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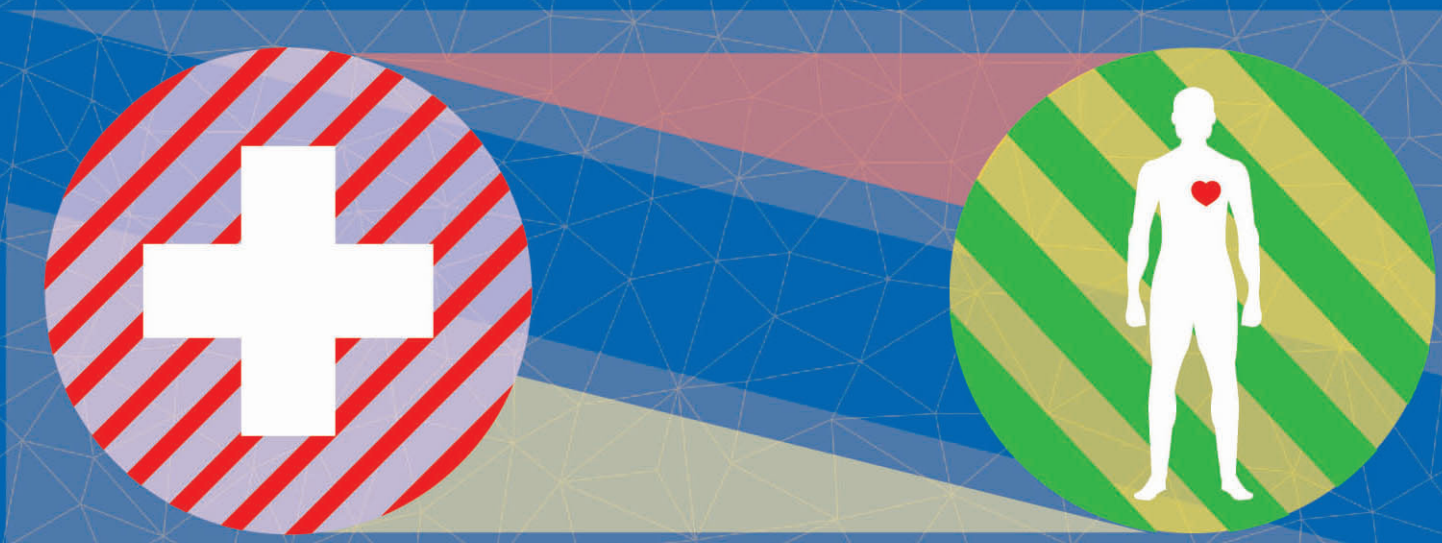

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Taiwan Society of Health Promoting Hospitals

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Health Promotion
健康促進研究與實務 Research and Practice

出版宗旨

社團法人臺灣健康醫院學會為推展醫院與健康照護機構在健康促進領域學術研究，建構健康促進研究與實務資訊交流平台，特別規劃「健康促進研究與實務」雜誌出版。本雜誌旨在刊登健康促進相關之綜論、專論、原著論文、簡報、短評、個案報告及讀者來函等論文，以未曾投稿於其他雜誌者為限。期望藉由本雜誌之發行，提供多元的學術研究與實務資訊交流，共同推動健康促進領域的永續發展。

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專論 Monograph

原著論文 Original Article

[Monograph]

The Effectiveness of OnabotulinumtoxinA in Enhancing the Quality of Life of Patients with Migraine: Evidence-Based Medicine

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Abstract

Chronic migraine is a disease that leads to considerable anxiety and pain in patients. Generally, most patients with chronic migraine resort to the use of painkillers and preventive medications to relieve pain, but often to no avail; the lack of effective treatment often causes patients with chronic migraine to feel helpless. Botulinum toxin is a type of neurotoxic protein that was originally used in medical cosmetic treatments, especially in the treatment of facial wrinkles. However, in recent years, botulinum toxin has been discovered to be potentially useful for alleviating migraine pain. According to the medical treatment guidelines published by the Taiwan Headache Society, botulinum toxin can be used for treating chronic migraine. Nevertheless, its use in Taiwan as a medication for treating chronic migraine remains rare. Thus, the cost-effectiveness of using botulinum toxin to treat migraine is a crucial clinic topic that is worth exploring. Applying the 5-step procedure of evidence-based medicine（EBM）, the researchers entered certain keywords into several EBM databases to search for relevant studies that utilized a randomized controlled trial study design, from which clinical evidences were found and appraised. The articles selected were classified as Level 2 evidence and constituted the best existing evidence for the effectiveness of using botulinum toxin to treat migraine. Main research findings: After receiving botulinum toxin treatment, patients with chronic migraine have exhibited substantial improvements in their migraine frequency, quality of life, and depression level. Apart from EBM, the researchers also conducted a pilot study to further verify the effectiveness of botulinum toxin in treating migraine. The researchers hope that EBM and clinical findings of the current study can serve as a reference for medical personnel and aid them in providing high-quality care for patients with migraine.

Key words: migraine, onabotulinumtoxinA, quality of life, cost-effectiveness, evidence-based medicine

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Introduction

Migraine is a primary disease that is prevalent worldwide; it is characterized by recurring headache and is usually accompanied by symptoms such as nausea, vomiting, photophobia, and phonophobia. According to the 1990 and 2013 Global Burden of Disease surveys, migraine ranked 6th out of the 25 leading causes that forced people to spend "years lived with disability" [1]. Between 2009 and 2010, headache was the 4th leading cause of seeking medical services at emergency departments in the United States; patients who sought treatment for migraine comprised 3.1% of emergency department patients [2]. Despite its prevalence, researchers are not entirely certain of the physiological and pathological mechanisms of chronic migraine [3]. However, there is no doubt that migraine is a nightmare for many patients. Migraine is defined as recurring headache, characterized by pain that lasts for 4 to 72 hours and aura symptoms that limit a patient's ability to perform daily tasks [3]. Results of a study verified that a type of OnabotulinumtoxinA, could reduce the occurrence of migraine and in turn improve the health-related quality of life of affected patients, and that the effects could be maintained for at least 2 years [4]. However, the effectiveness of OnabotulinumtoxinA has not been verified empirically in a medical setting in Taiwan; no Taiwanese medical studies have examined the matter empirically and reviewed existing evidence. In this study, the researchers searched and appraised articles related to the effectiveness of OnabotulinumtoxinA using the 5-step procedure of EBM, including Ask、Acquire、Appraise、Apply and Audit. On the basis of the appraisal results, the researchers answered the following questions regarding OnabotulinumtoxinA: (1) Is OnabotulinumtoxinA administration clinically effective as a treatment for migraine? (2) how cost-effective is OnabotulinumtoxinA administration as a treatment for migraine? The researchers hope that the findings of the current study can aid health care personnel in providing high-quality care for patients with migraine.

Literature review

(1) The epidemiology of migraine

A study conducted in Australia reported that the prevalence rate of migraine ranges from 2.6% to 21.7%, with an average of 12% [5]. Another study reported that the prevalence rates of migraine in men and women living in western countries are approximately 5% to 9% and 12% to 25%, respectively [6]. The results of relevant studies have also indicated that migraine occurs across a wide range of age groups. For adolescents aged 13-15 years, the yearly prevalence rate of migraine was reported to range from 5% to 7%; of older adults aged 65 years and older, at least 3% reported experiencing a migraine episode in the past year [7]; such results indicate that migraine generally occurs in younger rather than older individuals.

A nationwide health interview and survey study conducted in the United States reported that the incidence of migraine was highest among individuals aged 18 to 44 years; 17.9% of the interviewees experienced episodes of migraine or severe headache three months before the interview. However, the incidence rate appeared to sharply decrease with the increase of age. Among participants older than 75 years, only 5.1% reported experiencing migraine or severe headache. Additionally, the incidence of migraine was also higher in families with financial difficulties or families with an annual household income less than $35,000. In terms of ethnicity, the incidence of migraine was the highest among Native Americans and Alaskans（19.2%）and the lowest

among American Asians（11.3%）[2].

(2) Clinical features of migraine

According to the 3rd edition of the International Classification of Headache Disorders（ICHD-3）, chronic migraine is defined as headache that occurs ≥ 15 days/month for > 3 months, in which the headache episodes on ≥ 8 days of the month possess the typical characteristics of migraine [8,9]. Migraine is a type of recurring headache disorder characterized by pain that lasts 4 to 72 hours. Migraine can be classified into migraine with aura and migraine without aura. The aura of migraine includes a wide range of symptoms, including nausea, vomiting, photophobia, and phonophobia. Headache that an individual experiences in a migraine episode can be single-sided, pulsating, and moderately or severely painful; additionally, the headache may limit an individual's ability to perform daily living tasks（e.g., walking to climbing stairs）[3].

(3) Treatments for migraine

Currently, the types of medications available in Taiwan for migraine treatment include beta-blockers, antiepileptic drugs, calcium channel blockers, antidepressants, nonsteroid anti-inflammatory drugs, and botulinum toxin. Among these medications, the effectiveness of botulinum toxin in treating episodic migraine is still unclear. However, more concrete empirical evidence exists for the treatment effects of botulinum toxin for chronic migraine. In 2010, the use of botulinum toxin in the treatment of chronic migraine symptoms was approved by the United States Food and Drug Administration. Among the different types of botulinum toxin, OnabotulinumtoxinA is the only type of botulinum toxin that has been approved for this purpose [10]. Botulinum toxin（trade name: Botox）is a type protease exotoxin produced by the bacterium Clostridium botulinum, a type of spore-forming motile bacteria that is gram-positive, rod-shaped, and anaerobic. The pharmacological effect of botulinum toxin is as follows: it prevents the release of acetylcholine, a neurotransmitter, at the neuromuscular junction, causing the denervation of postsynaptic muscles, subsequently leading to muscle weakening, atrophy, and paralysis. Botulinum toxin was originally used in treating the pathological movements of muscles, such as dystonia or spasticity. It was also used in medical cosmetic treatments, especially in the treatment of facial wrinkles. In recent years, botulinum toxin has also been discovered to be potentially useful in alleviating migraine. However, its mechanism in treating migraine is still unclear [8,10].

(4) Impacts of migraine on daily life

As a disease, chronic migraine can lead to severe disability, which would in turn affect an individual's quality of life [11]. For example, individuals with chronic migraine often experience financial difficulties because their headache renders them unable to work and earn a living. Additionally, compared with patients with nonchronic migraine, patients with chronic migraine are also more likely to develop depression, anxiety, chronic pain, and respiratory system diseases [12].

In recent years, OnabotulinumtoxinA has been proven to be effective in alleviating headache and improving health-related quality of life [4]. Data from a longitudinal study have revealed that in most patients with chronic migraine who responded to OnabotulinumtoxinA, the effects were maintained for at least 2 years. Additionally, the study results revealed that after the cessation of OnabotulinumtoxinA treatment, a few patients could maintain an excellent health condition with no additional preventive treatments. Nevertheless, the same study also reported that certain patients reacted poorly to the proposed treatment despite repeated injection of

OnabotulinumtoxinA [13]. In a clinical setting, the degree of headache pain is often measured using the Headache Impact Test-6（HIT-6）. HIT-6 adopts a 5-point Likert scale, with scores ranging from 6 to 30 points; a higher score indicates more severe headache pain and more affected quality of life [14].

EBM processes

(1)Ask

In this study, the researchers appraised articles related to the effectiveness of OnabotulinumtoxinA by using the 5-step procedure of EBM. The first step of the 5-step EBM procedure is asking a clinical question. The clinical question addressed in this step was "Can treating migraine using botulinum toxin effectively enhance the quality of life of patients with migraine?" P（Patient）stands for patients with migraine; I（Intervention）is botulinum toxin; O （Outcome）is quality of life. All the possible keywords that were used in the search are presented in Table 1. Additionally, the Medical Subject Headings（MeSH）keywords were searched as well. Classification of the EBM question: effectiveness of treatment.

(2) Acquire

This step pertains to acquiring evidences. The ranking of the English databases used in this study is as follows: Cochrane Library, PubMed, and Trip. For the Chinese databases, the Airiti Libray and the National Digital Library of Theses and Dissertations in Taiwan were selected. Boolean algebra was then used to perform the union（OR）and intersection（AND）of the P, I, and O keywords. Then, the MeSH term was used to identify synonyms and relevant words. Next, the Boolean algebra was used to combine keywords for a thorough search of the selected databases. For the search, the following criteria were adopted: keywords were located in the Title, Abstract, and Key Word sections; the publication year was between January 2014 and April 2019; participants were adults aged 18 or older; the study was published in either Chinese or English; the study type was a meta-analysis, systematic review（SR）, or randomized controlled trial（RCT）. Lastly, manual searches were also conducted by the researchers using natural language.

The strategies and procedures used in searching for relevant literature in both Chinese and English databases were compiled and are listed in Table 2. The obtained search results were then filtered according to predetermined criteria. For details of the search results, see Table 3. The titles of articles, and their suggested level of evidence, classified according to the Levels of Evidence classification guidelines（developed by Oxford Centre for EBM）（2011）, are listed in Table 4.

(3) Appraise

The appraisers of this study consisted of a nurse practitioner and a director from the Department of Neurology and a nurse practitioner from the Department of Cardiovascular Medicine. Regarding the critical appraisal procedures for the selected articles, the three appraisers adopted the Critical Appraisal

Table 1：PICO Keywords（MeSH keywords underlined）

PICO	Chinese	English
Patient	偏頭痛	Migraine*、Headache、Migraine Disorders、Migraineurs
Intervention	肉毒桿菌	Onabotulinumtoxina、Botox
Botulism Antitoxin		
Comparison	無	None
Outcome	生活品質、憂鬱	Quality of life、depression

Table 2：Search Strategies and Procedures

Database	Means of search	Articles adopted
Cochrane	Cochrane Library/Advanced Search〔Keywords: (Migraine or Headache) and Botulism Antitoxin and Quality of life Index，select Title, Abstract or Keywords，Jan 2014 to Apr 2019〕→ searched articles：Cochrane Reviews〔0〕、Clinical Trials〔0〕→articles adopted: 0	0
	Cochrane Library/Advanced Search〔Keywords: (Migraine or Headache) and Botulism Antitoxin and Quality of life Scale，select Title, Abstract or Keywords，Jan 2014 to Apr 2019〕→ searched articles：Cochrane Reviews〔0〕、Clinical Trials〔0〕→articles adopted: 0	0
PubMed	Pubmed/Advanced Search〔Keywords: (Migraine* or Migraineur or Headache) and (Onabotulinumtoxina or Botox or Botulism Antitoxin) and (Quality of life or Depression), select Title/Abstract, published in last5 yesrs, Humans, English, Adult 19+ years〕→searched articles:〔20〕→ 19 studies were excluded non-SR or non-RCT study design→ articles adopted: 1	1
Trip	Trip/PICO Search〔Keywords: (Migraine) and (Onabotulinumtoxina) and Quality of life〕→searched articles：Systematic Reviews〔1〕、RCT〔12〕→**eleven fails to meet PICO standard**; repeat articles：1→ articles adopted: 1	1
Airiti Library National Digital Library of Theses and Dissertations in Taiwan	Airiti/ Search〔Keywords: 偏頭痛 or 頭痛 and 肉毒桿菌素 and 生活品質and 憂鬱，select abstract〕→searched articles: 0→articles adopted: 0	0
	Taiwanese masters and doctors / Search〔Keywords: 偏頭痛 and 頭痛 or 肉毒桿菌素 and 生活品質 and 憂鬱，select abstract〕→**two fails to meet PICO standard**→ searched articles: 2→articles adopted: 0	0
Total		2

Table 3：Search Results

Database	Searched articles	Articles that fit the criteria	Repeated article entries	Articles adopted
Cochrane Library	0	0	0	0
PubMed	20	1	0	1
Trip	13	2	1	1
National Digital Library of Theses and Dissertations in Taiwan	2	0	0	0
Airiti Library	0	0	0	0
			Total	2

Table 4：Articles and Their Suggested Level of Evidence

Code	Title	Level
A	Lipton, R. B., Rosen, N. L., Ailani, J., DeGryse, R. E., Gillard, P. J., & Varon, S. F. (2016). OnabotulinumtoxinA improves quality of life and reduces impact of chronic migraine over one year of treatment: pooled results from the PREEMPT randomized clinical trial program. Cephalalgia, 36(9), 899-908.	2
B	Aurora, S. K., Dodick, D. W., Diener, H. C., DeGryse, R. E., Turkel, C. C., Lipton, R. B., & Silberstein, S. D. (2014). OnabotulinumtoxinA for chronic migraine: efficacy, safety, and tolerability in patients who received all five treatment cycles in the PREEMPT clinical program. Acta Neurologica Scandinavica, 129(1), 61-70.	2

Skills Programme Randomized Controlled Trial Checklist developed by the National Health Services Department of the United Kingdom. In this instrument, 11 items were distributed for three dimensions: (1) Are the results of the study valid? (2) What are the results? and (3) Will the results help locally? Results of the critical appraisal conducted by the critical appraisal group are displayed in Table 5. Then, both articles were assigned an evidence level according to the Levels of Evidence classification guidelines developed by the Oxford Centre for EBM（2011）. Accordingly, because both articles employed a randomized clinical trial study design, they were classified as Level 2 evidences.

Both study A and B employed the Research Evaluating Migraine Prophylaxis Therapy（PREEMPT）study design. The age of participants in both studies ranged from 18 to 65 years. All participants in both studies had a medical history of migraine fitting the migraine definition outlined in Section 1 of the ICHD-2; chronic migraine is defined as headache that occurs ≥15 days/month for >3 months, whereas migraine without aura and the criterion for specific migraine treatment are both defined as headache that occurs ≥8 days/month. Study A and B had a combined total of 1384 participants. The experimental group participants received treatment of OnabotulinumtoxinA, whereas the control group participants received placebo treatments. The effectiveness indicators in study A were quality of life（indicated by the Migraine Specific Quality of Life Questionnaire score）and level of disability caused by the headache episodes（indicated by the HIT-6 score）; the effectiveness indicators in study B were the average frequency of headaches in one month（days per month）, the frequency of moderate and severe headache episodes, and the average number of headache episodes in one month.

The experimental group participants in study A reacted quickly and consistently to the administered long-term treatment（>1year）; they were less influenced by headaches after receiving treatment and demonstrated improvement in effects according to Health-Related Quality of Life（HRQoL）scores. The double-blind phase showed significantly reduced HIT-6 and MSQ for onabotulinumtoxinA versus

Table 5：Literature Appraisal Results

Question	Appraisal results
1. Did the trial address a clearly focused issue?	Yes
2. Was the assignment of patients to treatments randomised?	Yes
3. Were all of the patients who entered the trial properly accounted for at its conclusion?	No
4. Were patients, health workers and study personnel ‘blind’ to treatment?	Yes
5. Were the groups similar at the start of the trial?	Yes
6. Aside from the experimental intervention, were the groups treated equally?	Yes
7. How large was the treatment effect?	Yes
8. How precise was the estimate of the treatment effect?	Unclear
9. Can the results be applied to the local population, or in your context?	Yes
10. Were all clinically important outcomes considered?	Yes
11. Are the benefits worth the harms and costs?	Yes

placebo（all p<0.001）. During the 36-week open label treatment, the experimental group participants（who had previously received 24 weeks of double treatment）exhibited improvements in their HRQoL scores during the double-blind treatment period. For study B, the frequency of headache occurrence in days/month among the experimental group participants was reduced by 8.4 days, which was more than the reduction by 6.6 days in the control group according to baseline data. Additionally, the participants in the experimental group also demonstrated significant improvement in body function, activity level, mental disturbance level, and overall quality of life. At Week 24, onabotulinumtoxinA treatment significantly improved headache impact compared with placebo as measured by the proportion of patients who had a severe（≥60）HIT-6 score（63% onabotulinumtoxinA vs 79% placebo; p< 0.001）. Compared with placebo, onabotulinumtoxinA treatment significantly improved both total HIT-6 score（p< 0.001）and the proportion of patients who had a ≥5-point individual decrease in HIT-6 score at Week 24（p< 0.001）. Regarding side effects, most of those reported were temporary and mild to moderate in terms of severity; the most common side effect reported was neck pain. In brief, the participants exhibited a high tolerance for onabotulinumtoxinA treatment. Finally, with the dropout rate being 1.2% for the control group and 3.8% for the experimental group, the treatment dropout rates for both groups were quite low.

In summary, the results of the both articles indicated that onabotulinumtoxinA administration is an effective and safe preventive treatment method for treating migraine and that compared with other migraine treatment methods, onabotulinumtoxinA administration also tends to incur minimal side effects. The study results also indicated that repeated usage of onabotulinumtoxinA for migraine treatment is safe and well-tolerated. Although the mechanism of action of onabotulinumtoxinA in treating migraine remains unclear, available empirical data indicate that onabotulinumtoxinA could effectively alleviate the symptoms of migraine. Such results suggest that onabotulinumtoxinA may be a promising alternative treatment option for patients who do not respond well to traditional migraine medications.

(4) Apply

This step explores the clinical application. Clinical observation indicates that patients with migraine often experience excruciating pain during an episode. The level of pain that patients experience during such a migraine or headache episode is typically 7 or 8 points on a scale of 10. Severe headache episodes are often accompanied by photophobia, nausea, and phonophobia. Most patients take several painkiller pills per day to ameliorate the negative effects associated with their headache episodes, but the effects are fairly limited. Thus, these headache episodes greatly affect the daily lives of patients as well as their occupational and social functioning. Currently, the types of preventive medications available in Taiwan for the treatment of episodic or chronic migraine include beta-blockers, antiepileptic drugs, calcium channel blockers, antidepressants, and nonsteroid anti-inflammatory drugs. However, the treatment effects of these medications are unsatisfactory; this consequently leads to increases in treatment-seeking frequency and medication dosage. Most importantly, this hampers the mutual trust between physicians' and patients.

Among the different types of botulinum toxins, OnabotulinumtoxinA is the only variant that has been approved by the Food and Drug Administration（US）for use as a medication for migraine treatment. In Taiwan, the use of OnabotulinumtoxinA in migraine

treatment is currently classified as a form of self-financed treatment due to restrictions imposed by National Health Insurance regulations. The details of using OnabotulinumtoxinA in migraine treatment are as follows: OnabotulinumtoxinA is administered through injections once every three months, and each administration covers 31 body points. Approximately 155 to 200 units of OnabotulinumtoxinA are required for each OnabotulinumtoxinA administration. With the cost of each unit of OnabotulinumtoxinA ranging from NT$ 75 to NT$ 85, the total cost for an OnabotulinumtoxinA treatment session ranges from NT$ 20,000 to NT$ 25,000, and the effect of each treatment session can be maintained for 3 months. Due to advancements in the economy and technology, individuals with medium to high income levels now have a higher standard of living. Accordingly, they now demonstrate a greater demand for quality healthcare and are thus more willing to engage in self-financed treatments. For patients with migraine who respond poorly to conventional migraine preventive medications, OnabotulinumtoxinA may be a promising alternative medication. The articles identified in this study by using the critical appraisal process were classified as Level 2 evidence and are the best existing evidence for the effectiveness of botulinum toxin in treating migraine. To further verify the validity of the empirical evidence obtained, the researchers also conducted a small-scale pilot study in which both groups were treated with preventive medications for migraine. However, participants in the experimental group were given the additional treatment of OnabotulinumtoxinA injections, whereas those in the control group did not receive such treatment. Data for several effectiveness indicators were collected to verify the effectiveness of the OnabotulinumtoxinA treatment, such as the scores of participants in the experimental and control group on the HIT-6 and 9-item Patient Health Questionnaire（PHQ-9）. Results of relevant studies have revealed that the HIT-6 is a measurement tool with a high degree of internal consistency（α = 0.89） and test–retest reliability（r = 0.83）[14]. The PHQ-9 is a 9-item scale that is designed to measure depression. It adopts a 4-point Likert-like scale, with a total score ranging from 0 to 27 points; a higher score indicates more severe depression. A group of Taiwanese researchers have previously tested the reliability and validity of the Chinese version of the PHQ-9 on a clinical sample of 1,954 patients. The study results revealed that when the PHQ-9 score is ≥10 points, PHQ-9 possess a sensitivity of 86% and a specificity of 93.3% for diagnosis of severe depression. Such results indicate that the PHQ-9 is a suitable instrument for measuring depression[15].

(5) Audit

This step audits the proposed intervention. The analysis results of the pilot study are presented in Table 6. The researchers recruited 20 participants in this pilot study, and 80% of the participants in the experimental group were female. Compared with the control group, participants in the experimental group had a higher average age and pain scores but fewer photophobia symptoms. After intravenous administration of OnabotulinumtoxinA, the participants in the experimental group demonstrated more considerable improvement in HIT-6 and PHQ-9 scores compared with those in the control group. Similarly, participants in the experimental group exhibited more substantial improvement in terms of migraine frequency after receiving administration of OnabotulinumtoxinA compared with those in the control group, who were treated with only preventive medications.

When patients are diagnosed with chronic migraine and do not respond well to conventional preventive

medications, health care personnel can explain to them that OnabotulinumtoxinA administration does not cause harm to the body and that it is safe, effective, and currently the quickest treatment method for migraine. Additionally, the health care personnel should also explain the cost-effectiveness of self-financed OnabotulinumtoxinA injections to patients. If patients have the necessary financial means, then they should be given the freedom to use OnabotulinumtoxinA as a migraine medication. Preventive medications for migraine must be ingested every day, and patients must ingest the medications consistently for 2 to 3 weeks before they will notice the effects; However, throughout the course of treatment, some patients may be unable to cope with the side effects of the medication and others may be reluctant to complete the full course due to the large quantity of medication that they must take; these factors would affect the treatment effectiveness. If a patient has the necessary financial means, then regular injection of OnabotulinumtoxinA can be considered the optimal treatment option for chronic migraine.

Table 6：Comparisons Between the Experimental and Control Groups in Terms of Demographic Characteristics and Scale Scores（N = 20）

Variable	Experimental group（$N = 10$）	Control group（$N = 10$）
	Ingestion of preventive medication and injection of OnabotulinumtoxinA	Ingestion of preventive medication only
	N (%) / $M \pm$ SD	N (%) / $M \pm$ SD
Female	8（80%）	10（100%）
Age (years)	51.3 ± 9.8	33.4 ± 6.1
Pain score		
8–10 points	10（100%）	8（80%）
5–7 points	0（0%）	2（20%）
Accompanying symptoms		
Nausea	10（100%）	10（100%）
Vomiting	10（100%）	10（100%）
Phonophobia	9（90%）	10（100%）
Photophobia	5（50%）	10（100%）
Ingestion or injection of medication（before / after）		
Before- HIT-6 score	3.9 ± 0.6	4.3 ± 0.2
After-HIT-6 score	2.1 ± 0.5	3.6 ± 0.3
Before-PHQ-9 score	1.7 ± 0.8	1.9 ± 0.7
After-PHQ-9 score	0.6 ± 0.5	1.3 ± 0.5
Frequency of migraine		
Before injection / month	20.8 ± 8.3	
After injection / month	16.2 ± 4.2	
Before ingestion / month		12.0 ± 9.3
After ingestion / month		12.8 ± 3.5

Conclusions

The results of the highest-quality research（identified through the EBM process）indicate that onabotulinumtoxinA administration is an effective and safe preventive treatment method for treating migraine. Compared with other migraine treatment methods, onabotulinumtoxinA administration also tends to incur minimal side effects. The study results indicate that repeated usage of onabotulinumtoxinA for migraine treatment is safe and well-tolerated; treating migraine with onabotulinumtoxinA can lead to significant amelioration of mental disturbance and improvement in bodily functions, activity level, and overall quality of life. An examination using the Oxford（2011）revealed that Level 2 evidence research exists in support of using onabotulinumtoxinA as a migraine treatment medication. As a treatment for migraine, onabotulinumtoxinA only needs to be administered once every three months; patients do not need to attend outpatient sessions frequently for follow-up and medication adjustment. Neither do patients need to experience the common side effects associated with migraine medications if they opt to receive onabotulinumtoxinA for migraine treatment. In brief, onabotulinumtoxinA is a time- and cost-effective treatment option that meets the expectations of patients with migraine.

Shared decision-making is an emerging trend in the medical field. In the process of making a shared medical decision, physicians provide patients with empirical evidence for different treatment options and patients articulate their personal preference and values to the physicians. The value of the shared decision-making process is manifested when a consensus is reached regarding the optimal treatment option to adopt. In this study, the researchers combined both EBM and clinical research approaches; the results of the current study can aid health care providers in both clinical healthcare provision and the development of relevant clinical measures for patients with migraine. In the future, the research team of the current study hopes to further explore this topic by adopting a randomized control trial study design in order to scientifically validate the EBM results of the current study.

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［專論］

以實證為導向—偏頭痛病患接受肉毒桿菌素治療，能否改善生活品質？

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摘　要

慢性偏頭痛是一種令人憂心如薰、苦不可言的病症，常因此過度使用止痛藥和預防性藥物，但治療效果不彰而讓病患覺得生命似乎已經到了盡頭。肉毒桿菌素最初用在美容除皺，卻意外發現可以改善偏頭痛。台灣頭痛學會中治療準則指引建議，肉毒桿菌素可以治療慢性偏頭痛，但台灣地區仍不普遍。因此，肉毒桿菌素用於治療偏頭痛之成本效益是臨床重要的議題。本報告以實證過程5A，以關鍵字搜尋實證資料庫，搜尋到隨機分派控制試驗之文獻，並嚴格評讀其證據等級分類為Level 2，為現有的最佳證據。綜合研究結果：慢性偏頭痛病人經過肉毒桿菌素治療後，無論是在頭痛次數、生活品質或心理憂鬱均有改善。團隊成員更將結果落實於臨床應用，以前驅性試驗（pilot study）進行案例追蹤，以確認肉毒桿菌治療偏頭痛的有效性。依據此實證步驟過程與臨床應用結果，期望能提供醫護人員照護參考，並為病患健康福祉努力。

【關鍵詞】偏頭痛、肉毒桿菌、生活品質、成本效益、實證

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[Monograph]

EBM- Investigation of Novel Oral Anticoagulants' Efficacy in Reducing the Risks of Stroke and Intracerebral Hemorrhage in Patients with Atrial Fibrillation

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Abstract

Background: Strokes are a major cause of deaths and disability worldwide, and atrial fibrillation（AF）is a major risk factor of ischemic strokes. Thus, population aging exacerbates the risks of both atrial fibrillation and strokes. The prevalence of AF is 5% among older adults aged 65, whereas that of AF is 10% among older adults aged 80. Therefore, population aging increases the prevalence of AF. **Objective:** Warfarin is the only anticoagulant that patients with atrial fibrillation can take orally to prevent strokes. However, the therapeutic effect of Warfarin is slow, the international normalized ratio is difficult to monitor, and bleeding might occur; thus, prescription rates for AF prevention are relatively low. **Methods:** A five-step procedure of evidence-based medicine（EBM）was adopted: Ask a clinical question, enter keywords into EBM databases, search for and appraise appropriate clinical evidence, apply optimal evidence to clinical practice, and audit the performance of the EBM. **Results:** Level 1 evidence from a systematic literature review showed that novel oral anticoagulants are more cost-effective than Warfarin is in preventing strokes, embolism, and bleeding. Today, commercially available novel oral anticoagulants in Taiwan are partially covered by National Health Insurance. **Conclusion:** The 5A EBM procedure, combined with scientific evidence and the 3E principles of EBM, enable physicians and patients to practice shared decision making（SDM）.

Key words: atrial fibrillation, anticoagulants, stroke, cerebral hemorrhage, evidence-based medicine

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Introduction

According to statistics compiled by the World Health Organization, in 2012, 6.7 million people died from stroke. Stroke is one of the leading causes of death and disability; in European, American, and Asian countries, stroke-related medical costs impose heavy financial burdens on governments [1-2]. Approximately 80% of strokes are ischemic strokes, and common major risk factors of ischemic strokes include high blood pressure and hyperlipidemia, both of which can induce atherosclerosis and thus increase the risk of strokes. By contrast, the common risk factors of cardioembolic stroke include heart arrhythmia and myocardial infarction, both of which can induce thrombi, as well as atrial fibrillation（AF）, which is the most common of the three [3]. All over the world, effectively preventing AF-related strokes is crucial for public health.

Taiwan has become an aged society, which increases the likelihood of AF because the incidence of AF in older adults is higher than those of other age groups. Older adults also have higher CHADS2 scores（their CHADS2 scores are always greater than 1）than those of other age groups because they generally have more comorbidities. Therefore, they should be given anticoagulants as a stroke-prevention measure. Because novel oral anticoagulants（NOACs）are more stable than Warfarin, a traditional anticoagulant, and because patients taking NOACs are not required to submit to blood sampling to monitor NOAC concentration, this study conducted an empirical case study to analyze whether NOACs can be a viable stroke-treatment option.

(1)Stroke Epidemiology and Risk Factors

Circulatory system diseases are a leading cause of death among the 28 EU countries; more than 4 million people die from cardiovascular diseases in Europe each year, accounting for 45% of all deaths. Among cardiovascular diseases, strokes rank second [4-5] in the EU; are the fourth leading cause of death in the United States [6], accounting for 1.7% of the United States' total health expenditure [2]; and are the third leading cause of death in the United Kingdom. According to an analysis conducted by the UK National Health Service（NHS）in 2016, strokes are the main cause of adult disability. Among Asian countries, 105,000 people experience strokes in South Korea every year [7]. Strokes were ranked fourth among the leading causes of death in Japan, and the disability and related medical costs induced by strokes heavily burdened the Japanese government [1]. Statistics compiled by Taiwan's Ministry of Health and Welfare also indicated that over the past decade, cerebrovascular diseases have consistently ranked third or fourth among the causes of death in Taiwanese people [8].These results imply that effective prevention of AF-related strokes is a critical health topic worldwide.

(2)Atrial Fibrillation-related Clinical Treatment and Trends

When assessing the risk of strokes in patients with AF, the most commonly used method is the CHADS2 score; the letters C, H, A, D, S stand for congestive heart failure, hypertension, age（ i.e. ≥ 75 years old）, diabetes, and stroke（i.e., whether patient has had a stroke）, respectively. The method for calculating the point for each category is as follows: a minimum of one point is given to each category, and a score of two points is given to those who have had a stroke. The higher the total score is, the higher the risk of stroke becomes. In the United Kingdom, Professor Lip proposed a new scoring system called CHA2DS2-VASc in 2006. This assessment system demonstrates favorable accuracy in predicting the risk of stroke in people living in Western countries, particularly in those with a low level of risk; the assessment system also delivers satisfactory results in predicting the risk of

stroke in Asian people. The assessment items include congestive heart failure, hypertension, age（> 65 = 1 point, > 75 = 2 points）, diabetes, previous stroke or transient ischemic attack（2 points）, vascular diseases（including peripheral vascular diseases and having experienced myocardial infarction or atherosclerosis）, and sex（2 points for women）[9].

For people whose CHADS2 scores indicate a low level of risk, antiplatelet agents（e.g., Aspirin）may be taken to prevent strokes from occurring. By contrast, for those with middle to high CHADS2 scores, traditional anticoagulants（e.g., warfarin） or NOACs may be used[10]. Nevertheless, for patients with AF and low risk of stroke, the use of Aspirin cannot prevent them from experiencing stroke or transient ischemic attack, and the use of said drug creates a bleeding risk that is higher than that created by the use of warfarin [11-12].

(3)Analysis of Novel Oral Anticoagulant Mechanisms and Traditional Treatment

The traditional anticoagulant Warfarin must be orally taken to achieve anticoagulant effects. Its mechanism is to serve as an antagonist for vitamin K, preventing active vitamin K from participating in the operations of coagulation factors II, VII, IX, and X. To reach effective therapeutic drug concentration, prothrombin time（PT）and international normalized ratio（INR） must be monitored; the ideal INR for preventing stroke in patients with AF is 2-3 [13]. On Oct. 19, 2010, the Food and Drug Administration（US）approved the use of dabigatran, a direct thrombin inhibitor, in treating patients with non-valvular AF. Subsequently, numerous Factor Xa inhibitors, such as Rivaroxaban, Apixaban, and Edoxaban, were introduced as oral anticoagulant drugs. These drugs feature predictable pharmacokinetics, stable dose-related anticoagulant effects, and minimal drug interaction. Thus, providing patients with fixed doses of said drugs is allowed and anticoagulant regulation and monitoring are not required [14]. Many patients only learn about their AF condition after experiencing strokes; 50%-60% of patients do not receive Warfarin when they should; primary and secondary prescription rates for AF prevention are relatively low, even in patients with high stroke risks; and a high percentage of patients who are given Warfarin stop taking the drugs. Overall, only 10% of patients with high stroke risks maintain their Warfarin intake within an ideal therapeutic range [15-16].

In summary, the incidence of AF in older adults is higher than that of the other age groups. Older adults also have higher CHADS2 scores（their CHADS2 scores are always greater than 1）than those of the other age groups because they generally have more comorbidities. Therefore, they should be given anticoagulants as a stroke-prevention measure. Because NOACs are more stable than Warfarin, and that patients taking NOACs are not required to submit to blood sampling for monitoring NOAC concentration, this study conducted an empirical case study to analyze whether NOAC is a viable stroke-treatment option.

Methods

The empirical process is explained using the 5-step EBM procedure:

1. "Ask" a clinical question

The following clinical question, classified under the category of "treatment effects," was asked to collect all possible keywords shown in Table 1: "Can the use of NOAC treatment effectively lower the risks of stroke and intracerebral hemorrhage in patients with AF?" Additionally, MeSH terms were searched.

2. "Acquire" Evidences

First, English keywords were entered into evidence databases Cochrane Library, PubMed, and Trip, whereas Chinese keywords were entered into

Taiwan's National Digital Library of Theses and the Dissertations and Chinese Electronic Periodical Service of Airiti Library. Subsequently, MeSH terms were used to identify synonyms and related terms. Next, terms combined applying Boolean algebra were used to complete a comprehensive search. During the search, title, abstract, and keyword were selected as the search fields; the period from Jan. 2016 to Apr. 2019 was set as the article duration; Chinese and English were the languages chosen; and MA, SR, RCT, and Guideline were selected as the article types. Concurrently, a manual search was made together with the use of natural language. The strategies and steps for searching in Chinese and English databases are listed in Table 2, and studies from the databases were filtered, producing the results shown in Table 3. Table 4 lists the names of the studies and literature "levels" that are assigned according to Oxford CEBM.

3. Critical Appraisal

In this study, critical appraisal was conducted by three independent reviewers; a nurse practitioner from the department of neurology, a nurse practitioner from

Table 1：PICO Keywords（MeSH is Underlined）

PICO	中文	英文
Patient	心房顫動、心房纖維顫動	Atrial fibrillation
Intervention	抗凝血劑	Anticoagulant agent、Anticoagulants
Comparison	抗血小板藥物或沒有其他治療	Antiplatelet or non
Outcome	中風、血栓栓塞、出血	Stroke、thromboembolism、bleeding

Table 2：Search Strategies and Steps

Database	Means of search	Articles adopted
Cochrane	Cochrane Library/Advanced Search〔Keywords:（Atrial fibrillation） and（Anticoagulant agent or Anticoagulants） and（Antiplatelet）and（Stroke or thromboembolism or bleeding），select Title, Abstract or Keywords，Jan 2016 to Apr 2019〕→ searched articles: Cochrane Reviews〔1〕、Clinical Trials〔12〕→ 38 studies（with incompatible PICO and research methods） deleted →articles adopted: 1	1
PubMed	Pubmed/Advanced Search〔Keywords:（Atrial fibrillation） and（Anticoagulant agent or Anticoagulants） and（Antiplatelet） and（Stroke or thromboembolism or bleeding）, select Title/Abstract, published in last 4 years, Humans, English, Adult 19+ years〕→searched articles:〔40〕→ 38 studies（with non-SR and RCT research methods） deleted →articles adopted: 2	2
Trip	Trip/PICO Search〔Keywords:（Atrial fibrillation） and (Anticoagulant agent） and Stroke〕→searched articles: Systematic Reviews〔0〕、RCT〔5〕→ five studies（with incompatible PICO） deleted →articles adopted: 0	
Airiti Library	Airiti/ Search〔Keywords: atrial fibrillation, anticoagulant, and stroke, select abstract〕→searched articles: 0→articles adopted: 0	0
National Digital Library of Theses and Dissertations in Taiwan	Taiwanese masters and doctors / Search〔Keywords: atrial fibrillation, anticoagulant, and stroke, select abstract〕→searched articles: 0→articles adopted: 0	0
Total		3

the department of cardiology, and a clinical nurse. They used the Critical Appraisal Skills Programme（CASP）Systematic Review Checklist developed by the public health resources department of the UK's National Health Service as the review tool. The Checklist, which contained 10 check items, covered the following "dimensions": (a)Are the results of the study valid?(b) What are the results? And(c) Will the results help locally? The reviewers' answers are shown in Table 5. Next, Oxford CEBM（2011）was used to grade the evidence, where treatment-based systematic literature reviews were classified as the optimal literature and given a grade level of 1（i.e., Level 1）.

Results

1. Clinical Application

AF is the most common type of arrhythmia and increases with age. Patients with AF are at least five times more likely than normal people to experience stroke. Warfarin has been used as an anticoagulant in clinical applications for more than 50 years. However, patients using Warfarin must ensure that their INR values（measured by taking blood samples）are maintained at 2-3 to ensure Warfarin effectiveness（i.e., preventing thrombus and bleeding）. Although Warfarin can prevent thromboembolism complications when its concentration is properly maintained, the

Table 3：Search Results

	Database	Number of studies searched	Number of compatible studies	Number of repeat studies	Number of studies selected
English	Cochrane Library	13	1	0	1
	PubMed	40	2	0	2
	Trip	5	0	0	0
Chinese	National Digital Library of Theses and Dissertations in Taiwan	0	0	0	0
	Airiti Library	0	0	0	0
Total：3					

Table 4：References and Grade Levels

No.	Name of the literature	Grade level
A	Kumar, S., Danik, S. B., Altman, R. K., Barrett, C. D., Lip, G. Y., Chatterjee, S., . . . Danik, J. S.（2016）. Non-Vitamin K Antagonist Oral Anticoagulants and Antiplatelet Therapy for Stroke Prevention in Patients With Atrial Fibrillation: A Meta-Analysis of Randomized Controlled Trials. *Cardiology in Review*, 24(5）, 218-223. doi:10.1097/crd.0000000000000088	1
B	Lopez-Lopez, J. A., Sterne, J. A. C., Thom, H. H. Z., Higgins, J. P. T., Hingorani, A. D., Okoli, G. N., . . . Sofat, R.（2017）. Oral anticoagulants for prevention of stroke in atrial fibrillation: systematic review, network meta-analysis, and cost effectiveness analysis. *British Medical Journal*, 359, j5058. doi:10.1136/bmj.j5058	1
C	Melkonian, M., Jarzebowski, W., Pautas, E., Siguret, V., Belmin, J., & LAFuente-LAFuente, C.（2017）. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *Journal of Thrombosis and Haemostasis*, 15(7）, 1500-1510. doi:10.1111/jth.13697	1

Table 5：Empirical Literature Review

Topic \ Literature	A	B	C
Research method	Meta-analysis involving randomized controlled trial	Systematic literature review and meta-analysis	Systematic literature review and meta-analysis
Research participants	71,683 patients with AF	94,656 patients with non-valvular AF	43,199 patients with AF aged 65 or above
Intervention measure	NOAC	NOAC	Antiplatelet agent
Treatment methods	Only anticoagulants; and a combination of anticoagulants（i.e., NOACs or warfarin） and antiplatelet drugs（e.g., Aspirin）	Direct acting oral anticoagulant and warfarin	antiplatelet drugs and oral anticoagulants for older adult patients
Result indicators	Probability of thromboembolism and bleeding	Risks of stroke and systemic embolism; risks of all-cause mortality and bleeding; and sAFety and cost effectiveness	Risk of bleeding
Clear problems and PICO themes	[Yes] Keyword search: various combinations of *atrial fibrillation, stroke, anticoagulants, Apixaban, Rivaroxaban, Edoxaban, Dabigatran, Aspirin, and ASA and Aspirin*	[Yes] Keyword search: *direct acting oral anticoagulant（DOAC）, vitamin K antagonist, antiplatelet agent, prevention of stroke, and atrial fibrillation*	[Yes] Keyword search: performed using MeSH terms: *aged, anticoagulants, aspirin, hemorrhage, and platelet aggregation inhibitors*
Complete search strategies	Used the most keyword combinations to search for studies. Searches included four recently published NOAC studies. Additionally, NOAC and antiplatelet drug-related randomized controlled trials were performed, and comprehensive database searches were made on MEDLINE, PubMed, EMBASE、Web of Science, and Cochrane	Searched related data on Medline, PreMedline, EMBASE, Cochrane library, and NHS Economics Evaluation Database. Searches were also made for ongoing studies and unpublished studies and literature	Performed keyword searches on databases including Medline, PubMed, EMBASE, and Cochrane
Appropriate inclusion and exclusion criteria	Set up randomized controlled trials in English; and removed articles that were repeats, topics not related to the topics of this study, and unrandomized studies	Randomized controlled trials without any language restrictions; and removed articles that were repeats, not related to this study, and not related to the results of this study	Removed case-control studies, historically controlled studies, cross-sectional studies or case reports, surgery-caused bleeding, and patients who received both anticoagulant and antiplatelet drug treatments

Literature / Topic	A	B	C
Sufficient evidence confirming favorable research quality	Searched for anticoagulant-based randomized controlled trials; used Cochran Q and I2 to assess the suitability of heterogeneous and pooled data tests; and adopted random effect models, and Mantel-Haenszel and Peto weight evaluations. During the various stages of the review process, two reviewers independently selected the studies.	Collected only randomized controlled trial tests. Two members independently collected screening headlines and abstracts, and used Cochrane tools to extract data and conduct risk bias assessments	Incorporated randomized controlled trials and cohort studies; calculated risk ratios by adopting random effect models; used chi-square and I2 statistical assessments to determine whether heterogeneity existed between the included studies; used the Cochrane risk of bias tool and funnel charts to assess the risk of bias in the included studies; for randomized controlled trials with an INR of 2-3, the test results showed no heterogeneity and were consistent. Two reviewers independently completed the reviews.
Study results supporting other studies	Yes	Yes	Yes
Main study results	1.There is no advantage in combined treatment [RR, 1.02(95% CI, 0.90-1.15] 2.The bleeding rate is higher than that of treatment using solely anticoagulants [RR, 1.31(95% CI, 1.25-1.37] 3.Compared with the risk of bleeding caused by Warfarin, that of NOACs may be lower（8.7 % vs 6.6 %） 4.The use of anticoagulant shows more favorable performance compared with the combined used of antiplatelet drugs	1.Compared with Warfarin（which demanded an INR of 2.0-3.0）, direct oral anticoagulants showed superior performance in lowering the risks of stroke and systemic embolism [OR scores of 0.79, 0.65, 0.86, and 0.88] and hemorrhage [OR scores of 0.71, 0.80, 0.46, and 0.78] 2.Showed superior performance in all-cause mortality and intracerebral hemorrhage. However, some drugs increased the risk of gastrointestinal bleeding 3.Apixaban showed the highest Expected QALYs and superior cost-effectiveness to that of Warfarin	1.No significant differences in hemorrhage caused by Aspirin, Plavix, and Warfarin 2.No significant differences in hemorrhage caused by Aspirin and NOAC Apixaban for older adults over 75（1898 patients, RR 0.81, 95% CI 0.57 to 1.15, p = 0.24）。 3.The risks of intracerebral hemorrhage or other bleeding caused by Aspirin or Plavix were lower than those caused by Warfarin 4.For older adults aged ≥ 80, the risk of bleeding caused by Warfarin significantly increased（RR 0.80, 95%, CI 0.69-0.90, p = 0.004）
Evidence grade level	1	1	1

constant taking of blood samples to measure its blood concentration and its tendency of interacting with numerous drugs and food types make bleeding and favorable treatment effects difficult to prevent and maintain, respectively. Thus, its prescription rate for AF prevention is relatively low. As a result, in clinical practice, antiplatelet drugs are often used as a replacement of Warfarin. Nevertheless, whether antiplatelet drugs can successfully replace Warfarin remains an issue of concern for medical personnel, patients, and patients' family members.

2. Audit performance

In recent years, four novel anticoagulants (NOACs) were introduced to treat non-valvular AF and prevent thromboembolism. Although NOACs are more expensive than traditional anticoagulant, they are covered by Taiwan's National Health Insurance for patients who meet conditions such as (1) having had a stroke or systemic embolism, (2) having a left ventricle emission rate of less than 40%,(3) presenting heart failure symptoms, (4) being aged 75 or above, (5) being aged 65-74 and having diabetes, hypertension, or a coronary artery disease, with exclusion of (1) patients with a severe heart valve disease, (2) having had a stroke within the past 14 days or a severe stroke within the past six months, (3) having conditions that increase the risk of bleeding, (4) presenting hepatic and renal dysfunctions, and being pregnant.

Since 2010, the European Society of Cardiology has used the revised CHA2DS2-VASc scores to assess the risk of patients with AF experiencing strokes. Said scale increased the scoring for patient age, thereby increasing the number of patients who used anticoagulants in the field of geriatric medicine, validating experts' attention to preventing strokes in older adult patients.

Conclusion

The best evidence in this EBM process showed that although antiplatelet drugs decrease the likelihood of bleeding, even the combined use of two antiplatelet drugs cannot be as effective as anticoagulants in decreasing the risks of stroke or thromboembolism. NOACs are less likely to cause bleeding than warfarin does; this phenomenon is observed even in older adults aged more than 80. Of all NOACs, Apixaban demonstrates the most favorable therapeutic benefits and cost-effectiveness. The level of evidence of these advantages has been determined to be Level 1 by the standards of Oxford（2011）. Although NOACs involve higher medical costs, they are easier to use than warfarin, require no drug concentration monitoring, are more effective in preventing stroke and thromboembolism, and are less likely to cause bleeding in older adults. The positive effects of NOACs can be shown by medical personnel when providing health education. These positive effects can eliminate the doubts of patients or their family members, can facilitate appropriate treatment, can diminish the social costs and family burdens created by strokes, and can meet patients' expectations. For example, a 75-year-old woman who diagnoses AF, she has long-term round-trip hospital to receive continuous prescriptions for anticoagulants and to blood test and adjust drug does, is inconvenient and time consuming（Expectation）. Introducing a new oral anticoagulant by a physician without monitoring the blood drug concentration（Experience）, prevent stroke, and have a lower risk of bleeding. The indications covered by Taiwan's National Health Insurance. Evidence confirmed.

The optimal treatment option can be achieved when physicians and patients exchange information and engage in discussions, where the physicians provide empirical evidence and patients offer their

personal preferences and perspectives. Such an activity exemplifies the concept of shared decision making. This study combined the 3E EBM principles and new clinical knowledge and focused on providing patient-centered care to derive findings that can be applied in clinical practice.

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［專論］

實證綜論—心房顫動病患使用新型抗凝血劑能降低中風與腦出血風險？

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摘　要

背景：腦中風是全世界主要死亡及殘障失能的原因，而心房顫動是缺血性中風的重要因素。老年化社會更凸顯了兩者共同的問題與風險。據統計，65歲老年人口中約有5%患有心房顫動，而在大於80歲以上的族群中，其盛行率高達10%；隨著人口老化，心房顫動的盛行率將會越來越高。**目的**：心房顫動病人預防中風的唯一口服抗凝血藥物為Warfarin，但起效慢，INR調控不穩定，有出血的副作用，各國在調劑適當處方比例偏低。**方法**：運用實證五步驟，提出臨床問題，將關鍵字置入實證資料庫，搜尋適當文獻並評讀，更將最佳證據應用於臨床並檢視成效。**結果**：搜尋系統性文獻回顧之Level 1最佳證據顯示，新型口服抗凝血劑用於預防中風 / 栓塞或出血風險，具有更佳的成本效益。現今，台灣新型口服抗凝血劑上市，亦已納入健保給付。**結論**：實證過程5A，完整以科學化證據，融合實證3E考量，實踐醫病共享決策精神。

【關鍵詞】心房顫動、抗凝血劑、腦中風、腦出血、實證

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[原著]

護理交班資訊系統導入暨成效分析：某區域教學醫院先導研究

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摘　要

目的：護理交班是傳遞病人照護資訊的正式途徑，資訊不完整輕則延誤治療，重則影響病人安全。探討交班資訊系統導入對護理師交班的滿意度與工作績效之影響，並期望將正面的系統實施經驗形塑於個案醫院，作為日後其他護理資訊持續推廣的基礎。**研究方法**：跨部門合作，初期導入系統於婦兒科病房。以使用系統3個月以上共41位護理師進行問卷調查，收集評價資料。使用SPSS 23.0軟體進行敘述性統計分析，並以SmartPLS 3.0軟體執行測量模式分析及結構模式分析。**結果**：模式驗證共六項假說皆支持，資訊品質與服務品質正向影響使用者滿意度（R^2=0.875），任務特性與科技特性正向影響任務科技適配度（R^2=0.819），模式解釋力達90.5%（依變數為『工作績效』）。**結論**：個案醫院將婦兒科病房作為推展新系統的前哨站，逐步擴散成功經驗至全院。護理師對系統功能、資訊品質、服務品質皆有正向感受，在交班工作上同時感受到系統介入後所帶來的正面幫助與良好的滿意度。系統導入後交班完整率達100%，有效提升工作績效並進而增進護理師工作價值。

【關鍵詞】護理交班、資訊系統、先導研究

前言

護理交班是傳遞病人重要照護訊息給下一位照護者的溝通型態，也是護理師每日重要且頻密的工作項目之一。傳統的紙本交班方式，護理師需花費許多時間於書寫交班單上，護理師因忙碌趕時間、字跡潦草等因素，而有交班紀錄遺漏等情形發生。

交班資訊化能有效減少訊息之遺漏[1-2]，確保交班內容的一致性與完整性。過去研究指出交班不完整恐影響病人治療排程之進行、增加病人住院天數及降低病人住院滿意度，或造成給藥錯誤，進而影響病人安全。

由於個案醫院婦產科、兒科病房的交班事務具有結構性的基礎且過去對於新系統的接受度上較

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高因而作為標的系統初始導入的示範單位。資訊系統介入交班工作，護理師多年習慣的工作流程因而改變並須學習與須熟悉系統操作，對較年長的護理師形成額外的工作負荷。本研究希冀透過具有理論基礎的問卷設計與調查進行系統成效分析，收集使用者對系統的主觀評價資料與客觀的管理性報表資料，讓整體的成效分析結果更具可參考價值，除了解交班系統介入後對工作績效的影響，也希望作為日後系統持續擴大實施的參考基礎，促成交班系統全院成功上線，促進病人安全。本研究目的：了解護理人員交班系統上線後對於護理工作績效之影響。了解護理人員對交班系統的使用狀況與滿意度感受。透過研究的完成將正面的系統實施經驗形塑於個案醫院護理部作為日後個案醫院及其他分院護理資訊持續推廣的基礎。

文獻探討

一、交班之重要性

衛生福利部將「提升醫療照護人員間的有效溝通」納入醫院八大病人安全工作目標之第一項[3]，交班系統的導入是有助於醫護人員之間的溝通有效性與完整性。交班不完整，輕者影響病人治療排程之進行、增加病人住院天數及降低病人住院滿意度，重者造成給藥錯誤，進而影響病人醫療和病人生命安全[4-6]。

二、交班內容

交班內容應包含病人過去病史、入院護理評估、此次入院原因、身體評估、檢驗報告、檢查排程、給藥以及經評估後之病人照護計畫和護理措施，跨單位交班應說明轉病房、執行該項檢查或手術之原因以及後續之照護[7-8]。交班需有結構性，及依標準交班規範及流程執行，以落實正確與即時的完整交班，確保病人安全與提升照護品質[9-10]。

三、資訊系統介入護理交班工作

護理部門導入交班系統，降低人為的遺漏及抄寫的疏失發生，增加溝通之有效性及交班完整性；以及隨時可查閱病人資訊，補足容易遺漏及忘記之人類特性及依時完成治療處置之優點；透過此交班資訊平台，傳遞共同之訊息，降低醫護團隊因溝通不良所發生之錯誤[11][4]。

四、任務-科技適配模式與資訊系統成功實施模式

資訊管理學門著名的任務科技適配理論（Task-technology Fit, TTF）強調當資訊系統的功能與其設計若能與使用者的工作和需求互相適配將有助於增進工作績效並增進使用者對系統的採用[12]。此外，DeLone and McLean於1992年統整、分析1981年至1987年間與資訊系統實施成功相關的研究，結合既有定義及其相應的構面及實證研究結果[13]，並於2003年提出更新的資訊系統成功模式（IS Success Model）[14]，將服務品質構面納入模式中。更新後的模式以資訊品質、系統品質及服務品質等三個品質構面為自變數，並以使用行為和滿意度作為中介因子，以淨效益作為依變數。醫療產業具有高度的產業特殊性，例如：生命不可逆、醫療服務無法儲存等特性，尤其重視醫療品質並以追求病人安全與零失誤為目標。此為本研究以TTF和IS Success Model為理論基礎的理由，採用科技特性（Technology characteristics,TECH）、任務特性（Task characteristics,TASK）、資訊品質（Information Quality, IQ）與服務品質（Service Quality, SEQ）、使用者滿意度（Satisfaction, SA）作為自變數以工作績效（Performance,PF）作為依變數進行研究。

材料與方法

本研究以TTF和IS Success Model作為理論基礎，建構研究模式與發展問卷。個案醫院婦兒科單位原以ISBAR結構性模式進行紙本護理交班，且該單位護理師對於導入新的護理資訊系統接受度高，故以婦兒科單位為先導病房，針對使用系統超過三個月以上且有意願參與研究的護理師為研究對象。

探討護理師對交班系統的滿意度與系統介入後對護理工作績效的影響。研究架構內，護理工作（任務）特性、交班系統（科技）特性、資訊品質及服務品質為自變數，觀察、分析是否會影響任務-科技適配度及使用者滿意度，並以工作績效為最終的依變數，探討個案醫院交班資訊化對護理工作績效的影響。

本研究採結構式問卷，內容係參考國內外文獻查證之相關問卷內容，再依據臨床實務設計而成。採用李克特（Likert）五點尺度量表（1=非常不同意，5=非常同意），於2018年1月3日～1月31日針對實際使用過交班資訊系統3個月以上之護理師，予以說明研究目的，同意者進行問卷填寫。針對回收樣本之基本資料，使用SPSS 23.0統計分析軟體進行敘述性統計分析，並以Smart PLS 3.0軟體驗證模式與假說。

結果

個案醫院婦產科、兒科病房為病房交班系統先導實施單位並為問卷發放的場域，共回收有效問卷41份。

一、敘述性統計與樣本特徵

41位樣本中，女性佔97.6%（40位），與目前醫療院所內護理人員以女性為主的現況相符。在年齡層方面，以21-25歲之比例39%（16位）最高，31-35歲者次之19.5%（8位）。在職稱方面，以護理師所佔比例最高95.1%（39位），護理長次之4.9%（2位）。在護理能力進階層級方面，以N2層級所佔比例最高46.3%（19位），N層級次之22%（9位）。在學歷方面，以大學所佔比例最高82.9%（34位），專科次之17.1%（7位）。在工作年資方面，則以年資10年以上之比例43.9%（18位）最高，年資未滿1年者次之19.5%（8位）。

二、信度、效度

以結構方程模式與Smart PLS 3.0進行檢定，以95%信賴水準執行PLS Algorithm進行測量模式（measurement model）分析。各構面包含任務特性、科技特性、資訊品質、服務品質、任務-科技適配度、使用者滿意度、工作績效，因素負荷量皆至少達0.66。各構面之平均變異萃取量（Average Variance Extracted, AVE）皆大於0.5門檻且至少為0.72，組合信度（Composite Reliability, CR）和Cronbach's Alpha皆超過0.7且至少達0.8，顯示量表具有良好的內部一致性（如表1），以上分析結果皆符合收斂效度的門檻值。

任務特性、科技特性、資訊品質、服務品質、任務–科技適配度、使用者滿意度、工作績效等構面，每一題項皆採用Likert五點尺度量表（1=非常不同意，5=非常同意），各構面描述性統計，如表2。此外，本研究參照Fronell-Larcker的建議進行區別效度的檢測，結果如表3、表4所示，以交叉負荷量檢驗區別效度之結果顯示，除問項SA7及TECH5

表 1、各構面之收斂效度、組合信度分析表

構面名稱	代號	AVE	Composite Reliability	R^2	Cronbach's Alpha
任務特性	TASK	0.722	0.947		0.934
科技特性	TECH	0.811	0.981		0.978
資訊品質	IQ	0.877	0.980		0.976
服務品質	SEQ	0.841	0.955		0.936
任務-科技適配度	TTF	0.871	0.982	0.819	0.979
使用者滿意度	SA	0.878	0.981	0.875	0.977
工作績效	PF	0.872	0.984	0.905	0.981

表 2、任務特性、科技特性、資訊品質、服務品質、任務 - 科技適配度、使用者滿意度、工作績效等構面之描述性統計　　n=41

構面名稱	操作變項	平均數	標準差
任務特性	交班的項目是明確的	4.1	0.6
	交班的項目是例行性的(可被常規執行)	4.1	0.5
	跨單位交班的內容是可以掌握的	3.9	0.7
	我負責照護的床數符合我的工作負荷	3.7	0.8
	交班的內容是低複雜度的	3.9	0.6
	我需掌握病人資訊，以即時回答醫師詢問	4.2	0.5
	我需掌握病人資訊，以即時回答病人或家屬	4.2	0.5
科技特性	交班系統上線前，操作簡報對我有幫助	4.1	0.5
	交班系統病人相關資訊的分項介面呈現清楚	4.1	0.5
	交班系統分項的操作是容易的	4.1	0.6
	交班系統的操作模式符合我的使用習慣	4.1	0.6
	交班系統的功能選項設計是完整的	4.0	0.6
	交班系統的功能選項設計符合工作需要	4.1	0.5
	因有異地備援系統，我不擔心系統當機問題	3.8	0.7
	交班系統，讓我容易取得交班所需資訊	4.1	0.5
	交班系統所提供資訊，對交班成效有幫助	4.1	0.6
	整體交班系統整合病人資訊是完善的	4.1	0.5
	醫師詢問病人情況，我能使用交班系統即時查詢與回答	4.1	0.6
	病人或家屬詢問病況，我能使用交班系統即時查詢與回答	4.1	0.6
資訊品質	交班系統所提供的資訊是清楚的	4.1	0.5
	交班系統所提供的資訊是正確的	4.1	0.5
	交班系統所提供的資訊是詳細的	4.0	0.5
	交班系統所提供的資訊是完整的	4.0	0.5
	交班系統所提供的資訊符合交班的即時需求	4.1	0.5
	交班系統所提供的資訊符合交班的需求	4.1	0.5
	交班系統能即時更新病人相關的各項資料	4.1	0.5
服務品質	當我遇到操作問題，護理長會協助正確操作	4.1	0.4
	當系統有問題時，資訊師會排除系統障礙	4.0	0.6
	當我提問交班系統問題時，能受到重視	4.0	0.6
	當我提出交班系統意見時，能得到回應	4.0	0.6
任務－科技適配度	交班系統的作業方式與我的工作流程相容	4.1	0.5
	使用交班系統讓我即時掌握照護對象的狀況	4.1	0.5
	我認為交班系統有助於縮短交班時間	4.1	0.6
	我認為交班系統有助於提昇交班工作的品質	4.1	0.5
	交班系統的功能符合我的工作需求	4.1	0.6
	交班系統提供的資訊符合我的工作需求	4.1	0.5
	交班系統運行順暢能促進醫護團隊的合作	4.1	0.6
	交班系統上線所提供的教材足夠	4.0	0.5
使用者滿意度	交班系統的功能讓我滿意	4.0	0.5
	交班系統的介面分項設計讓我滿意	4.0	0.6
	交班系統的運作速度讓我滿意	4.0	0.7
	交班系統的穩定度讓我滿意	3.9	0.7
	交班系統的便利性讓我滿意	4.0	0.6
	交班系統的即時更新讓我滿意	4.1	0.5
	我樂於使用交班系統	4.0	0.5
工作績效	使用交班系統後，統整交班內容時間縮短	4.1	0.5
	使用交班系統後，個人的工作負擔相對減輕	4.0	0.7
	使用交班系統後，個人的工作壓力相對緩解	4.0	0.7
	使用交班系統後，個人的交班正確性提高	4.1	0.5
	使用交班系統後，個人的整體工作效率提高	4.1	0.5
	使用交班系統後，個人的交班完整性提高	4.1	0.5
	使用交班系統後，助我提昇個人工作能力	4.1	0.5
	使用交班系統能減輕護理師跨單位交班壓力	4.1	0.6
	使用交班系統能減輕新進護理師交班壓力	4.1	0.6

表 3、量表特徵 (區別效度)

	IQ	PF	SA	SEQ	TASK	TECH	TTF
IQ	0.936						
PF	0.871	0.934					
SA	0.844	0.934	0.937				
SEQ	0.776	0.866	0.909	0.917			
TASK	0.835	0.848	0.858	0.819	0.849		
TECH	0.852	0.875	0.854	0.838	0.921	0.901	
TTF	0.876	0.939	0.940	0.906	0.887	0.886	0.933

表 4、各構面指標之交叉負荷量分析表

	IQ	PF	SA	SEQ	TASK	TECH	TTF		IQ	PF	SA	SEQ	TASK	TECH	TTF
IQ1	**0.971**	0.814	0.796	0.731	0.779	0.768	0.840	TASK1	0.753	0.799	0.812	0.745	**0.935**	0.820	0.846
IQ2	**0.974**	0.871	0.843	0.782	0.815	0.826	0.891	TASK2	0.839	0.817	0.841	0.763	**0.887**	0.832	0.874
IQ3	**0.962**	0.873	0.824	0.747	0.781	0.798	0.855	TASK3	0.717	0.723	0.768	0.660	**0.874**	0.757	0.751
IQ4	**0.962**	0.873	0.824	0.747	0.781	0.798	0.855	TASK4	0.686	0.735	0.755	0.670	**0.821**	0.746	0.698
IQ5	**0.931**	0.814	0.796	0.772	0.787	0.804	0.817	TASK5	0.507	0.499	0.515	0.594	**0.662**	0.627	0.578
IQ6	**0.904**	0.762	0.748	0.714	0.818	0.842	0.758	TASK6	0.710	0.712	0.683	0.712	**0.870**	0.838	0.743
IQ7	**0.844**	0.687	0.689	0.575	0.715	0.756	0.711	TASK7	0.710	0.712	0.683	0.712	**0.870**	0.838	0.743
PF1	0.718	**0.853**	0.784	0.707	0.693	0.724	0.794	TECH1	0.847	0.821	0.780	0.791	0.866	**0.888**	0.873
PF2	0.734	**0.938**	0.862	0.764	0.732	0.785	0.821	TECH2	0.862	0.872	0.839	0.834	0.917	**0.963**	0.867
PF3	0.779	**0.943**	0.873	0.767	0.746	0.784	0.829	TECH3	0.801	0.808	0.824	0.764	0.859	**0.933**	0.836
PF4	0.865	**0.962**	0.896	0.844	0.835	0.855	0.920	TECH4	0.771	0.768	0.770	0.722	0.831	**0.921**	0.809
PF5	0.892	**0.956**	0.902	0.844	0.835	0.847	0.920	TECH5	0.838	0.773	0.825	0.749	0.918	**0.917**	0.851
PF6	0.825	**0.936**	0.896	0.864	0.836	0.864	0.930	TECH6	0.862	0.872	0.839	0.834	0.917	**0.963**	0.867
PF7	0.837	**0.947**	0.927	0.879	0.807	0.822	0.892	TECH7	0.442	0.586	0.560	0.626	0.560	**0.648**	0.538
PF8	0.856	**0.964**	0.872	0.807	0.828	0.847	0.904	TECH8	0.543	0.664	0.618	0.639	0.681	**0.813**	0.652
PF9	0.803	**0.899**	0.829	0.783	0.801	0.814	0.872	TECH9	0.665	0.779	0.763	0.776	0.769	**0.912**	0.774
SA1	0.789	0.871	**0.965**	0.861	0.855	0.815	0.921	TECH10	0.765	0.819	0.817	0.825	0.846	**0.940**	0.797
SA2	0.804	0.890	**0.961**	0.873	0.809	0.830	0.886	TECH11	0.830	0.842	0.774	0.718	0.830	**0.900**	0.818
SA3	0.754	0.837	**0.949**	0.847	0.780	0.764	0.850	TECH12	0.855	0.800	0.761	0.758	0.874	**0.961**	0.818
SA4	0.742	0.823	**0.936**	0.847	0.766	0.752	0.836	TTF1	0.789	0.908	0.905	0.939	0.805	0.819	**0.924**
SA5	0.815	0.852	**0.933**	0.797	0.849	0.811	0.914	TTF2	0.878	0.871	0.829	0.848	0.832	0.845	**0.928**
SA6	0.848	0.954	**0.957**	0.928	0.849	0.858	0.936	TTF3	0.816	0.802	0.780	0.734	0.811	0.795	**0.900**
SA7	0.776	0.890	0.855	0.801	0.716	0.763	0.817	TTF4	0.868	0.933	0.896	0.856	0.832	0.876	**0.958**
SEQ1	0.744	0.822	0.844	**0.855**	0.760	0.743	0.832	TTF5	0.845	0.901	0.929	0.863	0.857	0.840	**0.952**
SEQ2	0.702	0.773	0.824	**0.925**	0.784	0.780	0.841	TTF6	0.865	0.918	0.927	0.866	0.888	0.850	**0.974**
SEQ3	0.676	0.777	0.813	**0.942**	0.731	0.800	0.808	TTF7	0.762	0.873	0.869	0.818	0.812	0.832	**0.940**
SEQ4	0.719	0.799	0.850	**0.943**	0.726	0.751	0.837	TTF8	0.708	0.797	0.881	0.834	0.786	0.752	**0.887**

之區別效度未達標之外，其餘指標的交叉負荷量都符合區別效度的要求。

三、路徑分析與假設檢定

執行PLS Bootstrapping運算，以t值1.96作為路徑顯著性的判斷依據，結果如表5所示，路徑均達顯著，研究模式檢定結果如圖1。分析結果顯示，任務–科技適配度之R^2為0.819，使用者滿意度R^2為0.875，工作績效R^2為0.905，模式整體解釋力達90.5%。

整體分析結果顯示，本研究架構所有構面間路徑係數的顯著性均達顯著水準，所有研究假設的檢定結果均成立。由於婦兒科的護理交班有結構性，且護理師富有耐心及工作服從性高等因素，對於個案醫院導入新的護理資訊系統的接受度高，有較充裕的時間學習並適應新的系統，在使用滿意度佳的情況下，進而提升其工作績效。因此，任務–科技適配理論及資訊系統成功模式之各項實證研究結論，均在個案醫院婦兒科護理人員身上獲得驗證。

討論

交班資訊化減少訊息遺漏，降低護理師負荷，促進品質。本研究以中部地區某區域教學醫院之婦兒科病房護理人員為先導研究對象，探討交班系統使用成效，探究任務特性、科技特性、任務–科技適配度以及資訊品質與服務品質對於使用者滿意

表 5、路徑係數、顯著性及研究假設檢定結果分析表

研究假設	路徑	路徑係數	t-Value	p-Value	假說檢定結果
H1	TASK → TTF	0.468*	2.466	0.018	成立
H2	TECH → TTF	0.455*	2.207	0.033	成立
H3	IQ → SA	0.348**	3.046	0.004	成立
H4	SEQ → SA	0.639***	5.381	0.000	成立
H5	TTF → PF	0.526*	2.971	0.005	成立
H6	SA → PF	0.439*	2.561	0.014	成立

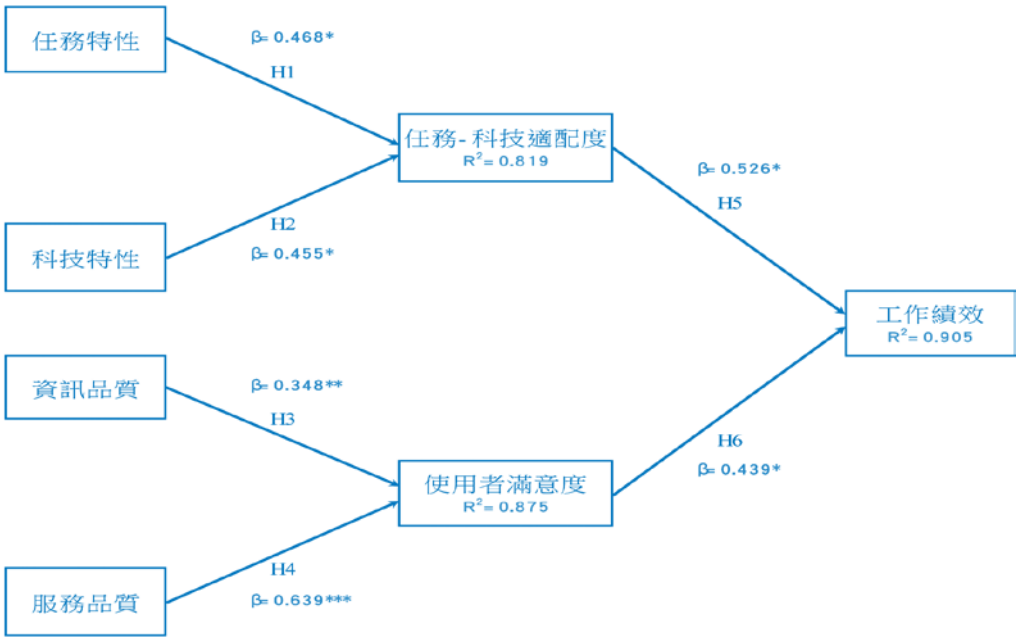

圖1：研究模式檢定結果

度之影響性，及使用者滿意度對於工作績效之影響性。總結主要研究結果與實務意涵如下：

一、先導階段：共收案婦產科、兒科病房之護理人員共41位。執行PLS Algorithm測量模式運算：任務特性、科技特性、任務-科技適配度、資訊品質、服務品質、使用者滿意度及工作績效等構面指標之因素負荷量皆大於0.6，收斂效度皆達0.7以上，組合信度皆達0.9以上，皆達標。檢驗路徑係數及其顯著性，任務-科技適配度之解釋力為81.9%，資訊品質、服務品質對使用者滿意度之解釋力為87.5%有顯著影響，使用者滿意度對工作績效之解釋力則為90.5%，均具有正向顯著影響。

二、由研究結果顯示，站在使用者立場及更貼近使用者期望思維考量的資訊系統，可有效提升使用者的滿意度，並進而提高其工作績效，可以做為個案醫院未來改善交班系統或導入其他資訊化系統之參考，進而提高醫療品質。再者，因為鄉村地區的醫院資訊化程度比較慢，本研究結果亦可做為其他鄉村型區域教學醫院導入護理資訊系統的參考。

此外，本研究限制為採以一定期間對於個案醫院護理人員所做的實體問卷，致產生有時間上及研究樣本上的限制，可能會因科別屬性不同、人員工作特性不同而產生差異；而隨著受訪者使用交班系統的時間增長，問卷調查的結果可能因護理人員在體驗交班系統後續服務過程中會產生主觀判斷上的偏差可能。

本研究以任務特性、科技特性、任務-科技適配度、資訊品質、服務品質、使用者滿意度及工作績效做為研究變數，惟仍有許多理論、模型及變數可以更完整探究交班資訊化的成效，未來可依據此研究架構加以擴充，尋求更完整之模式及變數，並增加樣本之完整性，持續探討影響交班資訊化成效的因子，做為個案醫院未來優化交班資訊系統或導入其他功能資訊系統的參考。

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[Original Article]

Effectiveness of Nurse Shifting Information System: a Pilot Study of a Regional Teaching Hospital

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Abstract

Purpose：Nursing shift reports are the official channel to deliver patient care-related information. Incomplete or misleading information could delay treatment, or worse, pose a threat to patient safety. This study investigated the deployment and performance evaluation of the new system in the case hospital. Base on the positive experiences, further to diffuse to the entire hospital and enhance new nursing information systems promotion. **Method**：The new system was implemented via inter-departmental cooperation while the OBS/GYN wards were selected as the pilot units. A total of 41 nurses who used the system for more than three months participated in the questionnaire survey. SPSS Version 23.0 was used to analyze the respondent characteristics, Smart PLS3.0 was adopted to verify the research model and hypotheses. **Results**：Six hypotheses were verified and were significantly supported in this study. "Information quality" and "service quality" has a positive effect on user satisfaction (R^2=0.875) respectively. "Task characteristic" and "technology characteristic" has a positive effect on "task-technology fit" (R^2=0.819) respectively. Finally, the model explanatory power was revealed 90.5% (dependent variable as "job performance"). **Conclusion**：The case hospital selected OBS/GYN wards as the outpost for the new system introduction, and it plans to further diffuse the successful experience to the whole hospital. Nursing staff have positive perceptions on system functions, information quality, and service quality. They received positive help and fully support from the new system intervention to advance the patient satisfaction level. The completion rate of the nursing shift report achieved 100% to improve work performance and nursing staff value after the system was introduced.

Key words: shift report, information system, pilot study

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[Original Article]

Effects of Working Conditions on Regular Physical Activity and Exercise Implementation among Caregivers in Disability Long Term Care Facilities

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Abstract

Physical activity has positive health benefits for people of all ages. Physical activity interventions can relieve stress, depression and burdensome feelings in caregivers, as well. However, there are few studies investigating physical activity among individuals who care for people with disabilities. This study aims to describe physical activity profiles among caregivers for people with disabilities in long term care facilities and to examine the possible factors associated with their physical activity implementation. Purposive sampling was conducted to recruit 455 caregivers of adults with intellectual disabilities, autism and associated disabilities providing care in seven welfare institutions in Taiwan. A total of 327 caregivers who provided complete data on their personal demographic characteristics, health and working status, and physical activity and exercise were included in the analyses. The results showed that 71.9% of caregivers undertook physical activity and exercise weekly; 31.2% of the caregivers reported that they participated in regular physical activity and exercise（more than three times per week and at least 30 minutes per episode）throughout the week. The main types of physical activity and exercise included walking（61.5%）, house cleaning（36.4%）, Nordic walking（25.1%）, general stretching（24.8%）, and cycling（20.5%）. After adjusting for factors including personal demographics, BMI and health status, multiple logistic regression models indicated that caregivers reporting more working days per week（>5 days vs. ≦5 days, OR=0.549, 95% CI=0.31-0.98）were less likely to participate in regular PA and exercise than their counterparts. This study highlights that caregivers are in need of interventions to increase physical activity, and to improve their health.

Key words: physical activity, exercise, intellectual disability, autism, caregiver, health promotion

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Introduction

Caregivers reported significantly greater anxiety, depression, stress, and negative health symptoms than people who did not provide care for others [1-3]. Some caregivers described a negative emotional impact and dissatisfaction with their roles in caring for adults with intellectual disabilities（ID）and special needs such as pain management [4], epilepsy [5-6], health care [7-8], psychiatric services [9-10] and dementia conditions [11-14].

Caregiving demands have been shown to contribute directly to both the psychological and the physical health of caregivers [15]. In a study of caregivers of children with ID in China, Chiu et al. [16] revealed that the mental health of caregivers is related to the affective dimension of affiliated stigma, loss of face and anxiety level. Ali et al. [17] also found that both individuals and family caregivers experience such stigma and that it may have a negative impact on their psychological wellbeing. Stults-Kolehmainen and Sinha [18] concluded that the majority of the literature finds that the experience of stress impairs efforts to be physically active. Individuals who are more active have lower rates of all-cause mortality, coronary heart disease, high blood pressure, stroke, diabetes, metabolic syndrome, colon cancer, breast cancer, and depression [19]. Social support, family function and caregiving experience could mediate the relationship between patient factors and caregiver burden [20].

Physical inactivity among caregivers may require health promotion interventions [21], particular for older caregivers [22]. Physical inactivity is a prevalent risk factor among family caregivers that requires systematic attention [23]. Previous research demonstrated that physical activity（PA）has physical and psychological benefits for people of all ages and that PA interventions improved stress, depression and feelings of burden among caregivers [24]. Family caregivers who start a regular moderate-intensity exercise program can achieve benefits including reductions in stress-induced cardiovascular reactivity and improvements in rated sleep quality [25]. However, there were few trials investigating the PA of institutional caregivers who are considering the potentially stressful caregiver role. This study aims to describe the profile of PA in institutional caregivers for people with ID, autism and associated disabilities and to examine the possible factors associated with their implementation of PA.

Methods

Purposive sampling was conducted to recruit 455 caregivers of adults with intellectual disabilities caring in 7 welfare institutions in Taiwan in 2012-2013, and the institutional review board was approved by Tri-Service General Hospital, National Dense Medical Center, Taiwan. The survey material included an introduction letter, an informed consent form, and a structured questionnaire. We analyzed data including caregivers' gender and age, body mass index（BMI: kg/m^2）, self-reported health status and illness, working conditions（first-line caregiver, working days and hours, shift work and job type）, and their PA and exercise habits. Our study defines regular PA and exercise according to the national recommendation in Taiwan, which suggests exercise at least 3 times per week and 30 minutes per episode at moderate intensity.

A total of 327 caregivers who provided complete data on their personal demographic characteristics, health and working status, and PA and exercise were included in the analyses. Data were analyzed using SPSS 20.0 statistical software; statistical methods included number, percentage, mean±S.D.（standard deviation）, and range to describe the caregivers' demographic characteristics, health conditions, working conditions, PA and exercise participation. Multivariate

analysis of multiple logistic regression method, odds ratio（OR）and 95% confidence interval（95% CI）were performed to examine the factors associated with participation in regular PA and exercise among caregivers of adults with ID.

Results

Table 1 shows the demographic and health characteristics of caregivers of institutionalized adults with ID; 82.9% were women and 17.1% were men with an average age of 45.3 years（range 20-76 years）. We found that 31.2% of caregivers were overweight and 17.7% were obese. In terms of self-reported health status, 54.1% of caregivers reported they were healthy, 41.0% were fair and 4.9% were unhealthy, with 34.9% reporting a current illness.

Table 2 presents the working conditions among the caregivers; 67.3% were first-line workers, 29.7% worked more than 5 days weekly and 22.6% worked more than 8 hours per day. Forty-one percent of caregivers performed shift work. A total of 17.1% of caregivers performed sedentary work, 38.8% had labor-based jobs and 44% performed a mix of sedentary and labor-based work.

Table 3 and Table 4 provide information on PA and exercise participation among the caregivers; results showed that 71.9% of them participated in PA and exercise weekly. Among these caregivers, 70.6%

Table 1：Demographic and health characteristics of the caregivers（n=327）.

Variables	n	%	Mean±S.D. (range)
Gender			
Men	56	17.1	
Women	271	82.9	
Age			45.3±11.6（20.2-75.8）
＜40	108	33.0	
≧40	219	67.0	
BMI			24.2±3.6（15.8-39.1）
Underweight	8	2.4	
Normal weight	159	48.6	
Overweight	102	31.2	
Obese	58	17.7	
Health status			
Healthy	177	54.1	
Fair	134	41.0	
Unhealthy	16	4.9	
Have an illness			
No	213	65.1	
Yes	114	34.9	

S.D.: standard deviation

Table 2：Working conditions among the caregivers （n=327）.

Variables	n	%	Mean±S.D. (range)
First-line caregiver			
Yes	220	67.3	
No	107	32.7	
Working days per week			5.3±0.55（2-7）
≦5 days	230	70.3	
＞5 days	97	29.7	
Working hours per day			8.4±1.2（4-16）
≦8 hours	253	77.4	
＞8 hours	74	22.6	
Shift work			
Yes	135	41.3	
No	192	58.7	
Job type			
Sedentary	56	17.1	
Medium (Sedentary+labor)	144	44.0	
Labor	127	38.8	

S.D.: standard deviation

performed PA more than 3 times weekly, and 42.8% of them did more than 30 minutes per PA and exercise session. The main types of PA and exercise included walking（61.5%）, house cleaning（36.4%）, Nordic walking（25.1%）, general stretching（24.8%）, cycling（20.5%）, bodybuilding stretching（15%）, mountain walking（13.8%）, and gardening（11.3%）. Overall, 31.2% of caregivers reported that they participated in regular PA and exercise（more than 3 times per week and at least 30 minutes per episode）throughout the week.

Table 5 illustrates the factors associated with participation in regular PA and exercise among caregivers of adults with ID by stepwise logistic regression analyses. Model 1 indicated that only one aspect of the caregiver's health status（fair vs. healthy, OR=0.557, 95% CI=0.33-0.94）can significantly predict their regular PA and exercise participation after controlling for demographic and BMI factors. After adjusting for personal demographics, BMI and health status, model 2 demonstrated that caregivers who reported more working days per week（>5 days vs. ≦5 days, OR=0.549, 95% CI=0.31-0.98）were less likely to participate in regular PA and exercise than their counterparts.

Discussion

Caregivers were more stressed than non-caregivers [26], and those support staff working with individuals with ID and challenging behavior experience high

Table 3：Physical activity and exercise among caregivers.

Variables	n	%	Mean±S.D.（range）
Implement physical activity and exercise weekly (n=455)			
No	128	28.1	
Yes	327	71.9	
Frequency (weekly)(n=327)			3.5±1.9 (1-20)
＜3 times	96	29.4	
≧3 times	231	70.6	
Duration per episode (n=327)			
＜30 minutes	187	57.2	
≧30 minutes	140	42.8	
Regular physical activity and exercise (n=327)*			
No	225	68.8	
Yes	102	31.2	

＊At least 3 times per week and 30 minutes per episode.
S.D.: standard deviation

Table 4：Types of physical activity and exercise（n=327）

Types*	n	%
Walking	201	61.5
House cleaning	119	36.4
Nordic（sport） walking	82	25.1
General stretching	81	24.8
Cycling	67	20.5
Body building stretching	49	15.0
Mountain walking	45	13.8
Jogging	44	13.5
Gardening	37	11.3
Push-up/ sit-up	21	6.4
Swimming	18	5.5
Sports	16	4.9
Aerobic exercise	14	4.3
Gym exercise	10	3.1
Yoga	10	3.1
Dancing	3	0.9
Other	9	1.8

＊Multiple choices

Table 5：Multiple logistic regression analyses of regular physical activity and exercise in caregivers（n=327）

	Model 1			Model 2		
Variable （reference）	β	OR （95% C.I）	p-value	β	OR （95% C.I）	p-value
Constant	-0.608	0.544		-0.602	0.548	
Gender （men）	-0.653	0.521 （0.28-0.96）	0.036	-0.593	0.553 （0.29-1.07）	0.079
Age （＜40 years）	0.163	1.177 （0.68-2.03）	0.560	0.193	1.213 （0.68-2.15）	0.509
BMI （underweight vs. normal）	-0.345	0.708 （0.13-3.82）	0.688	-0.317	0.728 （0.13-4.09）	0.719
BMI （overweight vs. normal）	-0.222	0.801 （0.46-1.40）	0.888	-0.192	0.825 （0.46-1.47）	0.512
BMI （obese vs. normal）	0.150	1.162 （0.60-1.80）	0.577	0.140	1.151 （0.58-2.27）	0.685
Health status （fair vs. healthy）	-0.586	0.557 （0.33-0.94）	0.028	-0.616	0.54 （0.32-0.92）	0.022
Health status （unhealthy vs. healthy）	0.100	1.105 （0.36-3.41）	0.862	0.138	1.148 （0.36-3.65）	0.814
Have an illness （no）	0.043	1.044 （0.61-1.80）	0.877	0.073	1.076 （0.62-1.86）	0.793
First-line caregiver （yes）				0.012	1.012 （0.56-1.85）	0.969
Working days （≦5 days）				-0.600	0.549 （0.31-0.98）	0.043
Working hours （≦8 hours）				0.369	1.447 （0.80-2.62）	0.224
Shift work （yes）				-0.213	0.808 （0.48-1.35）	0.417
Job type （medium vs. sedentary）				-0.190	0.827 （0.39-1.77）	0.624
Job type （labor vs. sedentary）				-0.095	0.909 （0.41-2.00）	0.812

levels of work-related stress [27-28]. PA was found to be inversely associated with care burden, and interventions to increase the PA levels of older caregivers may improve their health status and quality of life [29]. This study provided information on factors related to PA among institutional caregivers for people with ID, autism and associated disabilities. The results revealed that 71.9% of caregivers participated in PA and exercise weekly. However, only 31.2% of caregivers reported they undertook regular PA and exercise（defined as more than 3 times per week and at least 30 minutes per episode）. According to the recommendation of the WHO [19], adults aged 18-64 years should do at least 150 minutes of moderate-intensity aerobic PA throughout the week, or do at least 75 minutes of vigorous-intensity aerobic PA throughout the week. The institutional caregivers in this study were less likely to participate in PA and exercise not only in terms of exercise frequency but in exercise duration as well.

Caring for children with ID was perceived as difficult and frustrating, yet rewarding [30]. Our previous study examining depressive symptoms in caregivers found that 8.2% of caregivers expressed that it was very difficult, and 4.5% felt that it was extremely difficult to work, care for things at home, or get along with others. The study highlights the need to strengthen appropriate health initiatives for monitoring mental health status and to provide necessary services for caregivers for adults with ID [31]. Understanding and responding to the changing needs of family caregivers is vital to the disability service system to effectively prioritize formal resources and services [32].

Previous research has shown that caregivers had a greater number of metabolic syndrome factors over time than non-caregivers [33], Alzheimer's caregivers were less physically active than non-caregivers, and cardiometabolic risk was particularly high in caregivers reporting reduced levels of regular PA [34-35]. Caregivers also reported high levels of physical strain and musculoskeletal discomfort and they identified several activities related to mobility and self-care as the most physically demanding. Factors affecting physical demand included caregiver and care-recipient characteristics, activity requirements, and the physical environment [36]. Therefore, relieving caregiving burdens and improving caregivers' PA need to be considered as separate care issues in planning interventions for the caregivers of patients [21].

Conclusion

This study found that the variable of more working days per week among caregivers made them less likely to implement regular PA and exercise than their counterparts based on a stepwise logistic regression analysis. Both physical environmental and psychosocial factors were associated with PA in adults, with psychosocial factors being important especially for leisure-time PA [37]. Recreational PA was mainly determined by social support, self-efficacy, and perceived benefits and barriers [38]. One study in Taiwan revealed that cultural issues may play a critical role in PA behavior among Taiwanese family caregivers. Caregivers' age, relationship to the patient, and marital status were correlated with engagement in a regularly active lifestyle among family caregivers in Taiwan [39].

Caregivers are in need of interventions to increase PA and health. Efforts to help caregivers participate in multiple shorter bouts of exercise during the day could be more effective than recommending one continuous 30-minute bout [1]. To improve PA and exercise among caregivers of people with disabilities, the welfare institution can adopt, as Castro, Wilcox, O'Sullivan et al. [40] suggested, delivery of a feasible and successful health promotion counseling program aimed at improving PA

levels among highly stressed and burdened caregivers.

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1.Contribution details

LJD designed and performed the study, LLP, LWJ, and YCH collected and analyzed the data, and LLP drafted the manuscript. SWH overviewed the project / study. All authors read and approved the final manuscript.

2.Competing interests

None declared.

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[原著]

身障長照機構照顧者規律身體活動與運動：工作狀況效應分析

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摘　要

身體活動對所有年齡層的人都有正向的健康助益，身體活動的介入也會減輕主要照顧者的壓力、憂鬱情形和情緒負擔。然而，卻只有少數的研究調查身心障礙者之照顧者的身體活動狀況。本研究目的在探討身障長照機構中的照顧者的身體活動與運動狀況，以及分析可能的影響因素，尤其是工作狀況因素；研究調查對象為立意取樣選取台灣7家身心障礙福利機構中照顧智能障礙者、自閉症和其他有關障礙的照顧者，總共有455位；其中327位樣本有提供完整的身體活動與運動資料納入本研究統計分析。本研究結果顯示有71.9%的照顧者每週從事身體活動跟運動；其中31.2%的人表示每週進行三次、每次30分鐘的規律身體活動跟運動；主要身體活動跟運動類型為散步（61.5%）、家事清潔（36.4%）、北歐式健走（25.1%）、一般伸展運動（24.8%）以及騎腳踏車（20.5%）。在校正個人人口學變項、BMI、以及健康狀況後，多元羅吉斯迴歸模式顯示每週工作五天以上的人比另一群人（每週工作少於五天）較少從事規律活動跟運動（OR=0.549）。最後，本研究建議應針對照顧者的需求來增加他們的身體活動量，藉以改善他們的健康。

【關鍵詞】身體活動、運動、智能障礙者、自閉症、照顧者、健康促進

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［原著］

針對高風險單位運用組合式留置導尿管之實證照護與健康照護指引降低泌尿道感染及提高管理效能

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摘　要

目的：感染管制是提升醫療品質和健康促進的過程中受到廣泛討論的議題，與導尿管相關泌尿道感染在醫療照護相關感染中是常見的，尤其是在高風險單位。本神經外科加護病房導尿管相關泌尿道感染，年平均感染密度高達9.43‰，期藉本研究運用組合式留置導尿管之實證照護與健康照護指引降低泌尿道感染及提高健康促進管理效能。**方法：**研究執行期間2015年3月1日至2015年12月31日進行問題處理和改善，建立完善的處理架構、管理與流程改進，明訂清楚階段目標，以問卷調查法、技術查核、實地觀察、標準化稽核、常模比較以及審核規範、程序等方法進行資料收集，運用特性要因圖和決策矩陣分析找出重要影響因素，擬訂可行之對策。**結果：**彙整後確認問題為護理人員照護行為不確實及導尿管照護健康促進認知不足、未修訂導尿管照護標準步驟及流程、未訂定完整統合的導尿管照護稽核制度、缺乏組合式導尿管照護教育訓練和照護系統無資訊化建置。藉由明確策略，修訂加護病房特殊狀況之照護標準、實施在職教育訓練、建置資訊化系統、並執行稽核等，落實方案執行。評值策略之成效，導尿管相關泌尿道感染密度降至4.31‰，執行組合式留置導尿管照護正確率由65.6%提升為98.5%，導尿管照護健康促進認知正確性由68.7%提升到100%。**結論：**此研究成效明顯，有效提昇專業照護品質。透過跨領域團隊共同照護的合作模式、創新的想法、查核和監測機制、物料的更換、臨床技能之正確性及建構資訊化系統等，有效率的整合資源，強化健康促進專業知識。

【關鍵詞】管理效能、組合式留置導尿管照護、導尿管相關泌尿道感染、加護病房、健康促進

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前言

感染管制是提升醫療品質和健康促進的過程中受到廣泛討論的議題，也發展出許多指標，導尿管相關泌尿道感染（Catheter Associated Urinary Tract Infection, CAUTI）佔醫療相關照護感染（Healthcare-associated infections, HAIs）的35-45%，每留置導尿管一天會增加3-5%感染風險和增加0.5-1天的住院天數[1]。行政院衛生署疾病管制局[2]指出2015年醫學中心加護病房醫療照護院內感染中泌尿道感染佔第二名，其中89.8%與導尿管留置有關，若發生菌血症將威脅病人生命，延長住院天數，再者，與導尿管相關泌尿道感染是醫療照護相關感染常見之感染，尤其是在高風險單位的加護病房單位[3-5]，加護病房內的侵入性治療是病人發生感染的重要風險因子之一，其易導致併發症，更增加敗血症的死亡風險。高達69% CAUTI可藉由提供預防感染措施被避免的，造成CAUTI之危險因素分為可控制及不可控制，可控制的因素包含放置尿管天數、未依照導管無菌照護原則、缺乏導尿管放置之訓練，不可控制的包含潛在性重症疾病、長期臥床、非手術相關疾病、年齡等[6-8]。

Tannahill（1985）認為健康促進建議應包括「健康保護」（health protection）、「健康干預」（prevention）以及「健康教育」（health education）三個層次[9]，健康促進行為包含了認知、行為及環境等因素[9-10]，因此，健康促進乃是降低疾病發生的根基[10]，CAUTI的預防已成為醫院感染管制政策重點，故降低泌尿道感染及執行導尿管照護的正確性在照護品質中有極重要的角色，更攸關病人安全及照護的成效[6-7]。

CAUTI的預防約65%-70%是運用實證基礎的策略並著重在置入、照護和移除三大層面來執行，應用組合式照護（Bundle Care on Catheter-associated Urinary Tract Infection）的運用是降低感染的重要措施[8,11]，實施組合式照護策略，除了放置導尿管前評估醫療必要性，以及無菌技術和無菌設備，更強調標準流程的執行以維持專業照護品質，維持暢通的引流照護，以及導尿管的移除計劃，落實留置導尿管每日查核評估，持續稽核及監測，並確認符合導尿管適應症等，這些皆可大幅降低CAUTI[6,8,12-13]。更藉由臨床實務訓練，增加護理人員泌尿道感染之正確知識、態度、行為，跨團隊的合作，協助個案促進健康的生活型態[10]，更可降低留置導尿管相關泌尿道感染，提升醫療照護品質、減少病人住院天數及醫療成本[13-14]。

背景與動機

本研究依據疾病管制署侵入性醫療指引共同推行組合式照護措施以降低侵入性導管相關感染，神經外科加護病房在2014年導尿管相關泌尿道感染的年平均感染密度高達9.43‰（留置導尿管相關感染人次 / 留置導尿管使用人日=33/3500），不僅遠高於2014年台灣臨床成效指標（Taiwan Clinical Performance Indicator, TCPI）同儕年平均感染密度2.77‰（308/111183），更大幅超出全院加護病房年平均感染密度4.64‰（62/13374），以下為現況背景之分析結果：

一、醫護人員照護留置導尿管現況分析

1. 組合式導尿管照護未逐項執行：以查檢表查核醫護人員置入導尿管操作正確性，正確率67.1%，其中以手部衛生正確率最低（26.7%），原因為忙碌或自覺不需要（表一）。實際查核時也發現照護行為不確實。
2. 以查檢表監測護理人員執行導尿管照護過程，正確率64.3%。發現經護理師評估留置導尿管天數，並與醫師討論是否拔除僅佔33.3%（表一）。由「導尿管置入流程正確率」和「每日導尿管照護正確率」發現醫護人員執行組合式留置導尿管照護之正確率為65.7%。
3. 組合式導尿管照護認知不足：以「留置導尿管照護健康促進認知評量」了解護理人員對導尿管照護認知程度，結果顯示了解組合式

導尿管照護查核清單及正確填寫內容僅佔30%（表二）。

4.擦拭會陰不確實，倒尿時尿袋口不慎觸碰尿桶，懸掛尿袋位置不正確，尤其是移動病人接受影像和腦部檢查前後忘記將尿管放置正確位置。

表 1：組合式留置導尿管照護正確率前後測分數（人數 =30）

項　　目	改善前正確		改善後正確	
	人數	百分比	人數	百分比
導尿管置放流程正確率				
1.置放導尿管前、後執行手部衛生	8	26.7	30	100
2.無菌技術操作	28	93.3	29	96.7
3.戴無菌手套，並鋪上無菌洞巾	30	100	29	96.7
4.尿道口周圍以消毒劑消毒	13	43.3	30	100
5.使用無菌技術連接導尿管及尿袋	28	90.3	29	96.7
6.導尿管固定方式正確	30	100	30	100
7.尿袋位置正確	8	26.7	30	100
	67.1%		98.6% (A)	
護理人員執行每日導尿管照護正確率				
1.導尿管固定正確	24	80	30	100
2.尿袋不可超過8分滿	21	70	30	100
3.尿道口清潔後尿管上無分泌物或痂狀物	27	90	29	96.7
4.避免尿管拉扯	24	80	29	96.7
5.倒尿時出口勿接觸尿桶，倒尿後尿袋出口立刻關閉	18	60	29	96.7
6.導尿管確實維持密閉、通暢，無扭曲或壓折	11	36.7	30	100
7.評估留置導尿管天數，並與醫師討論是否拔除	10	33.3	30	100
	64.3%		98.6% (B)	

組合式留置導尿管照護正確率計算方式：(A)+(B) ÷ 2

表 2：護理人員留置導尿管照護健康促進認知評量前後測（人數 =30）

項　　目	改善前正確		改善後正確	
	人數	百分比	人數	百分比
1.了解組合式導尿管照護查核清單及正確填寫內容	9	30	30	100
2.每日查房時評估導尿管天數並與醫師討論是否拔除	10	33.3	30	100
3.術後盡可能24小時內移除，了解術後尿瀦留時的處理方式	10	33.3	30	100
4.執行技術前後洗手	24	80	30	100
5.放置導尿管前以肥皂水進行會陰及男性尿道口清潔	23	76.7	30	100
6.留置導尿管固定方式正確	24	80	30	100
7.導尿管維持密閉、引流通暢，避免管路扭曲或壓折	30	100	30	100
8.尿袋不可超過8分滿	23	76.7	30	100
9.維持尿道口清潔無異味	30	100	30	100
10.在不會漏尿前提下，使用最小號的導尿管	23	76.7	30	100
護理人員認知成績平均分數	68.7%		100%	

二、政策現況分析

1.缺乏定期稽核機制：雖然已制定「組合式留置導尿管照護」，卻缺乏定期稽核機制，無法定期監測人員執行組合式留置導尿管照護的實際狀況以及正確率；亦無稽核員定期監督指正。

2.缺乏組合式導尿管照護之教育訓練及健康促進概念，缺乏機會透過課程講授和訓練進行臨床實務學習，和接受整合性的輔導，也缺乏回覆示教以瞭解人員實務學習效果。

3.標準化照護流程需修訂：缺乏加護病房特殊照護標準、評估流程和放置標準可依循。

4.缺乏組合式留置導尿管的資訊化系統的建置，對於「預防導尿管相關泌尿道感染置放查檢表」和「預防導尿管相關泌尿道感染每日照護查檢表」表單填寫完整性，正確率分別僅有26.7%和30%。

5.院內規範需及時更新：已制定的「導尿管護理業務規範」其規範內容僅陳列一般導尿管照護，未將組合式留置導尿管照護列入其中，以致照護措施不一致。

三、物料現況分析

1.導尿管為橡膠材質，尿袋引流系統管徑小質軟、易彎折，引流管連接尿袋口處易扭曲或壓折，造成尿液蓄積。

2.目前尿袋設計易造成逆行性感染。

研究目的

因此，本研究運用組合式留置導尿管之實證照護與照護指引降低泌尿道感染及提高管理效能，也藉此提升加護病房護理人員健康促進照護認知與執行組合式留置導尿管照護之正確率。本研究依據加護病房導尿管照護品質監測閾值、加護病房平均感染密度設定目標值，研究目的為：

一、降低本單位導尿管相關泌尿道感染的感染密度至4.64

二、提升護理人員執行組合式留置導尿管照護正確率由65.6%提升至90%。

三、提升護理人員健康促進照護認知正確性由68.7%提升至100%

材料與方法

一、研究方法

以問卷調查法、技術查核、實地觀察、標準化稽核、常模比較以及審核規範、程序等為此研究之方法。

二、研究問題與研究架構

針對護理人員留置導尿管照護執行不完整及缺失進行分析，實際查核置放流程正確與否、執行導尿管每日照護正確率以及導尿管照護健康促進認知三個層面，將結果依醫護人員、物料及政策三大面向歸納成泌尿道感染偏高、以及組合式留置導尿管照護執行正確率低特性要因圖（圖一）。

經由上述現況分析及特性要因圖歸納出，加護病房護理人員執行組合式留置導尿管照護正確率低的主要原因為：（一）、護理人員照護行為不確實及導尿管照護健康促進認知不足。（二）、未修訂導尿管照護標準步驟及流程。（三）、未訂定完整統合的導尿管照護稽核制度。（四）、缺乏組合式導尿管照護健康促進教育訓練。（五）、照護系統無資訊化建置。

針對現況分析及特性要因圖，進行問題的整理及原因的探索 並將主要問題進行討論，依決策矩陣分析擬訂可行之對策之可行性、重要性、經濟性及迫切性列出解決方案，以分數高於或等於90分為採行對策（表三）

三、研究執行期間

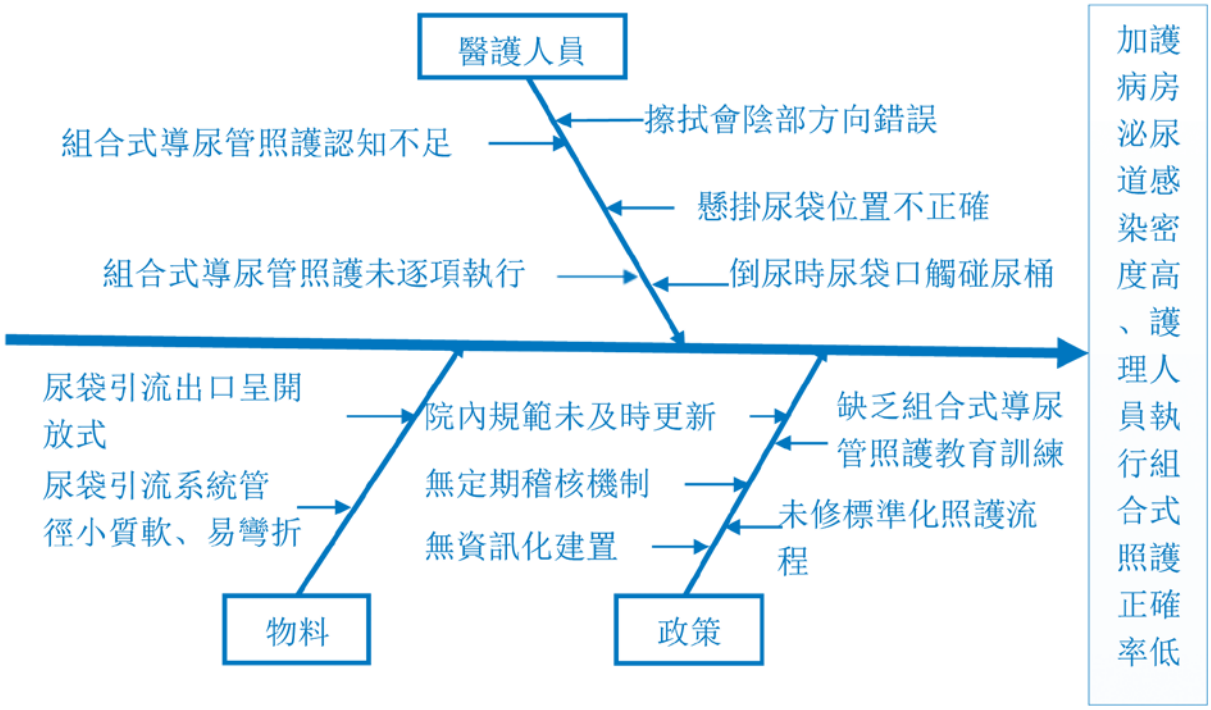
研究執行期間為2015年3月1日至12月31日，依計劃期、執行期、評值期，三階段實行。

（一）、計畫期（2015年3月1～4月30日）

1.規劃修訂組合式留置導尿管照護標準：依據

疾病管制署侵入性醫療指引修訂，每個 驟4至5個字，建構出簡單易記的「組合式留置導尿管照護」，含「預防導尿管相關泌尿道感染置放查檢表」及「預防導尿管相關泌尿道感染每日照護查檢表」二部分。

2. 制定移動病人接受檢查前後的導尿管引流系統照護標準：例如：與放射醫學部溝通，制定相關要項，避免逆行性感染風險。
3. 修訂導尿管護理業務規範：更新導尿管護理業務規範內容，新增常規評估項目，提供一致性的評估標準。
4. 制定重置留置導尿管流程和申購本單位專用膀胱掃描儀器，新增加護單位特殊流程（圖二ａ）。
5. 更換成一次性使用護理巾。
6. 規劃導尿管照護教育訓練及技術指導提升健康促進概念：規劃教育訓練課程、學習成效測量，並由臨床指導教師進行技術考核，以提升正確評估技巧與強化臨床技能。
7. 規劃培育洗手種子教師：規劃由感管護理師培訓3名護理師成為洗手種子教師，制定洗手稽核制度。
8. 規劃制定照護稽核機制：於病房會議公佈，將「組合式留置導尿管照護」列入單位品管稽核項目，稽核方法為每位導尿管新置入者均需依照置放查檢表和每日照護查檢表稽核護理人員，針對錯誤步驟和執行缺失，即時修正，針對有缺失者進行再次追蹤改善成效。
9. 規畫建置資訊化系統：與資訊室研擬建置組合式留置導尿管照護資訊化。
10. 製作組合式留置導尿管照護光碟：3月30日，進行導尿管相關泌尿道感染判讀，臨床評估和症狀處置之衛教影片實境拍攝，以利人員將正確健康促進認知與臨床實務相結合，並上傳院內數位教育平台進行數位學習。
11. 製作組合式留置導尿管照護提醒機制以及「ABCDE口訣」海報：發揮創意巧思製作組合式留置導尿管照護海報（圖二ｂ），

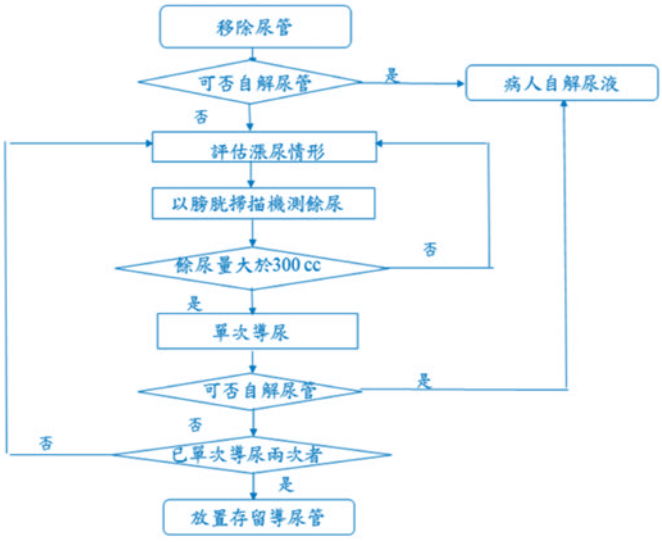


圖一、加護病房泌尿道感染密度高、護理人員執行組合式照護正確率低特性要因圖

表 3：組合式留置導尿管照護之決策矩陣圖

	導因	解決方法	可行性	重要性	經濟性	迫切性	總分	選定方案
政策	缺乏組合式導尿管照護教育訓練	規畫導尿管照護教育訓練及技術指導	26	30	16	22	94	★
	院內規範未及時更新	修訂導尿管護理業務規範	30	28	16	22	96	★
	無定期稽核機制	規畫制定照護稽核機制	26	30	16	22	94	★
	未修標 化照護流程	修訂組合式留置導尿管照護標準	30	28	16	22	96	★
	無資訊化建置	規畫建置資訊化系統	30	28	16	22	96	★
醫護人員	組合式導尿管照護認知不足	舉辦導尿管照護相關在職教育	24	26	16	28	94	★
		定期舉辦導尿管照護認知測試	26	28	16	24	94	★
		製作組合式留置導尿管照護光碟	26	28	16	24	94	★
		製作組合式導尿管照護海報	24	26	16	28	94	★
	組合式導尿管照護未逐項執行	製作留置導尿管照護提醒機制以及海報	26	28	16	24	94	★
	懸掛尿袋位置不正確	制定送檢時導尿管引流系統照護標準	26	28	16	24	94	★
	倒尿時尿袋口觸碰尿桶	舉辦導尿管照護相關在職教育	26	26	20	26	98	★
物料	尿袋材質易扭曲壓折	更換衛材尿袋	26	28	16	24	94	★

（註：三段評價，5分(優)、3分(可)、1分(差)；專案小組6人，執行對策通過標準以專案小組認可為優(5分)的75%為決策基準，6人x5分(滿分)x4項x75%＝90分，故總分90分以上為可執行對策。）



圖二a、重置留置導尿管流程圖

圖二b、組合式留置導尿管照護海報

更將照護內容設計為「ABCDE口訣」，以增強人員記憶，包括無菌操作（Aseptic，A）、尿袋固定位置（Bag，B）、手部衛生（Clean，C）、引流通暢（Drain，D）及每日導尿管留置評估並儘早拔除（Early，E），並張貼以達到提醒作用。

12. 更換衛材尿袋：向院方資材提出更改單位常備衛材設置，改用尿袋引流口為反摺式，且尿袋引流系統管徑較粗，讓尿液更容易引流，且不易扭曲或壓折。

（二）、執行期（2015年5月1日～9月30日）

1. 宣導改善方案：利用5月3日至6日交接班時及每月病房會議加強宣導，將「組合式留置導尿管照護」光碟片存放於護理站、各工作站的電腦桌面，並落實確保全體同仁皆已充分瞭解。
2. 舉辦導尿管照護教育訓練健康促進及技術指導：舉辦多場健康促進教育訓練課程，每場至少2小時，由講師講述、導尿管照護床邊演練回覆示教、錯誤步驟修正的示範與團體討論。並進行學習成效量測、授課內容的技術考核。
3. 建置資訊化系統：6月1日至7月31日，完成組合式留置導尿管照護資訊化建置，並於醫令系統設置導尿管放置天數提醒畫面。
4. 稽核組合式留置導尿管照護執行正確率：每月依「組合式留置導尿管照護」進行稽核標準步驟及流程，針對錯誤缺失即時指正，隔月追蹤改善成效，須達100%正確。
5. 遭遇困難與修正情形：專案執行過程中，5月時發現65%護理人員因工作忙碌，無法顧及組合式留置導尿管照護，45.2%未習慣每日逐床確認導尿管留置的必要性，未確實執行每日的評估及記錄，因此、針對上述狀況進行修正：(1)、晨間會議加強宣導；(2)、適時的提醒；(3)、提供獎勵；(4)定期召開共識會議，維持認知及技術的一致性。

（三）、評值期（2015年10月1日～12月31日）

1. 評值執行組合式留置導尿管照護正確率；依「預防導尿管相關泌尿道感染置放查檢表」查核每位導尿管新置入者執行正確性，及依「預防導尿管相關泌尿道感染每日照護查檢表」，查檢30位護理師，依結果評值研究之成效並做檢討與改善。
2. 評值護理人員留置導尿管照護健康促進認知，依「留置導尿管照護健康促進認知評量」，針對30位護理人員施測，比較研究執行前後認知的正確性。
3. 評值導尿管相關泌尿道感染的感染密度；依據加護病房每月品管指標，評值2015年第四季感染密度，比較研究執行前後的成效。

研究結果

（一）護理人員執行組合式留置導尿管照護正確率

依據相關評估表共稽核30人次，組合式留置導尿管照護正確率為98.5%，達護理研究目標值；比較本研究實施前後成長率29.2%。（表一）

（二）護理人員留置導尿管照護健康促進認知正確性

依「留置導尿管照護健康促進認知評量」施測，平均成績100%，即每題測試皆回答正確，達目標值。（表二）

（三）導尿管相關泌尿道感染的感染密度之改善成效

2015年10～12月導尿管相關泌尿道感染的感染密度，分別為，10月5.6 、11月4.7 、12月2.65 ，呈現逐月下降趨勢，本單位導尿管相關泌尿道感染的感染密度降至4.31 ，低於設定目標值4.64 ，達目標值，研究計畫實施前後降低了5 。

另外、在研究過程中為落實手部衛生遵從性及正確性，也執行洗手稽核，稽核結果於5月時平均68分、6月平均82分、7月平均94分。

討論與結論

正確執行組合式留置導尿管照護可提升醫療照護品質，進而降低導尿管相關泌尿道感染的感染密度，對於病人安全影響甚鉅[6,8-14]，稽核制度與標準化流程的建立協助更可以幫助臨床專業人員經過訓練後獲得更進階的照護措施[11]。本研究順利推動達到成效的最大助力在於以病人健康促進為中心的照護理念，經由健康促進行為的落實以及有效的策略與方式，從護理人力的投入、病人參與、醫療團隊支持及環境改善等層面來著手，才能獲得最佳效益[14]。透過跨領域團隊共同照護的合作模式、創新的想法、查核和監測機制、物料的更換、臨床技能之正確性及建構資訊化系統等，有效率的整合資源，強化專業知識。執行過程深刻體認此研究直接並有效解決問題，提昇醫療照護品質，提升病人及家屬對於護理專業之信任感，降低病人生命危害，這也是莫大鼓舞。

本研究之重要貢獻為藉由提升加護病房護理人員執行組合式留置導尿管照護正確率之改善過程中，從文獻查證，到實證整合到專業臨床實務可行的措施，制定院內「組合式留置導尿管照護標準」、「送檢時導尿管引流系統照護標準」及更新「導尿管護理業務規範」，藉此降低導尿管相關之泌尿道感染，依標準流程維持導尿管留置之照護品質，更間接提升病人的健康狀態，也讓臨床人員更容易將臨床指引應用於病人實際照護[12-13]。另外、更完成資訊化建置，配合制定的提醒機制，促使護理、醫療及感控三方同時連線監控臨床作業狀況，達到資料快速整合。

本研究將疾病管制署專業照護之標準和重要的品質指標，以及本院照護病人的特性，背景說明和需求分析納入研究策略規劃中，依據前述策略分析明訂本研究之研究目的與計畫，因此、建議各醫院之醫療團隊仍須依照個別醫療單位之特性和目標修正規劃所需之策略性相關計畫，這是本研究提出的限制。

本研究對護理業務也提出以下建議：1.導尿管照護知識與技術之教育訓練，應列入未來新進護理人員在職教育內容；2.每年應至少評核一次導尿管護理業務規範的相關內容；3.組合式留置導尿管照護執行正確率的稽核應每三個月持續進行稽核，以提升護理照顧品質。因本研究執行成效佳，已於本院其他加護病房平行推展，亦列入該加護病房護理品質指標之一，提升本院重症之照護品質。

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[Original Article]

Application of Clinical Care Guidelines of Bundle Care on Catheter- Associated Urinary Tract Infection to Reduce Urinary Tract Infections and Improve Management Efficacy in High Risk Unit

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Abstract

Objectives: Infection control has been a widely discussed issue in the context of improvement of health care quality and health promotion. Catheter-associated Urinary Tract Infections（CAUTI）are the most common type of healthcare-associated infection, especially in high-risk units. The average annual infection rate of CAUTI in this intensive care unit is as high as 9.43‰. Thus, the aims of this study were to decrease urinary tract infection and improve management efficacy by applying the evidence based clinical guidelines of the bundle care on indwelling catheter. **Methods:** The method of study was applied to establish a comprehensive study processing framework, improve management process, clearly define objectives by phases, discuss and review the possible strategies. Survey, skill examination, observation, standardized audit, norm comparison and reviews of clinical practice guidelines were used to collect data and analyze and find the possible causes. Cause and effect analysis diagram and decision-making matrix were also used to identify important influencing factors, and formulate feasible strategies. **Results:** The significantly influencing factors were confirmed which were related to elements of nursing care activities left incomplete and lack of awareness of catheter care by nurses which contributing to task incompletion, the unrevised catheter care standardized procedures, lack of an integrated clinical audit of urinary catheter cares, and lack of bundle catheter care and construction of related information systems. Educational training and care systems are

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not information-based. The schemes for problem-solving were developed and included strategies of revision of the clinical standards of the intensive care unit for the special conditions, implementation in-service training programs, establishment of an information system of the bundle care, and carrying out audits. The rate of CAUTI decreased to 4.31‰. Nurses' accuracy of indwelling catheter bundle care of nurses increased from 65.6% to 98.5%, and the awareness of catheter care increased from 68.7% to 100% after implementing the study. **Conclusions:** This study has achieved a remarkable effect and improved efficiently the quality of professional care. Through a multidisciplinary team work and cooperative model, innovative ideas, audit and monitoring system, material replacement for clinical practice, accuracy of clinical skills, and construction of an information system, effective resource integration is achieved and the improvement of professional capacity is gained.

Key words: management efficacy, bundle care on indwelling catheter, catheter-associated urinary tract infection（CAUTI）, intensive care unit, health promotion

「健康促進研究與實務」雜誌投稿規則

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2017.05.10 第二次修訂
2019.04.29 第三次修訂

本雜誌為社團法人臺灣健康醫院學會所出版的之學術性刊物，刊載有關醫院與照護機構推動健康促進之綜論、專論、原著論文、簡報、短評、個案報告及讀者來函等論文，以未曾投稿於其他雜誌之論文者為限；投稿論文經過匿名同儕審查（Anonymous peer reviewed）接受後始得刊登。

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