confidence interval)	P value	Hazard ratio (95% confidence interval)	P value
Age	1.07 (1.03-1.11)	<0.01	1.05 (1.00-1.09)	0.03
Male	1.48 (0.85-2.59)	0.17	-	
Diabetes mellitus	1.92 (1.05-3.53)	0.03	1.29 (0.66-2.51)	0.46
Hypertension	1.97 (1.09-3.58)	0.03	1.25 (0.61-2.56)	0.54
Hyperlipidaemia	1.45 (0.74-2.84)	0.27	-	-
Smoking	0.75 (0.30-1.88)	0.54	-	-
Atrial fibrillation	1.27 (0.60-2.71)	0.53	-	-
Chronic rheumatic heart disease	0.81 (0.43-1.52)	0.51	-	-
New York Heart Association class III/IV	1.89 (1.08-3.34)	0.03	1.65 (0.90-3.04)	0.11
Left ventricular ejection fraction	1.00 (0.97-1.04)	0.94	-	-
Pulmonary artery systolic pressure	1.01 (0.99-1.03)	0.48	-	-
Moderate-to-severe tricuspid regurgitation	2.11 (0.66-6.77)	0.21	-	-
Residual moderate-to-severe tricuspid regurgitation after surgery	1.18 (0.50-2.77)	0.71	-	-
Concomitant coronary artery bypass graft	1.43 (0.57-3.60)	0.45	-	-
Combined valvular surgery during tricuspid annuloplasty				
Mitral valve repair	0.49 (0.19-1.23)	0.13	-	-
Mitral valve replacement	0.88 (0.50-1.57)	0.67	-	-
Aortic valve replacement	2.50 (1.18-5.34)	0.02	1.25 (0.49-3.18)	0.65
Dual valvular surgery	1.12 (0.63-1.98)	0.70	-	-
Liver stiffness score	1.03 (1.01-1.04)	<0.01	1.02 (1.00-1.04)	0.038

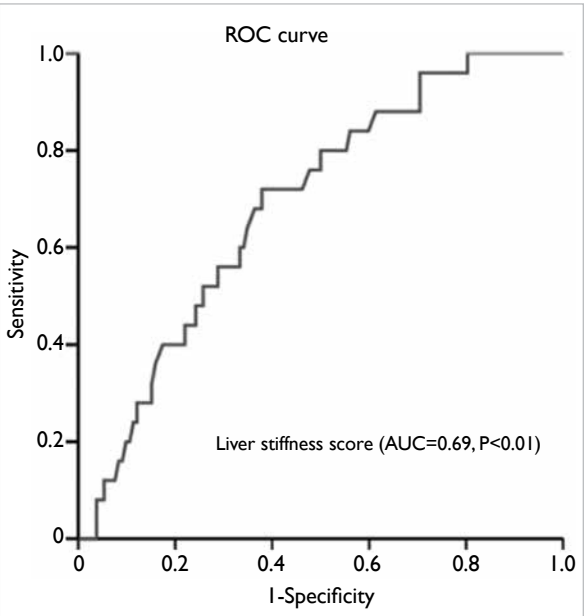

FIG. Receiver operator characteristic curve analysis to determine the accuracy of liver stiffness score associated with adverse events at the 1-year follow-up in patients who underwent combined tricuspid annuloplasty and left-sided heart valve surgery.

surgery but not in those who underwent only left-sided heart valve surgery. A possible explanation may be that moderate-to-severe TR is a major contributor of congestive hepatopathy, and liver congestion subsequently leads to increased liver stiffness. Another possible explanation may be that TA can reduce right-sided filling pressure that reflects the comprehensive status of right heart failure and liver congestion, which will relieve liver congestion and improve liver stiffness. In addition, liver stiffness tended to increase in patients who did not undergo surgery. This finding confirmed that liver dysfunction was common in patients with moderate-to-severe valvular heart diseases, and liver stiffness increased very quickly in patients who were denied surgery. Moderate-to-severe valvular heart diseases have a causative role in the development of liver dysfunction, and medical treatment alone is not sufficient to slow the progress. Therefore, combined TA and left-sided valve surgery is necessary for patients with moderate-to-severe valvular heart diseases to improve liver stiffness.

Liver stiffness can predict adverse outcomes in patients with heart failure.[3] In patients who

underwent combined TA and left-sided heart valve surgery, liver stiffness was associated with adverse outcomes during long-term follow-up. Combined surgical correction of valvular status is effective to prevent progression of liver stiffness in patients with moderate-to-severe valvular heart diseases.

At present, there are no guidelines that incorporate liver stiffness into risk stratification or that suggest the optimal time for combined TA and left-sided heart valve surgery. In the present study, liver stiffness score of ≥15.5 kPa predicted the 1-year adverse outcome, with sensitivity of 72% and specificity of 62%. Therefore, surgical intervention before increase of liver stiffness (liver congestion or right-sided filling pressure/central venous pressure[3,5]) may reduce adverse events. The cut-off value of ≥15.5 kPa may be used for pre-operative risk stratification.

Fibroscan examination should be evaluated frequently in patients with moderate-to-severe valvular heart diseases, especially in patients with moderate-to-severe TR. Liver stiffness should be considered an important indication for early TA surgery. Early identification of increased liver stiffness may improve risk stratification and clinical management.

Conclusion

There were reversibility change and significant improvement in liver stiffness among patients who underwent combined TA and left-sided heart valve surgery. Liver stiffness score can provide useful information to predict adverse outcomes in patients undergoing TA.

Acknowledgements

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Disclosure

The results of this research have been previously published in:

1. Chen Y, Liu YX, Seto WK, et al. Prognostic value of hepatorenal function by Modified Model For End-Stage Liver Disease (MELD) score in patients undergoing tricuspid annuloplasty. J Am Heart Assoc 2018;7:e009020.

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5. Millonig G, Friedrich S, Adolf S, et al. Liver stiffness is directly influenced by central venous pressure. J Hepatol 2010;52:206-10.

Circulating transforming growth factor-β and aortic dilation in repaired hearts: abridged secondary publication

YF Cheung *, PC Chow, EKF So, KW Chan

KEY MESSAGES

1. Compared with healthy controls, patients with repaired tetralogy of Fallot had significantly higher circulating levels of transforming growth factor-β1, metalloproteinase-2, and metalloproteinase-9, whereas patients with atrial switch operation or Fontan procedure had significantly higher circulating levels of metalloproteinase-2.
2. The circulating transforming growth factor-β1 level correlated significantly with metalloproteinase-9 and aortic sinus dimension.
3. The ascending aortic dimensions were significantly greater, and elastic properties were significantly worse in all patient groups, compared with healthy controls.
4. Aortic stiffness correlated positively with sinus dimension and negatively with indices of systemic ventricular systolic and diastolic deformation.

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Introduction

Progressive dilation of the aortic root is a concern in patients with congenital heart disease. Histological abnormalities of the aortic root as characterised by medionecrosis, fibrosis, and fragmentation of elastic fibres have been documented in different congenital heart lesions including tetralogy of Fallot (TOF) with or without pulmonary atresia, complete transposition of the great arteries (TGA), and functionally univentricular hearts.[1] Understanding of vascular remodelling in such patients may shed light on therapies for progressive aortic root dilation and the risk of its associated complications.

The transforming growth factor-beta (TGF-β) superfamily of cytokine is important in vascular remodelling.[2] Increased circulating level of TGF-β1 in patients with Marfan syndrome is associated with aortic root dilation and is predictive of cardiovascular events including aortic dissection, and the need for aortic root replacement.[3] Overexpression of TGF-β1 has been found in the ascending aorta of those with congenital heart disease.[4] We hypothesised that the circulating TGF-β1 level is increased and associated with aortic root dilation in patients with repaired hearts at risk of ascending aortopathy. We aimed to determine the circulating levels of TGF-β1 and their associations with aortic dilation and elastic properties in patients who underwent surgery for congenital heart disease.

Methods

This study was approved by the Institutional Review Board, and all patients (or parents of minors) gave written informed consent. Adolescent and adult patients with congenital heart disease who underwent repair for TOF, arterial or atrial switch operation for TGA, or Fontan procedure for functionally univentricular heart were recruited. Staff members of the hospital and their relatives and friends were recruited as healthy controls.

Vascular and echocardiographic assessments were performed using the Vivid 7 ultrasound machine after resting for >15 minutes. The size of the aortic root was measured at diastole from the parasternal long-axis view at four levels: annulus, sinus of Valsalva, sinotubular junction, and proximal ascending aorta. Severity of aortic regurgitation was assessed using Doppler colour flow mapping. Elastic properties of the ascending aorta were determined using M-mode echocardiography based on the parasternal long-axis view. Ascending aortic systolic and diastolic dimensions and systolic and diastolic blood pressures were measured to assess aortic elastic properties: strain, distensibility, and stiffness. The brachial-ankle pulse wave velocity was determined using an automated device.

Systemic ventricular function was assessed using tissue-Doppler and two-dimensional speckle tracking echocardiography. The peak systolic myocardial tissue velocity, peak early and late diastolic myocardial tissue velocities, early/late ratio, and myocardial isovolumic acceleration were calculated. For patients with Fontan procedure, the mean right and left-sided annular tissue velocities was used for analysis. Global longitudinal and

circumferential strain and strain rate of the systemic ventricle were assessed using two-dimensional speckle tracking echocardiography.

Total TGF-β1 level was measured using commercially available assay. Serum levels of metalloproteinase-2 (MMP-2) and metalloproteinase-9 (MMP-9) were also determined using enzyme-linked immunosorbent assay.

The aortic dimensions were measured by a single investigator to avoid inter-observer bias. Cardiovascular indices and circulating levels of TGF-β1, MMP-2, MMP-9 among different groups were compared using analysis of variance. Cardiovascular and blood indices between the control group and each of the patient cohorts were compared using unpaired Student's *t* test. Associations between TGF-β1 and MMP levels and those between TGF-β1 and aortic dimensions and elastic properties were assessed using Pearson correlation analysis. Multivariate analysis was performed to identify significant correlates of circulating levels of TGF-β1. A P value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS (Windows version 19; IBM Corp, Armonk [NY], US).

Results

Of 209 patients invited, 109 (66 males and 43 females) agreed to participate, whereas 36 (16 males and 20 females) healthy controls were recruited. Of the 109 patients, 46 underwent surgical repair for TOF (43 had TOF with pulmonary stenosis and 3 had TOF with pulmonary atresia), 21 underwent arterial switch operation for TGA, 15 underwent atrial switch operation for TGA, and 27 underwent Fontan procedure. The mean follow-up duration was 24.0±5.7 years.

Compared with controls, patients had significantly larger aortic annulus, sinus of Valsalva, sino-tubular junction, and proximal ascending aorta (all P<0.05, Table 1).

Compared with controls, all four patient groups had significantly lower aortic strain (all P<0.001) and aortic distensibility (all P<0.001), and greater aortic stiffness index (all P<0.001) [Fig.]. For all patient groups and controls, aortic sinus dimension correlated with aortic strain (r= -0.50, P<0.001), distensibility (r= -0.51, P<0.001), and stiffness index (r=0.48, P<0.001). However, the mean right and left brachial-ankle pulse wave velocities, which reflect the composite effects of central and peripheral arterial stiffness, were similar among different patient groups and controls.

Doppler assessment of systemic ventricular inflow revealed significantly lower peak systemic atrioventricular inflow velocity at early diastole, and lower peak systemic atrioventricular inflow velocity

TABLE 1. Demographic and clinical data and aortic root dimensions

Clinical variable	Patients with congenital heart disease who underwent				Healthy controls (n=36)*
	Repair for tetralogy of Fallot (n=46)*	Arterial switch operation for complete transposition of the great arteries (n=21)*	Atrial switch operation for complete transposition of the great arteries (n=15)*	Fontan procedure (n=27)*	
No. of males: females	23:23	12:9	13:2	18:9	16:20
Age at surgery, y	4.22±2.65	0.04±0.02	1.32±1.17	4.79±3.28	
Duration after repair, y	25.1±6.6	21.5±2.3	29.1±3.9	20.9±3.7	
Age at study, y	29.6 ±7.2	21.9±2.2	30.6±4.5†	26.1±4.6	26.9±7.4
Weight, kg	59.5±13.2	59.9±11.0	61.4±8.7	55.1±13.2	59.9±14.5
Height, m	1.6±0.1	1.7±0.1	1.7±0.0	1.6±0.1	1.6±0.1
Body mass index, kg/m^2	22.2±4.0	22.1±4.3	21.8±2.9	20.4±3.8	21.9±3.6
Body surface area, m^2	1.6±0.2	1.7±0.1	1.7±0.1	1.6±0.2	1.6±0.2
Systolic blood pressure, mmHg	113±10	119±12†	120±9†	110±13	107±10
Diastolic blood pressure, mmHg	65±5	68±8†	69±5	66±5†	62±6
Annulus, cm	2.21±0.41†	2.45±0.36†	2.40±0.34†	2.33±0.52†	1.90±0.23
Sinus of Valsalva, cm	3.36±0.37†	3.38±0.38†	3.32±0.33†	3.32±0.52†	2.63±0.35
Sino-tubular junction, cm	2.83±0.43†	2.96±0.45†	2.66±0.35†	2.66±0.50†	2.05±0.36
Ascending aorta, cm	2.80±0.44†	3.04±0.48†	2.76±0.41†	2.68±0.52†	2.11±0.39

* Data are presented as mean ± standard deviation

† P<0.05 compared with controls

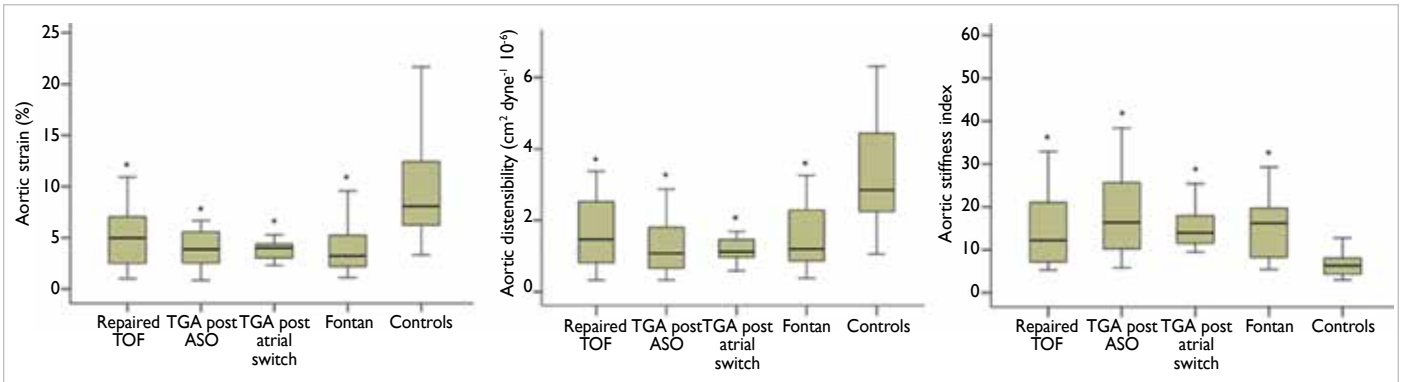

FIG. Aortic elastic properties in patients and controls.

at early/late diastole ratio in patients with Fontan procedure, compared with controls (both P<0.001, Table 2). Tissue Doppler echocardiography revealed evidence of worse systolic and diastolic function of the systemic ventricle in all patient groups, compared with controls, as demonstrated by the significantly lower systolic annular myocardial velocity, early diastolic annular myocardial velocity, and systemic ventricular myocardial isovolumic acceleration (all P<0.01). Strain imaging revealed primarily impairment of systolic and diastolic deformation in the longitudinal dimension of the systemic ventricle in all patient groups who had significantly reduced global systolic longitudinal strain and strain rate, and early and late diastolic strain rates (all P<0.001).

For all patient groups, aortic stiffness was negatively associated with systemic ventricular global longitudinal systolic strain (r= -0.37, P<0.001), systolic strain rate (r= -0.29, P<0.001), and early diastolic strain rate (r= -0.32, P<0.001) [Table 2]. Furthermore, aortic stiffness correlated negatively with systemic atrioventricular valvar tissue velocities including the systolic annular myocardial velocity (r= -0.34, P<0.001) and early diastolic annular myocardial velocity (r= -0.30, P=0.001).

The circulating levels of TGF-β1, MMP-2, and MMP-9 differed significantly among patient groups (P<0.001). Patients with repaired TOF had significantly higher circulating levels of TGF-β1 (P=0.005), MMP-2 (P=0.001), and MMP-9 (P<0.001), compared with controls (Table 2). Additionally, patients with atrial switch operation for TGA (p=0.034) or Fontan procedure (p<0.001) had significantly higher MMP-2 levels, compared with controls.

In patients, the circulating TGF-β1 level correlated significantly with MMP-9 (r=0.44, P<0.001) [but not MMP-2 level] and the size of the aortic sinus (r=0.22, P=0.035). There were no significant associations between circulating levels of TGF-β1, MMP-2, MMP-9, and indices of aortic elasticity.

Multivariate analysis revealed that the diagnosis of TOF was an independent correlate (β=6.82, P<0.001) of higher circulating TGF-β1 levels, after adjusting for other congenital heart disease categories, age, sex, aortic sinus dimension, and aortic stiffness index.

Discussion

Compared with healthy controls, patients with repaired TOF had significant higher circulating levels of TGF-β1, MMP-2, and MMP-9. Among patients with congenital heart disease, circulating TGF-β1 was associated with magnitude of aortic sinus dilation and positively correlated with MMP-9. Furthermore, increased aortic stiffness was associated with greater aortic root dilation and worse systemic ventricular systolic and diastolic function. Subgroup analysis showed increased TGF-β1, MMP-2, and MMP-9 levels in patients with repaired TOF, whereas MMP-2 levels also increased in patients with arterial switch operation or Fontan procedure. Circulating TGF-β1 level was associated with the size of aortic sinus. Thus, there is possible perturbation of the TGF-β1 signalling pathway with consequential increased MMP activities in the pathogenesis of aortopathy in patients with repaired TOF, and possibly in patients with TGA after atrial switch operation or Fontan procedure.

Our findings suggest that modulation of the TGF-β1 signalling pathway by angiotensin-converting enzyme inhibitor and angiotensin-receptor blocker[1,5] and MMP inhibition by doxycycline[1] may be useful in the management of congenital heart disease–related aortopathy, in particular in patients with repaired TOF.

Limitations to this study include the lack of a longitudinal trajectory of circulating TGF-β1 and

TABLE 2. Echocardiographic indices of systemic ventricular function

Systemic ventricular function variable	Patients with congenital heart disease who underwent				Healthy controls (n=36)*
	Repair for tetralogy of Fallot (n=46)*	Arterial switch operation for complete transposition of the great arteries (n=21)*	Atrial switch operation for complete transposition of the great arteries (n=15)*	Fontan procedure (n=27)*	
Systemic atrioventricular inflow Doppler indices					
Peak systemic atrioventricular inflow velocity at early diastole (E), cm/s	93.3±22.0	98.6±21.8	91.8±21.6	64.1±13.1†	97.3±20.2
Peak systemic atrioventricular inflow velocity at late diastole (A), cm/s	47.5±14.1	44.8±14.2	49.7±18.4	46.3±9.3	46.4±9.9
E/A ratio	2.1±0.7	2.5±1.2	2.0±0.6	1.5±0.4†	2.2±0.7
E deceleration time, ms	171.6±44.7	163.1±32.9	140.5±34.3†	174.8±51.8	162.8±31.3
Systemic atrioventricular annular tissue velocities					
Systolic annular myocardial velocity, cm/s	5.6±1.7†	5.9±2.2†	5.0±0.9†	3.7±0.9†	7.9±1.5
Early diastolic annular myocardial velocity (e), cm/s	10.6±3.1†	11.5±2.6	5.4±1.9†	5.9±1.4†	12.1±2.3
Late diastolic annular myocardial velocity (a), cm/s	4.5±1.9†	4.5±1.5†	4.7±1.8	4.2±1.3†	5.7±1.2
e/a ratio	2.8±1.2†	2.9±1.2†	1.4±0.5†	1.6±0.6†	2.2±0.6
E/e ratio	9.3±2.9	8.8±3.2	18.5±8.2†	10.4±2.7†	8.3±2.1
Myocardial isovolumic acceleration, m/s^2	0.6±0.3†	0.9±0.6†	0.7±0.4†	0.9±0.4†	1.2±0.4
Subpulmonary atrioventricular annular tissue velocities					
Systolic annular myocardial velocity, cm/s	6.0±1.5†	4.7±1.3†	4.9±1.3†	-	10.0±1.6
Early diastolic annular myocardial velocity (e), cm/s	7.8±3.2†	8.9±2.0†	7.2±2.8†	-	11.9±2.1
Late diastolic annular myocardial velocity (a), cm/s	4.1±1.9†	5.2±1.1†	3.7±0.9†	-	7.1±1.7
e/a ratio	2.5±1.9†	1.8±0.5	2.1±1.0	-	1.8±0.5
Myocardial isovolumic acceleration, m/s^2	0.4±0.4†	1.0±0.4†	0.9±0.8†	-	1.8±0.6
Systemic ventricular longitudinal deformation					
Global longitudinal strain, %	13.5±3.1†	13.0 ±2.4†	12.1±1.9†	12.1 ±2.6†	17.4±2.3
Systolic strain rate, /s	0.72±0.17†	0.69±0.14†	0.62±0.12†	0.69±0.11†	0.92±0.15
Early diastolic strain rate, /s	1.00±0.31†	1.16±0.22†	0.80±0.20†	0.81±0.28†	1.53±0.33
Late diastolic strain rate, /s	0.51±0.17†	0.48±0.12†	0.42±0.14†	0.51±0.21†	0.63±0.15
Systemic ventricular circumferential deformation					
Global longitudinal strain, %	16.7±3.57	14.5±4.2	13.5±5.4	15.1±3.0	16.3±2.4
Systolic strain rate, /s	0.94±0.20	0.92±0.22	0.81±0.23†	0.75±0.22†	1.01±0.21
Early diastolic strain rate, /s	1.65±0.43†	1.32±0.31	1.30±0.71	1.20±0.44	1.35±0.31
Late diastolic strain rate, /s	0.33±0.17†	0.37±0.15	0.38±0.23	0.41±0.18	0.43±0.17
Transforming growth factor-β1, ng/mL	38.7±9.1†	30.5±10.1	34.4±6.1	33.8±10.9	32.6±9.9
Matrix metalloproteinase-2, ng/mL	234.0±41.5†	219.2±37.8	227.1±36.0†	261.7±39.1†	204.3±33.2
Matrix metalloproteinase-9, ng/mL	325.0±151.0†	163.1±97.3	197.5±71.0	226.9±193.4	196.3±113.6

* Data are presented as mean ± standard deviation
† P<0.05 compared with controls

MMP levels, the small sample size, the modest correlation between aortic stiffness and indices of ventricular deformation and between circulating TGF-β1 level and aortic sinus dimension, the undetermined origin of the circulating TGF-β1 and MMP levels, and the difficulty in assessing anteriorly located aorta in a few patients with atrial switch operation for TGA. Nonetheless, our findings provide basis for medical therapies that target at the TGF-β1 signalling pathway and MMP activation in the management of aortopathy.

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Disclosure

The results of this research have been previously published in:

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Tai Chi versus brisk walking in reducing cardiovascular risk factors: a randomised controlled trial (abridged secondary publication)

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KEY MESSAGES

1. Tai chi was more effective than brisk walking in reducing levels of blood pressure, blood glucose, and glycated haemoglobin and in sustaining these positive effects at 9 months among Chinese adults with cardiovascular risk factors.
2. Exercise-only interventions without diet modification was not as effective as a combination of both in regulating blood lipid profiles and lowering the body mass index.
3. Tai Chi was effective in improving general health status and psychosocial wellbeing in adults with cardiovascular risk factors.

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Introduction

Cardiovascular disease (CVD) is the leading cause of death worldwide. Individuals with CVD risk factors have increased risks of death and developing CVD. This imposes a considerable health burden on society. Physical inactivity is a major risk factor for CVD. Staying physically active is recommended to lower the risk of CVD. Tai Chi has a higher compliance rate than other exercise types. Tai Chi is safe and requires similar energy expenditure as brisk walking.[1] This study aimed to evaluate the benefits of Tai Chi versus brisk walking in reducing CVD risk factors in patients with CVD risk factors.

Methods

This three-arm parallel randomised controlled trial was approved by the Joint Chinese University of Hong Kong – New Territories East Clinical Research Ethics Committee and the Kowloon West Cluster Research Ethics Committee. Informed consent was obtained from each participant. Participants were recruited from two outpatient clinics in Hong Kong. Inclusion criteria were those having hypertension and two to three CVD risk factors including diabetes, dyslipidaemia, overweight, physical inactivity, and smoking. Those were excluded if they had CVD, severe sensory or cognitive impairment, difficulty or inability to walk, or had participated in any Tai Chi programme within 6 months.

Based on previous studies,[2,3] 61 participants per arm would be needed to achieve a power of 80% at a significant level of 5%. Assuming a potential attrition rate of 25%, 246 participants were recruited and randomly allocated in a 1:1:1 ratio to Tai Chi, brisk walking, or usual care (n=82 per group).

Participants in the Tai Chi group practised 24-form Yang-style Tai Chi for 60 minutes twice a week for 3 months. The class was led by an experienced Tai Chi instructor. Participants were advised to self-practice at home for 30 minutes per day for ≥5 days a week. The weekly frequency and duration of self-practiced Tai Chi were recorded using a logbook. A compliance rate of ≥80% was considered as adherence.

Participants in the brisk walking group performed brisk walking (5 to 6 km/h) for 30 minutes every day for ≥5 days per week. A pulse oximetry was used to measure the heart rate during the brisk walking. Participants were advised to reach the individualised heart rate equal to moderate-intensity exercise based on their age. Their heart rate, frequency, and duration of brisk walking were recorded using a logbook. Participants were contacted by phone every week to encourage adherence to the prescribed frequency.

Participants in the usual care control group were advised to continue their routine care. All participants continued their prescribed medical treatments. Medications could be modified by their physicians according to their health conditions. Participants in the brisk walking and control groups were asked to participate in non-exercise community activities weekly for three months for social interaction.

Systolic and diastolic blood pressure (SBP and DBP) was measured in a seated position after resting for 10 minutes. Blood sample was collected after fasting for 8 to 10 hours using a finger-stick. Levels of total cholesterol, triglyceride, high-density

TABLE 1. Sociodemographic characteristics of participants

Characteristic	Control (n=82)*	Brisk walking (n=82)*	Tai Chi (n=82)*	P value
Sex				0.288
Male	38	42	32	
Female	44	40	50	
Age, y	65.13±10.22	63.22±11.11	64.70±7.59	0.422
Marital status				0.745
Single	6	12	7	
Married	56	54	57	
Separated	5	4	3	
Widower	15	12	15	
Job status				0.087
Full-time	25	25	11	
Part-time	8	10	11	
Retired	37	27	45	
Housewife	10	15	12	
Unemployed	2	5	3	
Financial support				
Self	38	38	26	0.090
Family	27	33	41	0.083
Allowance	17	11	15	0.454
Monthly income, HK$				0.064
≤10 000	46	38	51	
10 001-20 000	15	20	6	
20 001-30 000	8	6	6	
≥30 001	2	9	9	
Missing	11	9	10	
Living arrangement				0.792
Alone	13	12	10	
Live with others	69	70	72	
Housing				0.527
Public	67	64	61	
Private	15	18	21	
Religion				0.772
No	52	57	53	
Christianity	10	9	8	
Catholicism	3	4	2	
Buddihism	16	9	17	
Taoism	1	3	2	
Regular exercise				0.134
Yes	51	60	62	
No	31	22	20	
Smoking habit				0.292
Smokers	13	5	8	
Ex-smokers	13	12	10	
Non-Smokers	56	65	64	
Drinking habit				0.686
Drinkers	19	16	19	
Ex-drinkers	2	6	6	
Non-drinkers	61	60	57	
Change of diet in last 3 months				0.936
Yes	19	20	21	
No	63	62	61	
Weekly exercise frequency, days	3.14±2.89	3.33±2.84	3.79±2.93	0.338
Mean duration of exercise, mins	34.35±44.08	42.65±40.67	32.93±28.23	0.219
Hypertension				0.999
Yes	82 (100.0)	82 (100.0)	82 (100.0)	
No	0 (0.0)	0 (0.0)	0 (0.0)	
Type 2 diabetes mellitus				0.385
Yes	50 (61.0)	51 (62.2)	43 (52.4)	
No	32 (39.0)	31 (37.8)	39 (47.6)	
Dyslipidaemia				0.286
Yes	56 (68.3)	48 (58.5)	47 (57.3)	
No	26 (31.7)	34 (41.5)	35 (42.7)	

* Data are presented as mean ± standard deviation or No. (%) participants

lipoprotein, low-intensity lipoprotein, fasting blood sugar, glycated haemoglobin were assessed. The perceived stress scale was used to measure perceived stress level.

Data were collected at baseline and at 3, 6, and 9 months after intervention. Analyses were conducted using SPSS (Windows version 23; IBM Corp, Armonk [NY], US). A P value of <0.05 was considered statistically significant. The three groups were compared using Chi-squared test or one-way analysis of variance. Generalised estimating equation models were used to compare the differential changes of the outcomes across time and between the three groups based on the intention-to-treat principle.

Results

A total of 246 participants were recruited. The three groups were comparable in terms of baseline characteristics (Table 1). Treatment adherence was 90% in the Tai Chi group and 88% in the brisk walking group.

Compared with the control group, the Tai Chi group achieved greater reduction in SBP and DBP levels at 3 months and 9 months (all P<0.005, Table 2). There was no significant difference in the changes in SBP and DBP levels at all three time points between the brisk walking and control groups. The reduction in SBP and DBP levels was greater in the Tai Chi group than in the brisk walking group at 3 months (all P<0.001) and 9 months (all P<0.005).

Significant reduction in the fasting blood sugar level was observed at 9 months in the Tai Chi group only (P=0.002). Significant reduction in glycated haemoglobin level was observed at 9 months in the Tai Chi (P=0.002) and brisk walking (P=0.028) groups, compared with the control group. The Tai Chi group showed greater reduction in the levels of fasting blood sugar and glycated haemoglobin at 6 months (all P<0.007) and 9 months (all P<0.003), compared with the brisk walking group. Tai Chi group showed a significant increase in high-density lipoprotein level at 3 months (P=0.013), compared with the control group.

Compared with the control group, the Tai Chi group achieved a greater reduction of perceived stress levels at 6 months (P=0.022) and 9 months (P=0.005). The reduction in perceived stress at 9 months was greater in the Tai Chi group than in the brisk walking group (P=0.027).

Discussion

From baseline to 9 months, Tai Chi achieved a reduction of 12.4 mmHg in SBP and a reduction of 4.8 mmHg in DBP. On a population level, even a small reduction of 2 mmHg in DBP would result in a 17% decrease in hypertension prevalence and a 6% reduction in the risk of coronary heart disease,[4]

TABLE 2. Generalised estimating equation models comparing control and intervention groups across time

	Controls (n=82)*	Brisk walking × time (n=82)*	P value	Tai Chi × time (n=82)*	P value
Systolic blood pressure, mmHg					
3 months	-2.02 (-6.82 to 2.78)	5.00 (-1.79 to 11.80)	0.15	-10.28 (-16.47 to -4.09)	0.001
6 months	-2.32 (-7.35 to 2.70)	2.11 (-4.51 to 8.72)	0.53	1.19 (-6.03 to 8.41)	0.75
9 months	0.87 (-4.79 to 6.54)	3.37 (-3.72 to 10.47)	0.35	-13.33 (-20.53 to -6.12)	<0.001
Diastolic blood pressure, mmHg					
3 months	1.54 (-1.66 to 4.73)	2.08 (-2.22 to 6.38)	0.34	-6.56 (-10.66 to -2.47)	0.002
6 months	2.26 (-0.55 to 5.07)	-1.04 (-4.90 to 2.82)	0.60	-1.04 (-5.19 to 3.10)	0.62
9 months	1.41 (-1.82 to 4.63)	-1.16 (-5.38 to 3.07)	0.59	-6.45 (-10.84 to -2.05)	0.004
Fasting blood sugar, mmol/L					
3 months	0.36 (-0.071 to 0.80)	-0.032 (-0.92 to 0.28)	0.30	-0.20 (-0.70 to 0.31)	0.44
6 months	0.046 (-0.36 to 0.45)	-0.043 (-0.68 to 0.59)	0.89	-0.25 (-0.72 to 0.22)	0.30
9 months	0.26 (-0.13 to 0.64)	-0.18 (-0.96 to 0.59)	0.65	-0.72 (-1.18 to 0.26)	0.002
Glycated haemoglobin, %					
3 months	0.006 (-0.13 to 0.14)	-0.17 (-0.39 to 0.054)	0.14	-0.021 (-0.23 to 0.18)	0.84
6 months	0.067 (-0.11 to 0.24)	-0.19 (-0.45 to 0.07)	0.15	-0.24 (-0.49 to 0.014)	0.06
9 months	0.087 (-0.072 to 0.25)	-0.29 (-0.54 to 0.032)	0.028	-0.39 (-0.64 to -0.15)	0.002
Total cholesterol, mmol/L					
3 months	-0.21 (-0.55 to 0.13)	-0.25 (-0.72 to 0.22)	0.30	0.12 (-0.29 to 0.54)	0.57
6 months	-0.14 (-0.47 to 0.19)	-0.30 (-0.76 to 0.16)	0.20	-0.11 (-0.52 to 0.31)	0.62
9 months	-0.26 (-0.58 to 0.72)	-0.27 (-0.75 to 0.21)	0.27	-0.27 (-0.68 to 0.15)	0.21
Triglycerides, mmol/L					
3 months	-0.14 (-0.37 to 0.090)	-0.056 (-0.34 to 0.23)	0.70	0.11 (-0.17 to 0.39)	0.44
6 months	-0.12 (-0.32 to 0.070)	-0.052 (-0.35 to 0.25)	0.73	0.088 (-0.16 to 0.34)	0.49
9 months	-0.059 (-0.23 to 0.12)	-0.12 (-0.39 to 0.14)	0.36	0.12 (-0.14 to 0.39)	0.36
High-density lipoprotein, mmol/L					
3 months	-0.076 (-0.17 to 0.021)	-0.021 (-0.16 to 0.12)	0.77	0.16 (0.035 to 0.29)	0.013
6 months	-0.036 (-0.14 to 0.068)	-0.03 (-0.20 to 0.14)	0.73	0.090 (-0.05 to 0.23)	0.21
9 months	0.00 (-0.092 to 0.093)	-0.039 (-0.19 to 0.11)	0.60	0.091 (-0.041 to 0.22)	0.18
Low-density lipoprotein, mmol/L					
3 months	-0.077 (-0.32 to 0.16)	0.062 (-0.25 to 0.37)	0.69	-0.050 (-0.34 to 0.25)	0.74
6 months	-0.14 (-0.39 to 0.11)	0.070 (-0.27 to 0.41)	0.69	-0.17 (-0.48 to 0.15)	0.30
9 months	-0.32 (-0.60 to -0.042)	0.091 (-0.25 to 0.43)	0.60	-0.21 (-0.54 to 0.13)	0.22
Body mass index, kg/m^2					
3 months	-0.25 (-0.44 to -0.068)	0.12 (-0.17 to 0.41)	0.42	0.063 (-0.18 to 0.30)	0.61
6 months	-0.57 (-0.86 to -0.29)	0.14 (-0.22 to 0.51)	0.44	0.13 (-0.24 to 0.50)	0.49
9 months	-0.60 (-0.85 to -0.36)	0.08 (-0.26 to 0.42)	0.65	0.13 (-0.31 to 0.57)	0.56
Waist circumference, cm					
3 months	0.32 (-0.80 to 1.43)	-1.07 (-3.15 to 1.01)	0.31	-1.14 (-2.67 to 0.39)	0.14
6 months	-1.48 (-2.61 to -0.34)	0.39 (-1.27 to 2.06)	0.65	0.26 (-1.27 to 1.79)	0.74
9 months	-1.79 (-2.93 to -0.65)	0.46 (-1.27 to 2.20)	0.60	-0.54 (-2.18 to 1.10)	0.52
Perceived stress					
3 months	0.67 (-0.77 to 2.11)	-1.85 (-3.77 to 0.073)	0.06	-1.69 (-3.78 to 0.41)	0.11
6 months	0.64 (-0.78 to 2.05)	-1.04 (-3.03 to 0.96)	0.31	-2.30 (-4.28 to -0.33)	0.022
9 months	0.53 (-1.21 to 2.26)	-1.14 (-3.39 to 1.12)	0.32	-3.22 (-5.48 to -0.97)	0.005

* Data are presented as B (95% confidence interval)

whereas a reduction of 2 mmHg in SBP would result in 10% lower stroke mortality and about 7% lower mortality from ischaemic heart disease or other vascular causes.[5] These highlight the clinical significance of small reduction in resting blood pressure. However, our findings did not support the effect of brisk walking on blood pressure. These were in contrast to those of previous study that CVD risk decreases incrementally with high levels of walking (in terms of frequency, duration, distance, and energy expenditure, particularly high walking intensity or pace).[3] The differences might be due to over-reporting of walking activity by our participants or walking at a slower pace or shorter duration than prescribed. Tai Chi was more effective than brisk walking in reducing blood pressure among Chinese adults with CVD risk factors.

Both Tai Chi and brisk walking decreased levels of fasting blood sugar and glycated haemoglobin but did not improve levels of total cholesterol, triglyceride, low-intensity lipoprotein, and body mass index. These findings may be due to implementation of exercise-only interventions, without any weight-reduction intervention or diet modification. A combination of both diet medication and exercise intervention is more effective in regulating blood lipid profiles and weight reduction.

Among physically inactive adults, chronic psychosocial stress may contribute to the development of cardiometabolic and emotional diseases. The reduction in perceived stress was significantly greater in the Tai Chi group than in the control group. Tai Chi is effective in promoting psychosocial well-being and general health status among adults with CVD risk factors.

One limitation to the study was reliance on the self-reported exercise logbook. Participants may have performed interventions incompletely or incorrectly at home, particularly those in the brisk walking group. The use of an objective method to monitor the intervention such as pedometer or accelerometer is recommended.

Conclusion

Preventive strategies must be implemented to minimise the risk factors for CVD development. Both Tai Chi exercise and brisk walking have substantiated positive effects on reducing levels of blood pressure, blood glucose, and glycated haemoglobin, as well as on improving psychosocial well-being.

Funding

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Disclosure

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Cognitive behavioural therapy for adherence and sub-clinical depression in type 2 diabetes: a randomised controlled trial (abridged secondary publication)

A Au *, H Nan, R Sum, F Ng, A Kwong, S Wong

KEY MESSAGE

Cognitive-behavioural intervention for both adherence and depression significantly reduced depressed symptoms and diabetes mellitus (DM)–related distress as well as significantly increased glycaemic control and self-care. Higher effect sizes were observed for DM-specific measures with reference to glycaemic control, adherence, and DM-related distress. The significance of distress and the possibility of reducing it highlighted the importance of managing emotions in diabetes care.

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Introduction

In patients with diabetes mellitus (DM), even subclinical levels of depressive symptoms and emotional distress are associated with non-adherence to DM self-care. Cognitive-behavioural intervention (CBT) has been reported to be effective in treating depression, but its effect on glycaemic control and adherence is mixed. Treating depression alone may not result in changes in health behaviours and therefore a more integrative approach is necessary.[1] In patients with unipolar depression and uncontrolled type-2 DM, CBT for both adherence and depression has shown to be effective in improving adherence, depression, and glycaemic control.[2-5] We aimed to evaluate the efficacy of CBT for adherence and depression in reducing depressive symptoms and enhancing glycaemic control as well as in reducing DM-specific distress and enhancing adherence, self-care, perceived control, and health-related quality of life among adults with DM and subclinical depression.

Method

Community-dwelling patients with type-2 DM aged <70 years who were independent in activities of daily living (based on the Barthel Index) and scored 5 to 9 on the Patient Health Questionnaire Depression Scale were invited to participate. Those excluded were those who had major depression within the past 6 months, a lifetime history of other psychiatric disorders (including psychosis, schizophrenia, and bipolar affective disorder), serious suicidal risk, alcohol or substance abuse, medical illnesses with prognosis of <12 months to live, already taking medication or receiving psychological intervention for depressive disorders or related symptom, bedridden, memory loss, not being able to understand or communicate in Chinese language, or refusing to give consent.

Participants were randomly assigned to receive CBT for adherence and depression or enhanced treatments as usual. Based on the protocol in a study,[1] all participants received one session of brief discussion about patient-generated reasons for engaging in treatment and eleven cognitive and behavioural steps to adherence (eg, setting a daily schedule, having reminder cues for medications, getting to appointments). A psycho-education pamphlet was distributed, with four components: nutrition, preventing complications and self-care, emotion and stress management, and lifestyle.

The CBT consisted of eight weekly sessions of face-to-face group intervention followed by four weekly consolidation individual telephone calls and three monthly individual follow-up calls. Each group session lasted for about 2 hours. The four module themes included introduction to CBT for adherence and depression and self-care, behavioural activation and activity scheduling, thought monitoring and cognitive restructuring, and problem solving, relaxation training, and relapse prevention. The

four weekly individual telephone calls (each lasted for about 20 minutes) were used to review and consolidate the four module themes. Participant was asked to monitor, review, and revise each component to help incorporate them in the daily routines. The three monthly follow-up calls were delivered in the same manner to review and consolidate the four module themes.

In the enhanced treatments as usual group, participants received 20-minute weekly individual phone calls for 3 months, followed by three monthly calls. Simple and general verbal support was given to remind participants of referring to the psycho-education package and adherence issues. Regular bi-weekly supervision was carried out, subjected to participant approval. About 60% of sessions were recorded. Fidelity ratings of 90% to 95% were obtained by independent raters.

Participants were assessed at baseline, upon completion of intervention, and at 24 weeks. The 21-item Beck Depression Inventory was used to assess cognitive, behavioural, and somatic symptoms of depression. For glycaemic control, the haemoglobin Alc level was calculated by averaging fasting and the three-hour post-prandial (after a 300-calorie breakfast) blood glucose levels obtained by finger-pricking using Accu Chek. Secondary outcomes included the summary of DM Self-care Activities Questionnaire, DM Distress Scale, Perceived Control Scale, Medication Possession Ratio, and 20-item Short-Form Health Survey.

A previous study on CBT reported a large effect size (Cohen's d >0.6) for both depression and adherence. Assuming 20% attrition and 5% type I error, we estimated that 84 patients would be needed per arm to provide 80% power to detect a medium effect size (Cohen's d=0.33) on depression and adherence.

Results

A total of 168 participants were recruited and randomly allocated at baseline. Of them, 132 completed the assessment at 24 weeks, with the overall attrition rate being about 21%. Reasons for withdrawal included admission to hospital/residential care, other medical appointments, and change of commitment of caregivers. The two groups were comparable in terms of baseline characteristics.

In repeated-measures ANCOVA (group × time) tests, the effect sizes in terms of eta-squared ranged from 0.022 to 0.076. The reliability of scales ranged from 0.72 to 0.87. The intervention effects for the Beck Depression Inventory and glycaemic control were significant (Table). The strongest effect sizes were found for DM-specific distress followed by the summary of DM Self-care Activities Questionnaire and the Morisky Medication Adherence Scale. Higher effect sizes were obtained for DM-specific measures.

Discussion

CBT for adherence and depression was effective in enhancing adherence and reducing depressive symptoms. Higher effect sizes were observed for DM-specific measures including the reduction of

TABLE. Repeated-measures ANCOVA (group × time) tests for outcomes at baseline, upon completion of intervention, and at 24 weeks

Variable	Cognitive-behavioural intervention for adherence and depression			Enhanced treatments as usual			α	*F*	P value	ηp²
	Baseline	Upon completion of intervention	24 weeks	Baseline	Upon completion of intervention	24 weeks				
Beck Depression Inventory	13.29±8.30	8.54±5.59	8.63±5.49	12.10±6.31	10.54±5.17	10.92±4.93	0.87	9.23	0.029	0.053
Glycaemic control	7.22±0.79	6.52±0.69	6.81±0.74	7.17±0.67	6.86±0.77	7.09±0.65		7.79	0.001	0.108
Summary of Diabetes Mellitus Self-care Activities Questionnaire	33.31±7.12	39.93±3.99	38.08±4.81	32.35±5.82	35.17±3.85	34.70±3.72	0.85	12.92	0.001	0.167
Diabetes Mellitus Specific Distress Scale	35.57±16.74	24.58±9.79	28.77±10.40	31.96±13.03	29.59±9.96	30.18±10.83	0.83	6.19	0.003	0.091
Perceived Control Scale	5.81±1.08	6.43±1.05	6.36±0.88	5.85±1.38	5.78±1.01	5.88±1.17		6.07	0.003	0.090
Medical Possession Ratio	9.48±0.27	9.78±0.19	9.72±0.27	9.41±0.31	9.62±0.24	9.54±0.24		6.23	0.003	0.088
20-item Short Form Health Survey	48.14±10.59	50.22±12.76	50.23±13.60	46.84±9.10	46.70±8.73	47.18±8.87	0.86	4.28	0.016	0.060
Mental component	44.79±8.45	49.86±6.28	50.90±4.99	46.25±10.83	45.75±6.56	47.17±6.40	0.87	6.30	0.002	0.089
Body mass index	24.84±3.71	24.50±3.66	24.41±3.56	25.84±3.71	24.71±3.82	24.66±3.79		4.18	0.017	0.057
Systolic blood pressure	132.95±7.32	131.55±7.19	131.09±7.05	131.62±5.96	130.95±6.57	130.78±6.60		4.30	0.015	0.063
Diastolic blood pressure	76.69±3.68	76.64±3.59	75.72±3.51	75.95±3.46	75.63±3.79	75.46±3.80		3.87	0.023	0.057

DM-specific distress and the gains in glycaemic control, self-care, and adherence. Although sub-clinical depression is important in the context of adherence, the underlying construct of emotional distress is a core construct to link subclinical depression and even major depressive disorder in the understanding of management of diabetes.[6] The concept of distress marks the continuous struggle of the person living with a chronic illness. Reducing the diabetes distress highlights the importance of managing emotions in regular diabetes care. Thus, regular screening and monitoring of levels of distress and depressive symptoms among particular patients with DM in the community is warranted. Enhanced medical-social collaboration between the hospital and community settings may provide regular psycho-social support to DM patients with distress and depressive symptoms.

Our study provides a basis for determining the effectiveness of the support group interventions in the healthcare system (in terms of reducing admission, hospitalisation, and healthcare cost) and in patients (in terms of reducing complications and enhancing self-care). Further research on diverse age-groups (including younger participants) is warranted.

Conclusion

CBT for adherence and depression was effective in enhancing adherence and reducing depressive symptoms. Higher effect sizes were observed for DM-specific measures.

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Decision-making experiences of family carers of older people with moderate dementia towards community and residential care home services: a grounded theory inquiry (abridged secondary publication)

LPL Low *, DTF Lee, LW Lam

KEY MESSAGES

1. The burden of care for family carers of dementia elders can be relieved by formal services.
2. Types of decisions carers made were mainly the day-to-day management of distressing symptoms of moderately severe dementia.
3. Decision-making experiences included options perceived by family to meet the dementia caring needs, decisions about service options, and the degree to which the service decision has met needs.
4. 'Contested provocation' provided an understanding of the struggles, disputes, and battles carers contended with during the course of caring for elders with dementia while using formal services.

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Introduction

Caring and supporting older people with dementia is a public health priority. The number of family carers to provide dementia care is diminishing in the future.[1] Carers bear considerable psychological, practical, and economic challenges as the disease advances over time. The burden of care can be relieved by formal services.

This study retrospectively examined the decision-making experiences of family carers of elders with dementia towards the use of community care services (CCS) and residential care services (RCS). CCS and RCS play an important role in supporting older adults with dementia and their family members. The objectives were: (1) to explore the decision-making experiences and types of decisions families make for their elders with dementia, (2) to identify the extent to which CCS and/or RCS have helped families to meet their own needs and challenges when serving their elders with dementia, (3) to explore factors influencing the families decision on CCS and/or RCS for their elders with dementia, (4) to explore the families' perceived needs of elders with dementia and the degree to which CCS and/or RCS have met those needs, (5) to examine specific experiences and circumstances that have influenced the family to make a decision to continue using CCS and/or RCS for elders with dementia, (6) to examine the roles families play and the influences they have in shaping the elders' lives when they use CCS and/or RCS, and (7) to develop a theoretical framework for the decision-making experiences of family members towards CCS and/or RCS.

Methods

A 2-year constructivist grounded theory design[2] was used to collect the data. For CCS, we approached one district elderly community centre, two neighbourhood elderly centres, and four day-care centres for the elderly. For RCS, we approached three subsidised care and attention homes and one self-financed care and attention home. We did not approach private aged homes. Purposive sampling was used to select family carers of elders with moderate dementia. Screening for dementia was based on a confirmed diagnosis of dementia and a Mini-Mental State Examination score of 11-20 or an Abbreviated Mental Test score of <7. We interviewed 94 family carers (50 from district elderly community centre / neighbourhood elderly centre and 44 from day-care centre for the elderly) who used CCS and 51 family carers who used RCS (Table 1). An interview guide was used. Data were analysed using constant comparative analysis methods. The quality criteria addressed the credibility, resonance, and usefulness of the findings.

Results

Types of decisions warranting decision making to take care

Types of decisions made by the family carers for the elders was a generic theme identified (Table 2). It was not unusual to hear making decisions associated with managing the distressing symptoms of moderately severe dementia. Trying to engage in any form of discussion and decision making with older people required time and patience.

Options perceived by family carers to meet the caring needs

Making decisions on behalf of the elders was to meet their current needs and to make plans for future needs. When asked about the extent to which services could help the participants to meet their needs and help them take care of their elders, the usual responses were applying for and being put onto the waiting list for CCS and RCS. Approaching these services meant that they could have access to professional advice from the social worker about current situation, plan what to do, and be told about what could happen, and actions that could be needed. Other options to help them relieve the caring needs included giving up one's paid employment and becoming a full-time carer, and exploring other services to temporarily relieve them while still caring for the elders at home.

TABLE 1. Characteristics of family carers in district elderly community centre / neighbourhood elderly centre, day care centre for the elderly, and residential care services

Postoperative day	No. of family carers		
	District elderly community centre / neighbourhood elderly centre	Day care centre for the elderly	Residential care services
Age range, y			
35-59	16	23	27
60-64	10	9	12
≥65	24	12	12
Relationship with older person			
Daughter/son	27	24	38
Wife/husband	20	15	4
In-law (daughter, sister, cousin)	2	5	6
Other close relation (niece)	1		1
Grandchildren			2
Caring experience, y			
1-5	45	28	33
6-15	5	16	16
>20			2

Making decisions about service options

A lot of emotions were expressed when asked about what would be considered in deciding to use CCS and/or RCS. This highlighted the need to acknowledge the carers own needs and help them overcome the challenges of being a carer. There were well-intended carers who were willing to take care of their elders at home, but caring on a daily basis was more than they had expected and could cope with. Some carers tried the CCS first and then tried RCS when the circumstances at home with the elder and/or family carer changed. Carers were explicit about the reasons for using the services. Once a decision was made to consider CCS and/or RCS, carer emotions moved from one of guilt and a sense of abandonment to one of gradually acknowledging their own needs and challenges of caregiving. Carers provided specific experiences and circumstances that led to the need to consult services. There was a lack of service options for carers, especially when they faced with difficult circumstances at home that required immediate attention.

Degree to which the service decision has met needs

Carers may involve the elders in decision-making for using CCS and/or RCS. When elders were consulted, the decision was a more contented and informed one. For CCS, decision making about the future care and institutionalisation was still far away. Services that enable the elders to be occupied in the

TABLE 2. Types of decisions family carers made for their older relative with dementia

Healthcare and illness decisions	Hospitalisation, seeing family doctor, deteriorating health issues
Medical decisions	Medical follow-up, medical/psychiatric consultations, medications, health, and well-being
Everyday decisions	Activities of daily living relating to what to eat, when to exercise, who bath them, which pastime activities, where to eliminate; personal safety, and home alone
Lifestyle decisions	Personal habits, attitude changes, healthy choices, conduct, and behaviour
Future care decisions	Unknowing how to plan for the future, unsure of what could happen, learning to live for each day, managing residents and staff relations, options other than institutions

day helped ease the carers' mind. Data highlighted expressions of relief and more free time. Carers stated that they continued to make decisions for the elders. Some carers shared that the elders agreed to go into aged homes when they became cognitively unable to make decisions and incapable of caring for themselves. Therefore, the degree to which the selected service met the elders' needs should be accounted for how involved they were in making the decision. Another consideration was whether the carer was involved in the services used by the elders. Some wanted to be more engaged in the service provision and delivery of care. It is unclear what else they could do and contribute however willing. The importance of recognising the potential roles carers can play, and how they can continue to contribute to their care after institutionalisation of elders should be explored further.

Contested provocation

Contested provocation describes the struggles, disputes, and battles family members contended during the course of caring for the older relatives prior to making the decision to use CCS and eventually RCS (Fig). Making the decision to use RCS was the final outcome for the older person with dementia. Making the decision to use CCS may delay institutionalisation. Each family's experience was unique; it was not possible to delineate the time-points in which the changes of circumstances could be made. Identifying factors that provoked and irritated family members to lead the older person to use CCS and/or RCS may help ease the difficult caring situation at home.

Discussion

Contested provocation encapsulates the family decision-making process for CCS and/or RCS. It is highly practical and encompasses the stories of carers. However, decision making is an abstract concept, and some older carers have difficulties understanding the term. Deeper understanding of service needs, expectations, and hopes among carers for improving service support to elders with dementia in CCS and/or RCS are needed. Care by spouses is different from care by children, particularly when there is sex difference between the child and parent.

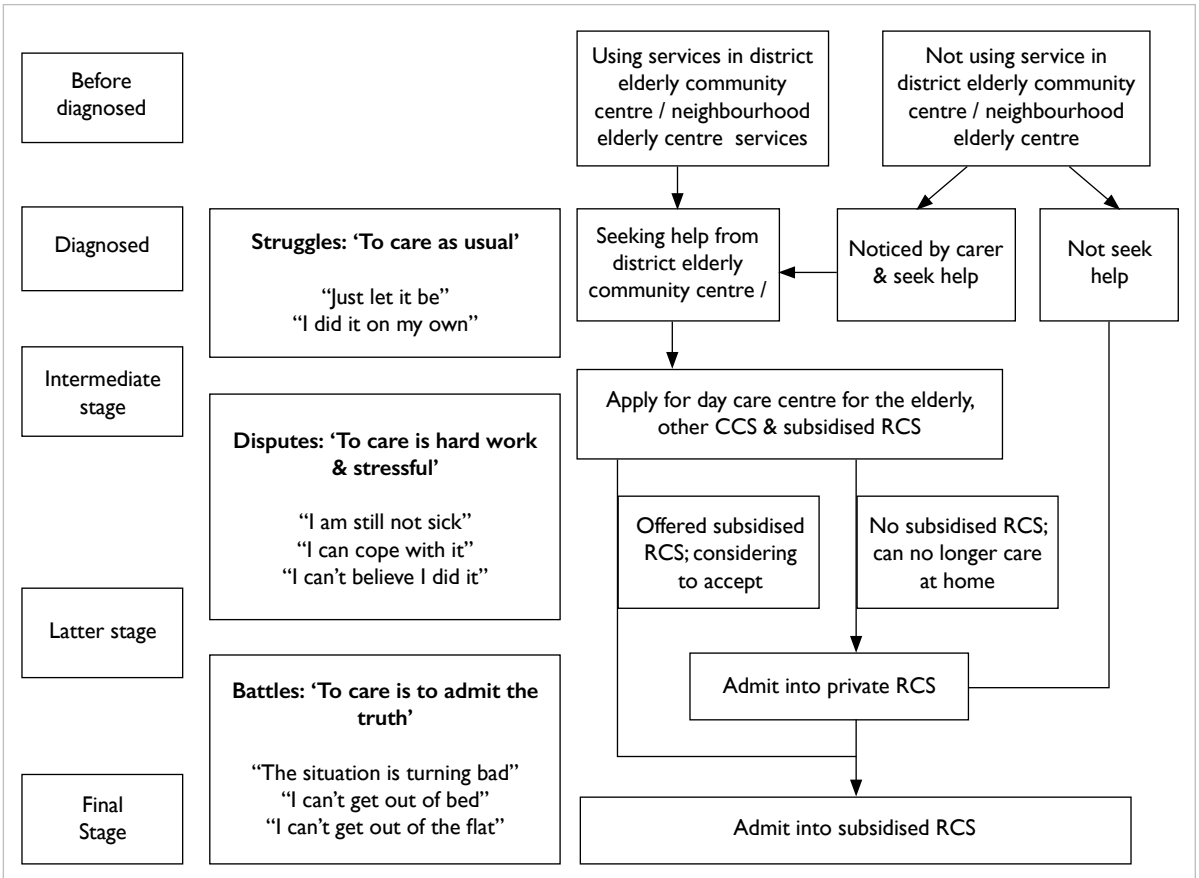

FIG. Contested provocation: family decision-making process when using community care services (CCS) and residential care services (RCS)

One constraint on sampling was the difficulty in getting a balanced ratio of male-to-female carers. Nonetheless, participants were recruited from multiple sites and thus the transferability of the study was enhanced. The constant comparative analysis method and theoretical sampling facilitated identification of most appropriate participants and thus the study credibility was enhanced. This study reflects different issues carers face, and how such issues were provoked by elders with dementia. Understanding these issues may promote the health and well-being of both parties. If caregivers are better supported, the need for CCS and/or RCS can be deferred. Future studies may use qualitative interviews with family carers in CCS and may consider a strategic measure to recruit participants. Given the struggles and challenges of family caregiving, views of carers using private RCS should be included.

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Disclosure

The results of this research have been previously published in:

1. Le Low LP, Lam LW, Fan KP. Decision-making experiences of family members of older adults with moderate dementia towards community and residential care home services: a grounded theory study protocol. BMC Geriatr 2017;17:120.

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Combined physical exercise-working memory training on slowing down cognitive decline in elders with mild clinical Alzheimer disease: a randomised controlled study (abridged secondary publication)

LCW Lam *, WC Chan, TCY Kwok, JSW Lee, BML Yu, S Lee, ATC Lee, SL Ma, ST Cheng

KEY MESSAGES

1. A total of 376 participants with mild dementia were randomly assigned to four 6-week programmes: (1) working memory training, (2) physical exercise, (3) combined working memory and physical exercise, or (4) health education, with 94 participants per group.
2. Immediately after training, all groups showed a time effect for better clinician-rated global cognition function (measured by Clinical Dementia Rating Sum of Boxes), episodic memory, and category verbal fluency. There was no significant between-group difference in cognitive outcomes.
3. The cognitive performance tended to deteriorate after intervention stopped. Adherence to training is important for sustainable benefits. More intensive schedule and longer duration of practice should be advised for sustained benefits.

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Introduction

In Hong Kong, over 10% of the population aged ≥70 years have clinical dementia.[1] There is an urgent need for developing adjuvant interventions to attenuate cognitive decline in people with dementia. Working memory (WM) training has been reported to improve cognitive function.[2] Higher levels of participation in physical exercise (PE) modulate cognitive decline and delay clinical impairments in dementia.[3]

The present study aims to determine whether PE augments the benefits of WM training in people with early-stage dementia. We evaluated the cognitive benefits of a 6-week twice weekly programme of combined PE and WM training over PE alone or WM training alone. We also evaluated the logistics of a structured training protocol as an adjuvant intervention for people with clinical dementia.

Methods

This study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee. The study protocol has been registered at the CCT Clinical Trials Registry of the Chinese University of Hong Kong (ChiCTR-IOR-15005942).

A total of 376 participants aged 60 to 90 years were recruited through social centres for elders in Hong Kong. Inclusion criteria were a diagnosis of major neurocognitive disorder secondary to Alzheimer disease, having Clinical Dementia Rating score of 1 indicating mild dementia, and being ambulatory with low risk of fall. Exclusion criteria were a past history of bipolar affective disorder or psychosis, physical frailty affecting attendance to training sessions, already attending regular cognitive training, a history of major neurological deficit (stroke and traumatic brain injury), and major communicative impairments. Participants were not enrolled in other structured cognitive or exercise training during the study period.

Participants were randomly assigned to four groups: (1) the WM training group (20 minutes of WM training, followed by 5 minutes of rest, and another 20 minutes of WM training), (2) the PE group (20 minutes of PE, followed by 5 minutes of rest, and another 20 minutes of PE), (3) the PE-WM group (20 minutes of PE, followed by 5 minutes of rest, and then 20 minutes of WM training), and (4) the health education (control) group (45 minutes of

health education interactive talks with a 5-minute break in between). There were 12 sessions in 6 weeks (twice weekly); each session lasted 45 minutes.

Participants were assessed at baseline, week 6 (intervention phase), and week 12 (monitoring phase). Primary outcome measure was the Chinese version of the Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog).[4] Secondary outcome measures were Clinical Dementia Rating sum of boxes (CDR-SOB), specific cognitive tests comprising episodic and working memory, attention, language, and executive function, the Chinese version of the Neuropsychiatric Inventory, the Disability Assessment for Dementia, and the Quality of Life – Alzheimer Disease.

Results

A total of 376 participants (301 women and 75 men) were equally randomised into the WM, PE, PE-WM, and control groups for intention-to-treat analyses. The mean age of participants was 80.4±6.5 years, and the mean years of education was 3.2±3.8 years. As for global cognitive function, the mean Mini-Mental State Examination score was 21.2±2.9, and the mean ADAS-Cog score was 16.5±5.8. The mean number of items in 10-minute learning delay recall was 2±2.3 out of 10. There were no significant group differences in baseline demographic, cognitive, or functional profile (Table 1).

At week 6 (intervention phase), the four groups demonstrated improvements in global cognitive function as measured by CDR-SOB (P=0.01, Table 2), but not in the ADAS-Cog score. The WM-PE group showed greater (but not significantly) improvement than other groups. In addition, the four groups demonstrated improvements in category verbal fluency test (P=0.01) and delayed recall (P=0.01). Delayed recall improved more (but not significantly) in the WM-PE group.

At week 12 (monitoring phase), there was no significant change in ADAS-Cog score. CDR-SOB

TABLE 1. Demographic and cognitive profiles of participants at baseline

Characteristic	Working memory training (n=94)*	Physical exercise (n=94)*	Working memory training & physical exercise (n=94)*	Control (n=94)*	ANOVA / Chi square	P value
Age, y	79.8±6.4	80.3±6.2	80.7±7.0	80.8±6.3	0.49	0.687
No. of men : women	19:75	16:78	18:76	22:72	1.25	0.741
Education, y	3.7±3.9	2.5±3.6	3.4±3.8	3.3±3.9	1.64	0.179
Clinical Dementia Rating sum of boxes	3.6±1.2	3.6±1.2	3.5±1.2	3.6±1.2	0.08	0.970
Mini-Mental State Examination	21.3±2.7	21.1±3.0	21.4±2.9	21.1±2.9	0.34	0.793
Alzheimer's Disease Assessment Scale – Cognitive Subscale	15.9±5.9	16.7±5.8	16.5±6.0	17.0±5.7	0.51	0.672
Delay recall	2.1±2.3	1.9±2.2	2.1±2.5	1.8±2.3	0.39	0.761
Category verbal fluency test	29.2±8.8	28.1±9.4	28.6±8.5	28.1±8.6	0.33	0.805

* Data are presented as mean ± standard deviation

TABLE 2. Change in cognitive profiles from baseline to week 6 after adjusting for attendance

Cognitive outcome	Working memory training (n=94)*		Physical exercise (n=94)*		Working memory training & physical exercise (n=94)*		Control (n=94)*		Linear mixed-effects model
	Baseline	Week 6	Baseline	Week 6	Baseline	Week 6	Baseline	Week 6	
Clinical Dementia Rating sum of boxes	3.6±1.2	3.2±1.5	3.6±1.2	3.2±1.5	3.5±1.2	3.1±1.5	3.6±1.2	3.3±1.6	Time effect, P=0.01
Alzheimer's Disease Assessment Scale – Cognitive Subscale	15.9±5.9	16.3±6.8	16.7±5.8	16.2±7.1	16.5±6.0	15.7±6.7	17.0±5.7	16.9±6.4	-
Delay recall	2.1±2.3	2.6±2.7	1.9±2.2	2.4±2.5	2.1±2.5	2.8±2.7	1.8±2.3	2.5±2.5	Time effect, P=0.01
Category verbal fluency test	29.2±8.8	31.2±11.3	28.1±9.4	29.7±10.2	28.6±8.5	30.3±9.2	28.1±8.6	29.6±9.2	Time effect, P=0.01
Digit span - backward	2.3±1.2	2.4±1.3	2.0±1.2	2.2±1.0	2.3±1.2	2.3±1.2	2.1±1.1	2.2±1.1	-
Visual span - backward	2.0±1.4	2.3±1.1	2.0±1.3	2.2±0.8	1.9±1.3	2.3±1.0	2.1±1.1	2.3±0.9	-

* Data are presented as mean ± standard deviation

score did not show any time or group effect. In addition, improvement in backward visual spans was observed (P=0.05). However, episodic memory deteriorated in all four groups (P<0.001).

From baseline to week 12, the ADAS-Cog score did not change significantly. From baseline to week 6, the four groups demonstrated improvements in global cognitive function as measured by CDR-SOB (P<0.01). There were no group differences in the changes of ADAS-Cog and CDR-SOB scores. From baseline to week 6, backward visual spans improved across time (P=0.01), with no significant group differences. Episodic memory was stable in all groups. Category verbal fluency test improved in all groups (P<0.001), with no significant group differences.

There was no significant change in scores of the Neuropsychiatric Inventory, the Disability Assessment for Dementia, and the Quality of Life – Alzheimer Disease across time from baseline to week 12.

Discussion

After the 6-week training programme, all groups showed improvement in clinician-rated global cognition function (measured by CDR-SOB) but not in ADAS-Cog. There was also improvement in cognitive test scores (delayed recall of list learning, category verbal fluency, and backward visual spans). There was no significant group difference in terms of outcome.

During the monitoring phase, most groups showed a decline in global cognition function as measured by ADAS-Cog. In participants with >70% attendance (completers), the programme was associated with stabilisation of ADAS-Cog and episodic memory scores, as well as improvements in global cognition, verbal fluency, and working memory scores, although practice effects could not be excluded. Nonetheless, we observed no significant change in quality of life, mood, behavioural symptoms, and daily functioning.

Regarding sustainability of cognitive benefits, only the WM group showed improvement in global cognition function after 6 weeks. The absence of similar improvement in the WM-PE group may infer that a dose effect is important. Further studies may consider exploring intervention programmes with higher duration, intensity, and frequency.

The intervention programme did not lead to an improvement in everyday functioning. This may infer that longer-term intervention, or specifically designed functional enhancement programmes, should be tested for its potential efficacy in maintenance of function in people with dementia.

Conclusion

The 6-week training programme was associated with improvements in global cognitive function, verbal fluency, and episodic memory, but sustainability of benefits was very limited beyond intervention periods.

Acknowledgements

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High-impact weight-bearing home exercises in girls with adolescent idiopathic scoliosis: a pilot study (abridged secondary publication)

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KEY MESSAGES

1. A 6-month home-based high-impact weight-bearing exercise programme has some benefits in improving bone mineral density, muscle endurance, physical activity participation, and self-image in girls with adolescent idiopathic scoliosis.
2. The exercises appear to be safe and feasible to perform in the home environment. They may complement conventional clinic-based regimen to optimise exercise benefits.
3. This pilot study provides information for sample size estimation and adherence enhancement, which are important for studies on exercise intervention for those with adolescent idiopathic scoliosis.

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Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional deformity of the spine commonly occurs in girls aged 10 to 16 years during growth spurt. Patients with AIS usually have lower level of physical activity and sports participation than healthy controls. They are associated with lower bone mineral density (BMD), lower skeletal muscle mass, lower muscle strength, and poorer quality of life.[1-3] Improper or no treatment may result in physical and psychological sequalae such as curve progression leading to functional disabilities and morbidities in later life.

Regular exercises during adolescence have metabolic, physiological, neuromuscular, and psychosocial benefits that can extend into adulthood. We aimed to assess the effect of the 6-month home-based high-impact weight-bearing exercise programme (E-Fit) on bone health, muscle functions, and quality of life in girls with AIS.

Methods

This study was conducted from July 2017 to August 2019. It was conducted in accordance with the Declaration of Helsinki and was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Committee (Ref: 2016.341). Written informed consent was obtained from each participant before commencement of the study.

Girls aged 11 to 14 years who had AIS (Cobb angle of ≥15°) without prior treatment and were cleared for physical activity by doctor were invited to participate. Those excluded were those with a Cobb angle of ≥40°, scoliosis with any known aetiology (such as congenital scoliosis, neuromuscular scoliosis, scoliosis of metabolic aetiology, and scoliosis with skeletal dysplasia), known endocrine and connective tissue abnormalities, known heart condition or other diseases that could affect the safety of exercise, eating disorders or gastrointestinal malabsorption disorders, or currently taking medication that affects bone or muscle metabolism.

Participants were randomly assigned to the E-Fit group or the control group. The E-Fit group received a 7-minute of home exercise for 6 months supplemented with online demonstration videos. This exercise was specifically designed to perform in the home environment and comprised a broad range of high-impact weight-bearing exercises at varying speeds and directions in order to increase heart rate and to load various muscle and skeletal groups in the upper and lower body. The exercise was performed 5 days per week, and the remaining 2 days were rest days. The control group had no intervention and received only standard care.

Anthropometrics, sexual maturity, and clinical features of participants were assessed at baseline. Participants were assessed at baseline, at 6 months after completion of E-Fit, and at 12-month follow-up for the areal BMD and bone mineral content of the femoral neck, whole body BMD, and muscle mass (by dual energy X-ray absorptiometry); muscle strength of trunk and limbs; muscle endurance of abdominal, back, and limb muscles; quality of life (measured by

the Scoliosis Research Society-22r Questionnaire); and physical activity level (measured by an accelerometer and Modified Baecke Questionnaire).

Two-way repeated measures analyses of covariance (age and body mass index were entered as covariates) were conducted to compare the differences between the two groups in terms of BMD, muscle mass, muscle functions, and curve severity across time.

Results

A total of 40 participants were randomly assigned to the E-Fit group (n=20) or control group (n=20). At 12 months, 14 participants in the E-Fit group and 16 participants in the control group completed the assessment. The post-exercise dropout rate was 15%. The loss to follow-up rate was 25%. The two groups were comparable in terms of baseline characteristics.

After completion of the programme, compared with the control group, the E-Fit group showed a better improvement in the whole-body areal BMD, with an interaction effect of $F(1,29)=2.97$ (P=0.096). The improvement was maintained from baseline to 12-month follow-up ($F(2,50)=2.60$, P=0.085). The E-Fit group showed a better improvement in the left arm lean mass between 6-month follow-up and 12-month follow up ($F(1,26)=4.38$, P=0.046). The E-Fit group showed better performance in muscle strength and endurance (based on the isometric curl-up test only) [$F(1,28)=2.95$, P=0.097], but the performance was not maintained after cessation of the programme.

The E-Fit group demonstrated continuous improvement in physical activity level from baseline to 6-month follow-up to 12-month follow-up in terms of work index, sport index, and total score of the Modified Baecke Questionnaire. The E-Fit group also showed an interaction effect in the self-image domain ($F(1,26)=3.67$, P=0.066) and the total score ($F(1,26)=3.31$, p=0.080) of Scoliosis Research Society-22r Questionnaire between 6-month follow-up and 12-month follow-up. In contrast, the control group gradually declined in physical activity level and quality of life measures across time.

Discussion

The E-Fit programme was well received and easy to perform at home. No adverse event was reported. This supports that high-impact weight-bearing exercises are safe for girls with AIS. After completion of the programme, the E-Fit group showed a trend of greater improvement in the whole body areal BMD and the left femoral neck bone mineral content at 6 months. The improvement on the whole body areal BMD showed an interaction effect from baseline to 12-month follow-up. Similar continuous improvement was also observed in the left arm lean mass across time, with an interaction effect from 6-month follow-up to 12-month follow-up. These findings may suggest that a short bouts of high-impact weight-training exercises may potentially induce positive physiological adaptations in skeletal muscle and bone mass. For muscle strength and endurance, both the E-Fit and control groups showed improvement across time, but no difference across groups and time was found. However, the E-Fit group exhibited a better improvement in isometric curl-up test only at 6-month follow-up. These findings may indicate a potential benefits of exercise in early life in improving muscle functions and performance.[4]

For quality of life, the E-Fit group showed a better trend of improvement in the self-image domain and total score of the Scoliosis Research Society-22r Questionnaire from 6-month follow-up to 12-month follow-up. The improvement in self-image domain may reflect a certain degree of perceived enjoyment with the E-Fit. Moreover, the E-Fit group showed a better trend in physical activity participation in the domains of work index, sport index, and total score in the Modified Baecke Questionnaire from baseline to 6-month follow-up to 12-month follow-up. On contrary, the control group showed a decline in physical activity level over all timepoints. These findings were in line with those reporting lower physical activity level and lower quality of life among patients with AIS.[3,4] The potential psychological benefits of exercise may improve self-image and encourage habitual physical activity and generate better self-image, relieve stress, and promote healthy lifestyle for preventing potential psychological and physical issues.

There are several limitations to this pilot study. The compliance to the accelerometer was low, which posed challenges to monitor exercise compliance and intensity to assess the optimal treatment effects. Using accelerometer with automatic data synchronisation and improving accelerometer wear protocol may enable a more accurate recording of compliance data. The sample size was small, which may explain the lack of treatment effects in some outcome measures. The actual exercise intensity was unable to quantify. Laboratory exercise testing can be used to determine the physiological responses and optimal intensity of E-Fit.

Conclusion

This pilot study provides information for sample size calculation. It seems feasible to replicate the study into a larger scale trial to evaluate the therapeutic effects and optimal dosage of the E-Fit in girls with AIS. High-impact weight-bearing exercises appear to be safe for girls with AIS and show a trend of improvement in bone health, muscle functions, self-image, and physical activity level, with enduring

benefits lasting up to 12-month follow-up. However, robust monitoring of exercise dose and compliance is needed to accurately assess the effectiveness of the programme.

Funding

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Disclosure

The results of this research have been previously published in:

1. Lau RW, Cheuk KY, Ng BK, et al. Effects of a home-based exercise intervention (E-Fit) on bone density, muscle function, and quality of life in girls with adolescent idiopathic scoliosis (AIS): a pilot randomized controlled trial. Int J Environ Res Public Health 2021;18:10899.
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Smartphone application-based school absenteeism reporting system for infectious disease surveillance in Hong Kong schools: abridged secondary publication

DKMI Ip *, EYC Lau, BJ Cowling

KEY MESSAGES

Smartphone application-based surveillance system is a feasible approach for infectious disease surveillance. Specific percentage of influenza-related sick leave may improve the surveillance performance of non-specific all-cause absent rate in terms of sensitivity, specificity, and positive predictive value. Epidemic peaks of influenza season as reflected by the rescaled school absenteeism data precede those shown by traditional surveillance data by 2 to 3 weeks.

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Introduction

Young children are susceptible to various infectious diseases, and thus schools are at constant risk for communicable disease (CD) transmission and institutional outbreaks.[1] School-based CD surveillance system using absenteeism data is useful for CD surveillance and is increasingly used as a core component of influenza surveillance systems in many countries. However, in Hong Kong, there is no prospective surveillance system for the routine and continuous monitoring of CD activity among schools. We previously developed a smartcard-based electronic surveillance system to automatically capture absenteeism data in primary and secondary schools in Hong Kong. Despite the good acceptability, its limitations included suboptimal specificity (owing to the paucity of cause-specific absenteeism data), workload implication for their ascertainment, potential delay in data submission, and data gaps during school holidays and school closure.[2] The current prove-of-concept study aims to explore the feasibility of a smartphone application platform for CD surveillance in a school setting.

Methods

We developed the Hong Kong University Disease Surveillance, which is a smartphone application of an electronic school administration system for the regular and prospective capturing of the nature, cause, and symptom details of sickness absence in Hong Kong schools. Three different data reporting models were developed: (1) making absence application and data submission by parents directly through the app, (2) submitting data by responding to the embedded link in a reminder push message generated and sent to the parent's smartphone when absence of the student was registered by the smartcard-based eAttendance system, and (3) reporting the data in a designated online platform by teachers. These three models were adopted to different extents by the 13 participating schools, according to their different experience and practice in using app-based administrative platform. All schools were also using the smartcard-based eAttendance system for tracking student attendance when students present their cards on entering their schools, which captured the number of all-cause absence, without detail on its nature or reason.

A summary list of absenteeism record of individual students was automatically updated for parents' easy reference, as was reporting of health/illness status during school holiday or closure by push message prompting parents to report in regular cross-sectional time points during the school break.

All surveillance was encrypted and anonymised for data transfer, automatically cleaned, and analysed using scripts in the software R. Alert signal is issued for 10 common infectious diseases of epidemic potential if their number reaches the corresponding threshold, to enhance early awareness and timely triggering of appropriate follow-up steps by the school. The activity trend of influenza infection was disseminated via an Influenza Surveillance Dashboard developed and maintained by the School of Public Health, The University of Hong Kong.

The performance of the surveillance system was evaluated according to the guideline proposed by the Center for Disease Control and Prevention of the United States in terms of its data quality, sensitivity, specificity, positive predictive value, timeliness,

acceptability, simplicity, flexibility, and stability. Sensitivity, specificity and positive predictive value were assessed by comparing the classification of weekly influenza epidemic status (epidemic/non-epidemic) using the gold-standard composite index (sentinel general practitioner influenza-like illness consultation rate × influenza isolation rate, both from the Centre for Health Protection), with a threshold of 30% of its annual peak rate,[3] and by the school absenteeism data with a threshold exceeding the 50 percentile (the median), using a standard two-by-two contingency table. Survey questionnaires were used to collect feedback on attitude, acceptability, and user experience from teachers and parents.

Results

Data were collected from November 2016 to June 2018. Our surveillance covered a total of 7711 students in 13 schools. All their absence episode were captured through the eAttendance system. For the seven schools adopting the Hong Kong University Disease Surveillance (S1-S7), 24.1% (975/4042) of parents consented for their app-based data to be used for informing disease surveillance in the present study.

A total of 95 412 person-days of absence was registered over the study period. Data completeness of absence episode data reported through the Hong Kong University Disease Surveillance (2621 person-days) and Teacher's Module (4162 person-days) were 100%, with full capturing of nature, cause, and symptoms. Among data submitted through the Hong Kong University Disease Surveillance, 67% were reported when the leave application was made by the parent through the app, and 33% were reported through reminder push message. Five rounds of holiday push messages were issued during the study period, with the response rate increased from 0.04% in the first round to 7.96% in the last round, and up to 27.23% in individual schools. A total of 55 alert signals had been issued to the corresponding schools, with 15 alerts for upper respiratory tract infection and 15 for hand, foot and mouth disease.

The temporal pattern of influenza-like illness activity was much better delineated by the all-cause absence rate (calculated as the number of absence / total number of students) than the reference gold standard of the Influenza virus activity in Hong Kong. For the peak in summer epidemic season of 2017 and winter season of 2018, the pattern of the epidemic peaks shown by the Hong Kong University Disease Surveillance preceded the peaks shown by the influenza virus activity in Hong Kong by 2 to 3 weeks (Fig 1). Rescaling of all-cause absent rate by the percentage of sick leave caused by upper respiratory tract infection (upper respiratory tract infection / sick leave) improved the performance of the surveillance system in terms of sensitivity (from 68.4% to 73.7%), specificity (from 55.8% to 57.7%), and positive predictive value (36.1% to 38.9%), and more accurately reflected the epidemic status compared with the gold-standard data (Fig 2). When using additional symptom data to define and estimate the percentage of influenza-related sick leave, including adding influenza-like illness (fever and cough) or respiratory infections (≥2 respiratory symptoms) to upper respiratory tract infection, gave the same amount of improvement in surveillance performance.

Most teachers and parents found the surveillance system stable, simple, and easy to use, and it is useful for monitoring absenteeism, understanding increased influenza activity, and

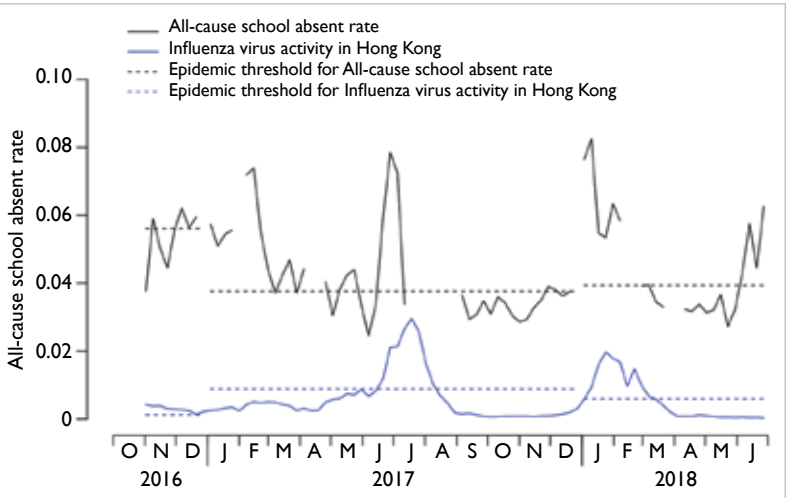

FIG 1. All-cause absent rate and influenza virus activity in Hong Kong from November 2016 to June 2018

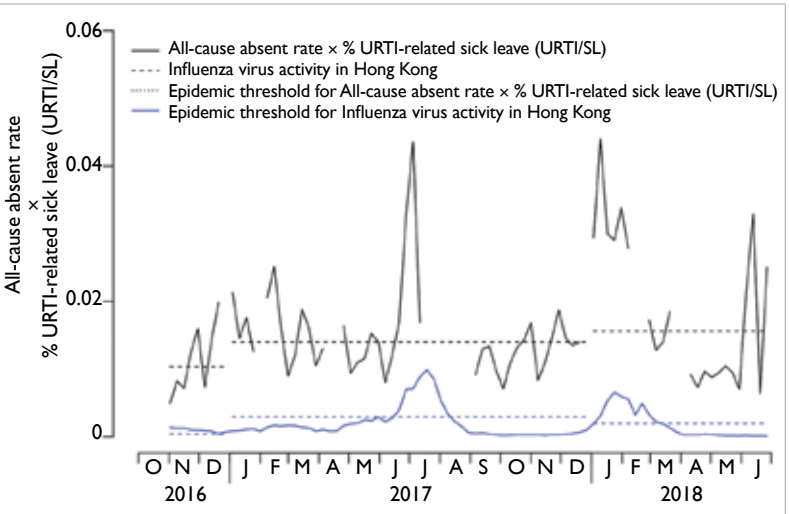

FIG 2. Rescaling of all-cause absent rate by its product with the percentage of upper respiratory tract infection among all sick leave

detecting influenza outbreaks among students. Most teachers and parents opined that using a mobile app-based approach for sick leave application is a trend, and that the app-based surveillance system should be introduced to more schools in Hong Kong.

Regarding the use of app-based platform for sick leave application and submitting surveillance data, 62.8% of parents had no particular concern but 20.7% expressed concern about privacy. 52.9% of teachers regarded the traditional paper-based method to be more reliable, and 11.8% regarded app-based technology may not be mature enough, but none expressed concern about data privacy.

Discussion

This project is the first school-based disease surveillance system using smartphone application technology in the world. There are benefits to using an app-based platform for capturing school absenteeism data for community disease surveillance. There is no trade-off between data specificity and timeliness. Our approach achieved an improvement in both data specificity and timeliness. The shifting of reporting duty from teachers to parents helped to reduce workload of teachers and avoided the usual problem of surveillance fatigue from data reporters. As parents have the best knowledge and incentive to strive for data precision, this contributes to better data accuracy and system sustainability.

The app-based influenza-like illness surveillance system was stable, giving good quality and timely data for prospective disease surveillance. It is feasible for capturing nature, cause, and symptom data of absence for informing prospective disease surveillance.

Collection of more specific data is useful for refining the existing system of monitoring the trend of influenza diseases activity. The improvement in sensitivity, specificity, and positive predictive value suggested that simple rescaling of a general and non-specific data (all-cause absent rate) by a more specific data (percentage of influenza-related sick leave), even if available only from a limited sample size, may improve the surveillance performance of the system. This observation is compatible with our previous finding in the smartcard-based system that symptom-specific data gave a better surveillance performance when compared with less-specific data.

Currently most schools are trying to familiarise with the usage and working out solutions for different technical and logistical issues. None is ready to rely exclusively on app-based platform for handling absence application. The usage pattern is expected to be improved once more schools have passed the initial phase of learning. Other potential areas for improvement include the concerns about reliability by teachers and privacy by parents. A more comprehensive assessment is needed after the system is implemented on a larger scale for a longer time.

Conclusions

The app-based surveillance system provided good quality and timely data by capturing nature, cause, and symptom data of absence for informing prospective disease surveillance. Most teachers and parents found the system simple and easy to use and learn. Simple rescaling of the non-specific all-cause absent rate by the specific percentage of influenza-related sick leave considerably improved the sensitivity, specificity, and positive predictive value of the system. Epidemic peaks of influenza season as reflected by the rescaled school absenteeism data preceded those shown by traditional surveillance data by 2 to 3 weeks. The system achieved an improvement of both data specificity and timeliness. It helped to reduce the workload of teachers and avoid the usual problem of surveillance fatigue.

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Physical activity and fundamental movement skills in children with developmental coordination disorder: abridged secondary publication

CHP Sit *, JJ Yu, CM Capio, R Masters, B Abernethy

KEY MESSAGES

1. Children with developmental coordination disorder had higher body mass index and poorer fundamental movement skills (FMS) proficiency and were less likely to participate in leisure time activities, compared with their peers with typical development.
2. There was a positive association between FMS and physical activity, which was stronger in children with typical development.
3. Using an error-reduced learning paradigm, FMS training was effective in improving FMS proficiency, facilitating active behaviour, and promoting enjoyment in activity participation of children. Some effects were even sustained for 12-months.
4. The school-based FMS training has potential in promoting physical and psychological health in children with developmental coordination disorder in the long run.

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Introduction

Children with developmental coordination disorder (DCD) have poor motor coordination, which interferes with activities of daily living, academic performance, and health.[1] Compared with children with typical development (TD), children with DCD are more obese, less physically active, and at higher risk for obesity-related chronic diseases.

Children's physical activity is associated with their surrounding environments. The common correlates of physical activity in children are enjoyment and mastery of movement skills such as fundamental movement skills (FMS).[2] FMS are building blocks for developing specific sporting skills and forming lifetime physical activity patterns. Based on the International Classification of Functioning, Disability, and Health Model for Children and Youth framework,[3] this study aimed to examine the relationship between FMS and physical activity, and the immediate-, shorter-, and longer-term effects of FMS training on motor skills proficiency, physical activity, and other psychological health effects such as enjoyment. The information gained is useful in identifying effective interventions that promote physical activity and health among children with DCD.

Methods

This study was approved by the Research Ethics Committee of the Chinese University of Hong Kong. It consisted of a cross-sectional study (study 1) and a randomised controlled trial (study 2). Hong Kong Chinese children aged 6 to 10 years from three primary schools were invited to participate. With parental consent, they were screened for DCD according to the Diagnostic and Statistical Manual of Mental Disorder diagnostic criteria. Motor difficulties were confirmed by teachers and/or parents using the Movement Assessment Battery for Children-2; and the score of ≤5th percentile was defined as the cut-off for DCD.

In study 1, based on power calculation, 88 (59 boys, 29 girls) children with DCD and 100 (49 boys, 51 girls) children with TD were included. Their body height, weight, and body mass index (BMI) were measured. Proficiency of five FMS (running, jumping, catching, kicking, and throwing) was assessed using the process-oriented measures of movement form and product-oriented measures of movement outcomes (speed of running, distance of jumping, successful catching, successful goal shooting, and successful throwing). Physical activity was assessed using an ActiGraph activity monitor, and the time

spent in sedentary, light, moderate, and vigorous physical activity were calculated and then converted to percentages of monitored time. Enjoyment and diversity in each of the five activities (recreational, physical, social, skill-based, and self-improvement activities) were assessed using the Children's Assessment of Participation and Enjoyment. Higher scores indicated greater enjoyment and diversity.

In study 2, based on power calculation, 69 children with DCD and 62 age-matched children with TD from study 1 were randomly allocated to either the FMS training group or conventional physical education lessons (control) group, with four subgroups formed: FMS-DCD, FMS-TD, control-DCD, and control-TD. The same outcome measures were used. The intervention period was 8 weeks, 40 minutes per week during physical education classes at schools. The FMS training used an approach to motor learning that reduces the occurrence of errors during practice.[4] Participants were assessed at baseline, prior to intervention, and at 1 week, 3 months, and 12 months after intervention.

Generalised linear (mixed) analyses were performed with controlling for confounders. Statistical significance was set at P<0.05 for all tests.

Results

In study 1, compared with children with TD, children with DCD had higher BMI and poorer scores in both process-oriented measures (locomotor skills and jumping, both P<0.001) and product-oriented measures (speed of running, P<0.05; distance of jumping, P<0.001; successful catching, P<0.01; successful goal shooting, P<0.05) of FMS proficiency. Children with DCD also spent less % sedentary (P<0.05) and were less likely to participate in leisure-time activities (P<0.05), especially in social (P<0.01) and self-improvement (P<0.01) activities.

The DCD status was a predictor for % sedentary and % light physical activity; children with DCD tended to spend less time in sedentary and more time in light physical activity (Table 1). Sex was also a predictor, with boys having less % sedentary and higher % light physical activity and % moderate physical activity. Object control skills proficiency was a predictor for % vigorous physical activity, whereas speed of running was a predictor for % moderate physical activity.

FMS proficiency (object control skills, speed of running, and successful goal shooting) was positively associated with % moderate physical activity and/or % vigorous physical activity in children with TD only. For sex, better object control skills were positively associated with higher % moderate physical activity and % vigorous physical activity in boys, whereas better locomotor skills proficiency (faster running) was associated with higher % vigorous physical activity and less % sedentary in girls (data not shown).

In study 2, compared with baseline, the FMS training group showed significant improvements in FMS outcomes over time, with significant group × time interaction effects for jumping (B=0.759, P<0.05), locomotor skills (B=1.069, P<0.001) at 1 week after intervention, and successful throwing (B=0.955, P<0.05) at 12 months after intervention. The control group also showed similar improvements

TABLE 1. Association of physical activity levels with variables after controlling for age and body mass index in generalised linear models

Variable	Physical activity, ß (95% CI)			
	% sedentary	% light	% moderate	% vigorous
Developmental coordination disorder status (children with typical development as reference)	-0.49 (-0.95 to -0.02)*	0.51 (0.04 to 0.97)*	0.10 (-0.20 to 0.40)	-0.08 (-0.38 to 0.22)
Sex (girls as reference)	-0.63 (-1.01 to -0.25)†	0.60 (0.23 to 0.98)†	0.35 (0.06 to 0.65)*	0.16 (-0.14 to 0.46)
Fundamental movement skills proficiency				
Process-oriented measure				
Locomotor skills	-0.05 (-0.20 to 0.10)	0.03 (-0.12 to 0.18)	0.08 (-0.07 to 0.23)	0.13 (-0.03 to 0.28)
Object control skills	-0.02 (-0.18 to 0.13)	-0.03 (-0.18 to 0.12)	0.13 (-0.03 to 0.28)	0.19 (0.04 to 0.34)*
Product-oriented measure				
Speed of running, s	0.01 (-0.14 to 0.15)	0.05 (-0.10 to 0.19)	-0.18 (-0.32 to -0.03)*	-0.14 (-0.29 to 0.01)
Distance of jumping, m	-0.02 (-0.17 to 0.13)	0.01 (-0.14 to 0.16)	0.05 (-0.10 to 0.20)	0.09 (-0.07 to 0.24)
Successful catching, n	0.06 (-0.09 to 0.21)	-0.08 (-0.23 to 0.07)	0.05 (-0.10 to 0.20)	0.07 (-0.08 to 0.22)
Successful goal shooting, n	-0.05 (-0.20 to 0.10)	0.02 (-0.13 to 0.17)	0.13 (-0.02 to 0.28)	0.10 (-0.05 to 0.25)
Successful throwing, n	0.10 (-0.05 to 0.26)	-0.14 (-0.30 to 0.01)	0.09 (-0.07 to 0.24)	0.07 (-0.09 to 0.22)

* P<0.05
† P<0.01

TABLE 2. Comparisons of physical activity levels across the study groups (mean coefficient)

Effects	Physical activity							
	Weekdays				Weekend days			
	% sedentary	% light	% moderate	% vigorous‡	% sedentary	% light	% moderate	% vigorous
Intervention								
Conventional physical education lessons	0	0	0	0	0	0	0	0
Fundamental movement skills training	-1.516	1.079	0.043	0.216	-1.807	1.752	-0.230	0.222
Participant								
Children with typical development	0	0	0	0	0	0	0	0
Children with developmental coordination disorder	0.519	-0.592	0.096	-0.097	-2.391	1.762	0.504	0.105
Group × time interaction								
Fundamental movement skills training								
Baseline	0	0	0	0	0	0	0	0
1 week after intervention	-1.741	0.626	1.133†	0.050	-2.047	1.467	0.623	0.126
3 months after intervention	0.980	-2.075	1.156*	0.082	-1.096	-1.066	1.828†	0.269
12 months after intervention	-1.107	-0.920	1.920†	0.218	-4.134	2.925	1.036	0.158
Conventional physical education lessons								
Baseline	0	0	0	0	0	0	0	0
1 week after intervention	-2.694	2.256	0.456	-0.011	-3.699	3.449	0.115	0.051
3 months after intervention	-1.025	0.009	0.938*	0.254	-0.589	0.210	0.151	0.162
12 months after intervention	-2.143	1.023	1.213*	0.182	2.905	-2.810	-0.144	0.088

* P<0.05

† P<0.01

‡ Compared with baseline, children with developmental coordination disorder in the control group had a mean coefficient of 0.441 (P<0.01) at 1 week after intervention and 0.497 (P<0.05) at 12 months after intervention

in FMS outcomes over time, with significant interaction effects for jumping (B=0.890, P<0.05), throwing (B=1.280, P<0.05), and speed of running (B=0.255, P<0.05), with the control-DCD group having significantly higher scores at 1 week after intervention than at baseline (data not shown).

Significant group × time interaction effects were found in both groups (Table 2). The FMS training group had higher % moderate physical activity on weekdays at 1 week, 3 months, and 12 months after intervention; and weekend days at 3 months after intervention. The control groups also had higher % moderate physical activity on weekdays at 3 months and 12 months after intervention. There was a significant interaction effect for % vigorous physical activity at weekdays, in which the control-DCD group spending more % vigorous physical activity at 1 week and 12 months after intervention than at baseline.

All FMS and control groups showed a decrease in overall diversity of participation over time. There was an interaction effect for enjoyment of activity participation; the FMS-DCD subgroup had greater enjoyment at 1 week after intervention (B=0.514, P<0.05), 3 months after intervention (B=0.583, P<0.05), and 12 months after intervention (B=0.837, P<0.01) [data not shown].

Discussion

FMS are the building blocks of future specific skills and play an important role in the lives of children with DCD. Based on the International Classification of Functioning, Disability, and Health Model for Children and Youth framework, our findings confirmed those reporting that children with DCD had higher BMI and poorer FMS proficiency, and were less likely to participate in leisure time activities than their peers with TD. FMS were associated with physical activity, but the association was stronger in children with TD. FMS skills, such as object control skills and locomotor skills (eg, running), were predictors for physical activity. These skills should be considered when designing and implementing motor skills interventions to facilitate active behaviour.

In children with DCD, FMS training was effective in improving FMS proficiency, facilitating active behaviour, and promoting enjoyment in participation during leisure time. The errorless motor learning model, which constraints the environment to minimise errors during practice,

enables children to experience a sense of mastery and success.[5] This suggests that this type of learning model can accommodate variations of motor ability and promote feelings of success and enjoyment in physical activity participation. Some of these gains were even sustained over a 12-month period, supporting promotion of physical and psychological health in children with DCD in the long run.

Conclusions

Children with DCD have higher BMI and poorer FMS proficiency than children with TD. FMS were associated with physical activity, but the association was stronger in children with TD. FMS training appears to be an effective school-based intervention for children with DCD. The error-reduced learning paradigm appears to be a promising approach for FMS training for educators and rehabilitation professionals working with children with DCD.

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Disclosure

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1. Sit CH, Yu JJ, Wong SH, Capio CM, Masters R. A school-based physical activity intervention for children with developmental coordination disorder: a randomized controlled trial. Res Dev Disabil 2019;89:1-9.

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Five-step hand hygiene programme for students with mild intellectual disability: abridged secondary publication

RLT Lee *, C Leung, H Chen, WK Tong, PH Lee

KEY MESSAGE

The simplified five-step hand-washing procedure is more effective than the World Health Organization seven-step hand-washing procedure in terms of improvement in hand-washing quality and absenteeism rate in children with mild intellectual disabilities.

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Introduction

School-age children with intellectual disabilities (ID) are more vulnerable to infectious diseases because of difficulties to follow procedures involving proper hand washing.[1,2] Frequent hand-to-mouth and close contact activities without proper hand washing place school-age children with ID at greater risk of acquiring infection.[3] Most school-age children with ID have limited cognitive ability to recognise their health problems, describe their symptoms, and express their needs to others. The Centre for Health Protection recommends that targeted hand hygiene programmes be implemented in special schools for children with ID to prevent the spread of infection in the early stages of an outbreak.[3]

Children in school settings are 18 times more likely to contract pathogens than those staying at home.[4] School-based hand-washing programmes are an important strategy to reduce the spread of illness.[5] The World Health Organization seven-step hand-washing procedure is commonly used in special education school settings.[6] We simplified it to a five-step procedure by rubbing palms and fingers at the same time and by eliminating the wrist-rubbing procedure. Thus, the five steps are rubbing (1) between fingers, (2) backs of hands, (3) backs of fingers, (4) fingertips, and (5) thumbs. We aimed to evaluate the simplified five-step procedure in terms of improvement in the quality of hand washing and reduction in school absenteeism in students with mild ID.

Methods

This quasi-experimental pilot study used a pre-test and post-test design, with a control group and a sustainability test. It was conducted over 12 weeks from 26 February to 30 May 2014 and consisted of four phases: (1) programme development, (2) programme validation, (3) feasibility testing, and (4) sustainability assessment (4 weeks post-intervention).

The simplified five-step hand-washing programme used multimedia visualisation teaching strategies. The World Health Organization seven-step hand-washing programme with standard teaching strategies was used as the control group.

Two special schools were selected based on convenience sampling. The schools were similar in terms of characteristics and socioeconomics. Neither school had ever participated in any simplified hand-washing programme. Both schools had full-time school nurses and only enrolled children with mild ID without any physical challenges. A total of 140 students with mild ID (70 students per school) was the recruitment target. The inclusion criteria were those aged 6 to 15 years with mild ID (IQ score of 50-69) who were able to follow simple instructions and understand the training materials. Exclusion criteria were moderate-to-severe ID (IQ score of ≤49) and inability to comprehend and remember the instructions and training materials.

A validated fluorescent stain rating test was used to quantitatively assess the quality of hand washing, with scores ranging from 0 to 3.[7] Direct observation of hand-washing practices was conducted by school nurses using a validated checklist. A sustainability assessment was conducted at 4 weeks after the completion of the programme. The 12-month absenteeism rate was acquired.

The Mann-Whitney *U* test was used to compare the outcomes between the intervention and control groups from pre-test to immediately post-test. For the sustainability assessment, the fluorescent stain ratings at immediately post-test and at 4 weeks after the completion of the programme were compared using the Wilcoxon Signed Ranks test. The efficacy of the programme in reducing school absenteeism was evaluated by comparing the one-year averaged sickness-related school absenteeism before and after

the intervention.

Results

A total of 155 students (112 boys and 39 girls) aged 6 to 16 years with mild ID were recruited in the intervention (n=78) and control (n=73) schools. Both samples were matched.

In direct observation, by the end of the first 2 weeks, more students in the intervention school than in the control school (45% vs. 18%) were able to wash their hands spontaneously without prompting.

In the fluorescent stain rating test, students in the intervention school had a significant increase in the hand-washing quality from pre-test to post-test in terms of the dorsum and palm aspects in both hands: left dorsum (+1.05, P<0.001), right dorsum (+1.00, P<0.001), left palm (+0.98, P<0.001), and right palm (+1.09, P<0.001), with a greater overall increase compared with students in the control school (+1.03 vs +0.34, P<0.001). Older students (secondary school form 1 to 3) performed hand washing better than younger students (primary school year 1 to 6) in the three time points.

In the sustainability test, 25 (32%) students in the intervention school were randomly selected at 4 weeks after the completion of the programme, the fluorescent staining rating of the 25 students at 4 weeks was not significantly different from that of the intervention group at immediately post-test in terms of the left dorsum (-0.04, P=0.82), right dorsum (-0.06, P=0.67), left palm (-0.08, P=0.72), and right palm (-0.04, P=0.73).

The intervention school had a significantly lower absenteeism rate than the control school in the same year (0.0167±0.033 vs 0.028±0.034, P=0.04).

Discussion

Multimedia visualisation teaching strategies such as video modelling with visual prompts including lyrics and posters have been integrated into our simplified hand-washing programme.[8,9] Both the intervention and control groups had a significant increase in the hand washing quality from pre-test to post-test, with a greater increase in the intervention group (P<0.001). This indicates that the programme is effective in enabling students with mild ID to learn proper hand-washing procedures. Our findings support the use of the simplified five-step hand-washing programme in students with mild ID in special school settings. Our findings have important implications for the prevention of infectious disease outbreaks in the early stages that are of concern to the public health sector.[10] Quantitative estimates of the efficacy of hand hygiene interventions and feedbacks from school nurse and teachers for programme implementation may inform resource allocation for infection prevention and control plans for the target schools, eventually benefiting the school community.

Conclusions

The simplified five-step hand-washing procedure is more effective than the World Health Organization seven-step hand-washing procedure in terms of improvement in hand-washing quality and absenteeism rate in children with mild ID.

Funding

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Disclosure

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1. Lee RL, Leung C, Tong WK, Chen H, Lee PH. Comparative efficacy of a simplified handwashing program for improvement in hand hygiene and reduction of school absenteeism among children with intellectual disability. Am J Infect Control 2015;43:907-12.

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Electrocoagulation versus gelantine-thrombin matrix sealant for haemostasis after laparoscopic surgery of ovarian endometriomas: a randomised control trial (abridged secondary publication)

PW Chung, TC Li

KEY MESSAGES

1. The use of haemostatic sealant after laparoscopic cystectomy for ovarian endometriomas achieved a greater increase in antral follicle count at 6 months, compared with bipolar coagulation.
2. FloSeal seems to provide greater ovarian protection. It is an alternative to bipolar coagulation for haemostasis during laparoscopic ovarian cystectomy for ovarian endometriomas, especially in those with fertility wish and compromised ovarian reserve.

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Introduction

Up to 44% of women with endometriosis have ovarian endometrioma.[1] Laparoscopic cystectomy, by the stripping method, is the most common technique. However, the procedure may reduce ovarian reserve, which may be further reduced when bipolar coagulation is used for haemostasis on the residual ovarian tissue.[1,2] The concern on bipolar coagulation and its impact on ovarian reserve has led to the use of non-thermal haemostasis approaches such as suturing or topical haemostatic agents. FloSeal (Baxter Healthcare, Deerfield [IL], USA) is a haemostatic sealant. It could be an alternative to bipolar coagulation during ovarian surgery. We aimed to determine the post-surgical ovarian reserve in women who achieved haemostasis using FloSeal or bipolar coagulation after laparoscopic cystectomy for ovarian endometriomas.

Methods

The study was approved by the Joint Chinese University of Hong Kong – New Territories East Clinical Research Ethics Committee (CRE 2011. 296-T). This was a patient-blinded, randomised controlled trial conducted at the Prince of Wales Hospital between February 2013 and December 2017. Women aged 18 to 40 years with unilateral or bilateral ovarian endometrioma (measuring 3 to 8 cm) and with no history of ovarian surgery or hormonal therapy who underwent laparoscopic ovarian cystectomy (by the stripping method) were invited to participate.

Participants were asked to return to the hospital on day 3±1 of the menstrual cycle preoperatively and day 3±1 of her 1st, 3rd, and 6th menstrual cycles after laparoscopic ovarian cystectomy for measurement of levels of follicular-stimulating hormone (FSH) and anti-mullerian hormone (AMH) and for ultrasonographic scanning of the ovaries to determine the antral follicle count (AFC) of each ovary. FSH, AMH, and AFC are markers for ovarian reserve. Particularly, AFC reflects the impact of any surgical treatment on the operated ovary. Perioperative outcomes including the success of haemostasis, complications, postoperative recovery, and pain and satisfaction scores (assessed using the Chinese version of the validated Client Satisfaction Questionnaire-8) were also analysed.

According to the preliminary result of an earlier study,[3] the postoperative AFC in bipolar diathermy group was reduced to ~27% of preoperative level, whereas the postoperative AFC in FloSeal group was reduced to ~57%, similar to the suture group. Thus, the sample size required for an alpha value of 0.05 and 80% power would be 42 cases in each group. Assuming that 10% of the patients were excluded owing to incomplete data or dropouts, 47 cases in each group were needed.

Results

A total of 94 patients were randomised to the FloSeal group (n=47) or the bipolar coagulation group (n=47). 38 patients in each group completed the 6-month follow-up. The two groups were comparable in terms of patient age, follow-up rate, operative details, and postoperative complications. The successful haemostasis rate was 95.7% in the FloSeal group and 97.9% in the bipolar coagulation

group. Histopathology examination confirmed endometrioma in all cases. The two groups were comparable in terms of postoperative outcomes and pain and satisfaction scores.

Repeated measures ANOVA revealed a significant time effect (P<0.001) and significant group × time interaction effect (P=0.028) on the AFC of the affected ovary. In both groups, the mean AFC at 1st, 3rd, and 6th months were all higher (but not significantly) than that before surgery. The change of mean AFC of the affected ovaries was significantly higher in the FloSeal group than in the bipolar coagulation group (P=0.018).

Repeated measures ANOVA revealed a significant time effect (P<0.001) but no group effect (P=0.320) or group × time effect (P=0.563) on the AMH level. In both groups, the mean AMH level at 1st, 3rd, and 6th months was lower (but not significantly) than that before surgery. The change of AMH levels between the two groups was not significant.

Repeated measures ANOVA revealed no significant time effect (P=0.740), group effect (P=0.473), or group × time effect (P=0.052) on the FSH level. The change in FSH level between 1st month and baseline was greater in the bipolar coagulation group than in the FloSeal group (p=0.041).

Discussion

Ovarian endometrioma is a common gynaecological condition and its surgical treatment may impair future fertility.[3,4] Our results suggested that applying haemostatic sealant after laparoscopic cystectomy for ovarian endometriomas achieved a greater increase in AFC at follow-up, compared with bipolar coagulation. The protective effect of FloSeal may be particularly important to patients with an already compromised ovarian reserve. Therefore, FloSeal is a viable alternative to bipolar coagulation in achieving haemostasis after laparoscopic cystectomy for endometrioma, particularly in women who wish to preserve fertility.[2]

There is no consensus on a single test or measurement that accurately reflects reserve of an operated ovary. In the present study, three common ovarian reserve markers were used: AFC, AMH, and FSH. AFC was the primary outcome measure as it reflects the ovarian reserve of each ovary, whereas AMH and FSH reflect the combined reserve of both ovaries. It is likely that normal function of the unoperated ovary may mask any adverse effect of the operation of the operated ovary. Therefore, AFC of the affected ovary is a more sensitive measurement. Not surprisingly, a significant difference between the two groups was noted in the change of AFC but not in other markers. The AFC was measured by a single sonographer who was blinded to the treatment modality to reduce inter and intra-observer bias.

Conclusion

The improvement in AFC of the operated ovary was greater in the FloSeal group than in the bipolar coagulation group at 6-month post-operation. FloSeal is an alternative to bipolar coagulation for haemostasis after laparoscopic cystectomy for endometrioma, particularly for women who wish to preserve fertility.

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Disclosure

The results of this research have been previously published in:

1. Chung J, Law T, Chung C, Mak J, Sahota DS, Li TC. Impact of haemostatic sealant versus electrocoagulation on ovarian reserve after laparoscopic ovarian cystectomy of ovarian endometriomas: a randomised controlled trial. BJOG 2019;126:1267-75.

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Effectiveness and safety of acupuncture for overactive bladder: a randomised controlled trial (abridged secondary publication)

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KEY MESSAGE

Both active and sham acupuncture had a beneficial effect on improving overactive bladder symptoms. Both significantly reduced the incontinence frequency, the daytime and night urinary frequency, as well as scores of Urinary Distress Inventory, Incontinence Impact questionnaire, and Overactive Bladder Symptom Score. The treatment effects could last for at least 3 months. The night urinary frequency decreased more significantly in the active acupuncture group than in the sham control group after controlling for baseline nocturnal micturitions. Adverse effects were mild. Further research is needed to investigate the placebo effect of acupuncture for overactive bladder.

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Introduction

Overactive bladder (OAB) is characterised by urgency, frequency, and nocturia and has negative impact on the quality of life of patients.[1] In Hong Kong, it is estimated that 15% of the population have OAB.[2] Treatment methods for OAB include pharmacological therapy, behavioural therapy, and physical therapy; all are largely unsatisfactory owing to the adverse effects of medication and limited efficacy of behavioural or physical therapies.[3] Acupuncture may have clinical meaningful effect on urge incontinence[4] and may improve OAB symptoms.[5] The present study aimed to determine the effectiveness and safety of acupuncture for OAB.

Methods

Patients aged 60 to 90 years who were diagnosed with OAB and were able to complete the 3-day voiding diary, Urinary Distress Inventory (UDI-6), Incontinence Impact questionnaire (IIQ-7), and Overactive Bladder Symptom Score (OABSS) were invited to participate. Those were excluded who had OAB symptoms caused by stroke or spinal injury, life-threatening infection, unconsciousness or severe cognition deficits, dementia caused by Alzheimer disease or other neurodegenerative diseases, previous incontinence surgery, short-term active diuretic treatment or diuretic medication, previous acupuncture for OAB within 2 months, pregnancy, or diseases such as untreated urinary tract infection, urogenital tumours, prostate tumour, benign prostatic hyperplasia, or chronic urinary retention.

Participants were randomly assigned to active or sham acupuncture for OAB. Treatments were administered twice per week for 8 consecutive weeks by registered Chinese medicine practitioners with ≥3 years of clinical experience. The active acupuncture group received a standardised 30-minute acupuncture session, in addition to standard care. Based on traditional Chinese medicine theory, the pathogenesis of OAB symptoms is mainly attributed to insecurity of kidney qi (腎氣不固).[6] The following acupuncture points were used: BL32 (Ciliao 次髎) [bilateral], BL33 (Zhongliao 中髎) [bilateral], BL40 (Weizhong 委中) [bilateral], BL23 (Shenshu 腎俞) [bilateral], SP6 (Sanyinjiao 三陰交) [bilateral], KI3 (Taixi 太溪) [bilateral], BL28 (Pangguangshu 膀胱俞) [bilateral], CV4 (Guanyuan 關元), and CV 3 (Zhongji 中極). The sham acupuncture group received sham acupuncture treatment in the same acupuncture points using blunt needles, with no penetration through the skin.

The primary outcome measure was the reduction in the frequency of incontinence episodes[3] as derived from the 3-day voiding diary. Secondary outcome measures included the scores of IIQ-7, UDI-6, and OABSS, as well as the level of nerve growth factor (NGF), which is a biologic marker related to OAB symptoms, at the baseline, week 8, and week 20. Adverse events were also recorded.

Between-group differences were tested by the independent *t* test for continuous data, the Chi-square test for frequency data, or the Mann-Whitney *U* test for incontinence episodes. The generalised linear model was used to compare primary and

secondary outcomes between two groups after controlling baseline night urine frequency. All tests were two-sided. A P value of <0.05 was considered statistically significant.

Results

A total of 55 female and 45 male patients (mean age, 68.5 years) with OAB were recruited between June 2016 and September 2019 through post advertisement. They were randomly assigned to received active acupuncture (n=51) or sham acupuncture (n=49). Two participants in each group withdrew from the study. The two groups were comparable in terms of baseline characteristics, except that the mean number of nocturnal micturitions was higher in the active acupuncture group than in the sham acupuncture group (8.08±4.66 vs 5.73±3.54).

In both groups, incontinence frequency and daytime and night urinary frequency decreased significantly after treatment and at follow-ups. The decrease in the night urinary frequency was greater in the active acupuncture group than in the sham acupuncture group after controlling for baseline nocturnal micturitions (P=0.0288). However, between-group differences in the decrease in incontinence frequency and daytime urinary frequency were not significant after controlling for baseline nocturnal micturitions.

Scores of IIQ-7, UDI-6, and OABSS decreased significantly after treatment and at follow-up in both groups, but there was no significant difference between groups. The level of NGF in urine samples was too low to be measured. Two patients reported mild adverse reactions such as mild uncomfortable feeling towards acupuncture treatment and skin allergic to the adhesive tape.

Discussion

Our study suggests a beneficial effect of acupuncture on improving OAB symptoms (in terms of reduction of the incontinence frequency and the daytime and night urinary frequency). The effect could last for at least 3 months. Active acupuncture achieved more pronounced improvement in the night urinary frequency than sham acupuncture did. The reduction in OAB symptoms was largely attributable to the acupuncture treatment. Nonetheless, sham acupuncture also produced treatment effect. Sham acupuncture can produce about 33% to 56% placebo effect for patients with OAB.[3,7] We applied sham acupuncture needles to the true acupuncture points. It is plausible that the sham acupuncture could elicit treatment effects. In addition, the possible specific acupuncture treatment effect may be too small to be differentiated from the placebo effect. OAB is a chronic disease with fluctuating symptoms affected by lifestyle, diet (alcohol and caffeine intake), mood, and sex (especially those with natural delivery of baby). It is difficult to measure all variables in the clinical trial. All these confounding factors render it difficult to test the effectiveness of acupuncture for the treatment of OAB.

This study has limitations. Like all acupuncture trials, it is difficult to keep the patients blinded to their treatment group, especially when the needles were on the acupuncture points for 30 minutes. Some patients had received previous acupuncture treatment for other disorders. The concentration of the NGF in the urine samples was too low to measure. In future trial, different sham acupuncture design that presses blunt needles outside true acupuncture points can be used. Those with no prior experience in acupuncture can be recruited. Objective outcome measures should be used to minimise the expectation of the acupuncture treatment.

Conclusions

Acupuncture treatment (both active and sham needling) could decrease the OAB symptoms in terms of the incontinence frequency and the daytime and night urinary frequency. Active acupuncture resulted in more significant improvement in night urinary frequency than sham acupuncture. Acupuncture may be a safe treatment option for patients with OAB.

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Disclosure

The results of this research have been previously published in:

1. Chan YT, Zhang HW, Guo YQ, et al. Effectiveness and safety of acupuncture for elderly overactive bladder population in Hong Kong: study protocol for a randomized controlled trial. Trials 2018;19:376.
2. Lin ZX, Chan NHT, Kwan YK, et al. A randomized controlled trial to assess the effectiveness and safety of acupuncture for overactive bladder: a study in Hong Kong population. Chin Med 2020;15:108.

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