



PREVENTION OF FRAGILITY FRACTURE AMONG
POST MENOPAUSAL WOMEN: NEEDS ASSESSMENT
AND THE DEVELOPMENT OF BONE HEALTH
EDUCATIONAL BOOKLET

BY

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ABSTRACT

Fragility fracture is extremely prevalent in older adults, and is known to have a staggering cost of treatment. Nearly 1 in 3 women, especially Post-Menopausal Women (PMW) over the age of 50, will develop fragility fracture in their lifetime. The management of osteoporosis in PMW involves pharmacological intervention as well as non-pharmacological methods, particularly in providing education and preventive behaviour programs. Education materials that suit and are tailor- made for our local PMW population are currently limited. Information inside the booklet can assist users in memorizing, and guide their health education activities. Realizing the importance of developing educational resources based on local needs, this study aims to develop and validate bone health educational booklet for PMW in preventing fragility fracture. This research was conducted in 2016, covering needs assessment study by distributing questionnaires on Knowledge, Attitude and Practice (KAP), and an assessment of fracture risk factors by using the Fall Free Prevention Questionnaire (FFPQ), the Activity Specific and Balance (ABC) scale, and the Fracture Risk Assessment (FRAX) tool; followed by conducting a physical examination using the Time up and Go (TUG) test, the Bone Mineral Density (BMD) analyses, and the Blood Serum Calcium level among local PMW. The process was continued by establishing the booklet content by including the findings from the needs assessment study, drafting of text, designing of illustrations and layout, validation process by content experts and end users, followed by the process of revising, editing and proofreading of the text. The needs assessments results shows respondents age and level of education was associated with their knowledge on bone health, ($\chi^2=8.515$; $p=0.014$), ($\chi^2= 16.514$; $p= 0.001$), and calcium intake among age of 70 and above having adequate intake based on calcium daily requirement intake (RDI) ($\chi^2= 12.544$; $p= 0.002$). The year of menopause was highly correlated to age ($r = 0.82$, $p < 0.001$) and FRAX major osteoporotic fracture shows a moderate correlation ($r = 0.581$, $p < 0.001$). The FRAX hip fracture was highly correlated to age (0.694 , $p < 0.001$). Significant level with highly correlation were found between BMD and independent variables FRAX major osteoporotic fracture score (-0.606 , $p < 0.001$) and FRAX hip fracture score (-0.708 , $p < 0.001$) respectively and ABC scale had positive with weak association with BMD (0.200 , $p < 0.001$). The booklet was validated using content and face validity. As a result, the booklet shows an excellent content validity with 0.77 of the global Content Validity Index (CVI). The level of agreement within the experts (91.1% - 100%) and representatives of the end users (100%) was excellent. Overall, all of the participating end users were satisfied with the booklet and found the booklet very useful in guiding them. In addition, improvements proposed by the experts were included and modification of the final version was made accordingly. Thus, this booklet can be considered as an instrument to promote the prevention of osteoporosis and fragility fracture among PMW.

خلاصة البحث

كسور هشاشة العظام منتشرة بشكل كبير لدى كبار السن، ومن المعروف أن علاجها مكلف جدا. حوالي واحدة من ثلاثة نساء ستعاني من كسور هشاشة العظام، وخاصة بين النساء فوق سن الخمسين اللواتي انقطع الطمث عندهن (Post-Menopausal Women, PMW). يتضمن التعامل مع هشاشة العظام عند PMW التدخل الدوائي، بالإضافة إلى الطرق غير الدوائية مثل توفير برامج التعليم والسلوكيات الوقائية. المواد التعليمية المصممة خصيصاً لتناسب PMW المميزات محدودة حالياً. بالإمكان للمعلومات داخل الكتيب أن تساعد المستخدمين في الحفاظ، وتوجيه أنشطتهم التثقيفية الصحية. إدراكاً لأهمية تطوير الموارد التعليمية على أساس الاحتياجات المحلية فقد هدفت هذه الدراسة إلى تطوير والتحقق من صحة الكتيب التعليمي لسلامة العظام للPMW لمنع كسور هشاشة العظام. تم إجراء هذا البحث في عام 2016، وقد شمل دراسة لتقييم الاحتياجات من خلال توزيع استبيانات حول المعرفة والسلوك والممارسة (Knowledge, Attitude, and Practice, KAP)، وتقييم عوامل الخطر للكسور باستخدام استبيان الوقاية من السقوط (Free Fall Prevention Assessment, FFPQ)، ومقياس النشاط المحدد والتوازن (ABC)، وأداة تقييم مخاطر الكسور (FRAX)، بعد ذلك تتم إجراء فحوص بدنية باستخدام اختبار (Time up and Go, TUG)، وتحليل كثافة العظام (Bone Mineral Density, BMD)، ومستوى الكالسيوم في مصل الدم بين PMW المميزات. استمرت العملية بإنشاء محتويات الكتيب من خلال إدخال نتائج دراسات تقييم الاحتياجات، وصياغة النصوص، وتصميم الرسومات التوضيحية، والتنسيق، وعملية المراجعة بواسطة خبراء المحتوى والمستخدمين، ومن ثم مراجعة، وتحرير، وتدقيق، وتصحيح النصوص. أظهرت نتائج تقييم الاحتياجات أن عمر ومستوى تعليم المشاركين في الدراسة مرتبطين بمعرفتهم بصحة العظام، ($\chi^2 = 8.515$ ؛ $p = 0.014$)، ($\chi^2 = 16.514$ ؛ $p = 0.001$)، وكان مرتبطين أيضاً بتناول الكالسيوم الكافي في المجموعة العمرية 70 وما فوق على حسب الاحتياج اليومي للكالسيوم ($\chi^2 = 12.544$ ؛ $p = 0.002$). ارتبطت سنة انقطاع الطمث ارتباطاً وثيقاً بالعمر ($r = 0.82$ ، $p < 0.001$)، وأظهرت نقاط FRAX لكسور هشاشة العظام الرئيسية وجود علاقة معتدلة ($r = 0.581$ ، $p < 0.001$) بالعمر، وارتبطت أيضاً نقاط FRAX لكسور الورك ارتباطاً كبيراً بالعمر ($r = 0.694$ ، $p < 0.001$). كان هناك مستوى مهم وارتباط كبير بين الBMD والمتغيرات المستقلة لنقاط FRAX لكسور هشاشة العظام الرئيسية ($r = -0.606$ ، $p < 0.001$) ونقاط FRAX لكسور الورك ($r = -0.708$ ، $p < 0.001$)، وكان لدى مقياس ABC ارتباط إيجابي ضعيف بالBMD ($r = 0.200$ ، $p < 0.001$). تمت مراجعة الكتيب باستخدام صحة المحتوى والصحة الظاهرية. أظهر الكتيب صلاحية محتوى ممتازة بمعدل 0.77 من مؤشر صحة المحتوى العالمي (Global Validity Index, CVI). كان مستوى الاتفاق بين الخبراء (91.1%–100%) ومثلي المستخدمين (100%) ممتازاً. كان جميع المستخدمين المشاركين عموماً راضين عن الكتيب ووجدوا الكتيب مفيداً جداً في توجيههم. تم أيضاً إدخال التحسينات المقترحة من قبل الخبراء وتم تعديل النسخة النهائية وفقاً لذلك. وبالتالي، بالإمكان اعتبار هذا الكتيب أداة لتعزيز الوقاية من هشاشة العظام وكسور هشاشة العظام بين PMW.

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DECLARATION

I hereby declare that this thesis is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

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LIST OF ABBREVIATIONS

ABC	Activity Specific and Balance
BMI	Body Mass Index
CKD	Chronic Kidney Disease
CVD	Cardiovascular Disease
CVI	Content Validity Index
ERT	Estrogen Replacement Therapy
PMW	Post Menopausal Women
PMO	Post Menopausal Osteoporosis
PTH	Parathyroid Hormone
BMD	Bone Mineral Density
BTMs	Bone Turnover Markers
KAP	Knowledge, Attitude and Practice
FFPQ	Fall Free Prevention Questionnaire
FRAX	Fracture Risk Assessment
MSC	Mesenchymal Stem Cell
NMRR	National Medical Research Registry
OPAAT	Osteoporosis Prevention and Awareness Tool
OAKT	Osteoporosis Attitude Knowledge Test
OSTA	Osteoporosis Screening Tools for Asia
RDI	Daily Requirement Intake
SERMs	Selective Estrogen Receptor Modulators
TLM	Therapeutic Lifestyle Modification
TNF	Tumor necrosis factor
TUG	Time Up and Go

CHAPTER ONE

INTRODUCTION

1.1 INTRODUCTION

This chapter is an introduction to the study, on needs assessment and the development of bone health educational booklet, in preventing fragility fracture among postmenopausal women (PMW). Overall, the chapter focuses on the background of the study and the problem statement. Then, the study framework and the significant role of the bone health educational booklet are highlighted, followed by the research questions and the objectives of the study. The next subchapter discusses the operational definition of all the variables used in the study, continued with a summary of all the chapters in the thesis. It ends with the conclusion of the chapter.

1.2 OVERVIEW OF STUDY

Fragility fracture is extremely prevalent in older adults, and is known to have a staggering cost of treatment. As the population ages, the number of fracture incidents will increase, placing a significant burden on healthcare systems, society, and patients. Fragility fractures are fractures that occur from any mechanical forces in low energy of trauma (Johnell and Kanis, 2001). The most common locations are the vertebrae, hip, and wrist. A fragility fracture implies the diagnosis of osteoporosis. Osteoporosis is classified by primary osteoporosis and secondary osteoporosis (Downey and Siegel, 2006). Primary osteoporosis occurs due to disturbances of sexual hormones, aging or both. On the other hand, secondary osteoporosis is mostly caused by chronic diseases

and certain types of drugs, such as corticosteroids (Downey and Siegel, 2006). Menopausal osteoporosis is one of the examples of primary osteoporosis, which occurs frequently, and becomes the most common health-related problem among women (Khosla and Riggs, 2005).

Osteoporosis is the most common disorder amongst the elderly, resulting in a low bone mass as well as the microarchitecture deterioration of the bone tissue, leading to increased bone fragility and prominently increasing the risk of fracture (Wheater, Elshahaly, Tuck, Datta, and Van, 2013). According to the World Health Organisation (WHO) (2004), the classification of osteoporosis in post-menopausal women is based on the Bone Mineral Density (BMD) T - score $\leq - 2.5$ of the young adult mean. Whereas, osteopenia or low bone density is defined as BMD T - score between -1.0 SD and $- 2.5$ SD. Fragility fractures commonly occur in these two different conditions, namely osteopenia and osteoporosis. Any patient with a fragility fracture (regardless of T- score) is defined as having osteoporosis.

For women, osteoporotic fractures pose a lifetime risk of death comparable to breast cancer, ovarian cancer, and uterine cancer combined. Figure 1.1 shows the incidence of chronic disease, highlighting fractures as the highest incidence compared to other chronic diseases of heart attack, stroke, and breast cancer.

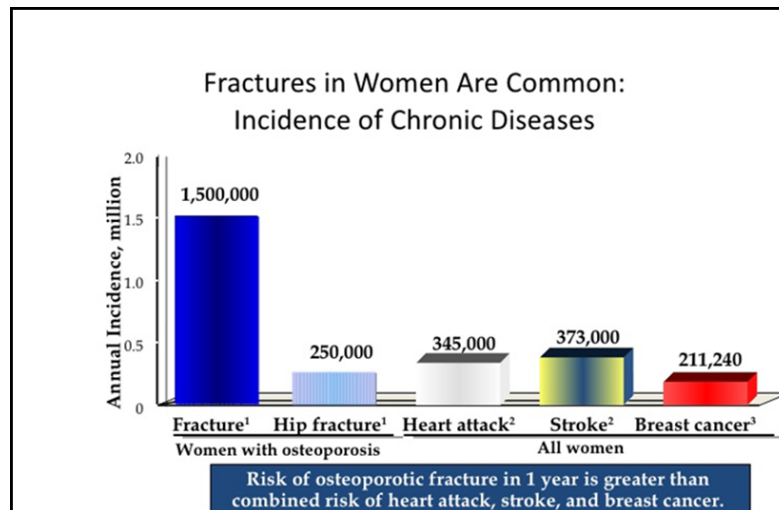


Figure 1.1: Incidence of Chronic Disease
Adapted from the Heart and Stroke Facts: Statistical Supplement, American Heart Association (2010)

Nearly 1 in 3 women over the age of 50 will encounter fragility fracture in their lifetime (International Osteoporosis Foundation (IOF), 2015). Sixty-one percent (61%) of osteoporotic fractures occurs in women, with the ratio of female to male at 1:6 (Johnell, and Kanis 2006). The increased incidence of fracture among the elderly suggests that osteoporotic fractures are a significant cause of morbidity and mortality (Wheater et al., 2013) that require proper prevention and treatment. Nowadays, there is a significant development in the pharmacotherapy of osteoporosis as well as efficacious treatments to reduce the risk of fractures, and these treatments have substantially improved the management of patients with osteoporosis. Unfortunately, the risk of fragility fractures is by far not being eliminated, and there are still unmet needs, requiring a broader range of preventive management steps (Appelman and Papapoulos, 2014). Due to the fact that the increased incidence of fragility fractures require further actions and preventive strategies, therefore, details on the incidents of osteoporosis as well as the preventive strategies will be discussed further in Chapter 2.

1.2.1 Incidence of osteoporosis and fragility fracture in worldwide

The incidence of osteoporosis is continuing to escalate with the increasingly elderly population. The global life expectancy is increasing steadily and the number of elderly individuals is rising in every geographic region. In the United Kingdom, the population aged over 60 is projected to increase by 50% between 2000 and 2030 (International Osteoporosis Foundation (IOF), 2015). By the year 2050, the global population of individuals aged ≥ 65 years is expected to reach to more than 1.5 billion. As increasing prevalence of osteoporosis the burden of fragility fractures also increase remarkably. Assuming a constant age specific risk of hip fracture, the projected number of osteoporotic hip fractures worldwide is estimated to increase from 1.66 million in 1990 to 6.26 million in 2050 (Melton, Campion, 1992). The report estimates that approximately one in two women and one in five men over the age of 50 will have an osteoporosis related fracture in their remaining lifetime (US Department of Health and Human Services, 2004). An analysis of the General Practice Research Database (GPRD, which includes 6% of the UK population) showed a similar figure in the UK (Dennison, Leufkens, and Cooper, 2001).

1.2.2 Incidence of osteoporosis and fragility fracture in Asia

Population of elderly individuals is increasing faster in the developing countries of Asia. Surprisingly, epidemiological information is more widely available for hip than for other sites, although fragility fractures in other sites significantly contribute to the burden of osteoporosis. While the burden of hip fractures is increasing markedly throughout the world, the greatest impact is expected to be felt in Asia; specifically, the percentage of hip fractures in Asia is expected to rise from 26% in 1990 to 37% in

2025 (Melton, et al., 1992). By the year 2050, half of all hip fractures in the world are projected to occur in Asia, particularly in China (Gullberg, Johnell, and Kanis, 2015).

For instance, mainland China previously had one of the lowest incidence of hip fracture in the world in 1988, at 10 per 10 000. However, this has noticeably increased at about 10% per year from 2002-2006 (International Osteoporosis Foundation, 2009, Xia et al., 2012). Similarly, in Hong Kong there is a 300% increase of hip fracture incidence from the 1960s to the 35 1990. However, the rates in Thailand and Malaysia increased 200% and 150% respectively (International Osteoporosis Foundation (IOF), 2015). As for Singapore, the hip fracture incidence was 5 times more from 1960 to 1998 (Koh et al., 2001a). In Japan, incidence of hip fractures increased by 1.6 fold in men and 1.5 fold in women from 1986-1998 (Hagino et al., 2005). Korea also shows an increase of more than 6 fold in women and 2.5 fold in men (Lim et al., 2008). The Philippines similarly noted an increase in the number of hip fractures from 28 000 in 2003 and 34 000 in 2005, expecting the number to reach 175 000 in 2050 (International Osteoporosis Foundation (IOF), 2015). Additionally, conservative estimates shows that the number of hip fractures occurring annually in India exceeds 140 000 (International Osteoporosis Foundation (IOF), 2015)

1.2.3 Incidence of osteoporosis and fragility fracture in Malaysia

Malaysia (located at the South East region of the Asian continent) is projected to have three times the amount of individuals aged 60 years and above from 1.4 million in year 2000 to 3.3 million in year 2020 (Mafauzy, 2000) . Similarly to 10 other Asian countries, Malaysia has a high prevalence of osteoporosis of 24.1 % (Lim, Ong, and Adeeb, 2005). The incidence of osteoporosis will almost certainly increase together with Asia's rapid growth in its aging population. A cross-sectional study was

conducted between December 2014 and December 2015, the incidence of osteoporosis was 10.6% in males and 8.0% in females and a concurrent increase in the incidence of osteoporosis and osteopenia were observed in females ($P<0.05$) but not in males ($P>0.05$) (Chin and Ain, 2016). There remains a serious lack of osteoporotic fracture data in Malaysia underscoring the need for large-scale epidemiological fracture studies to be funded and conducted.

The most reliable data are from analyses of hip fracture incidence for the years 1996 and 1997. Hip fracture incidence in 1996–1997 in those aged over 50 years was 90 per 100,000 individuals per year, and has likely increased due to the ageing population (Table 1) (J.-K. Lee and Khir, 2007). The Chinese portion of the population had the highest incidence of hip fractures compared to the Malays and Indians, accounting for 44.8% of hip fractures in women (J.-K. Lee and Khir, 2007). With an ageing population, hip fracture numbers and costs are expected to escalate (Yeap et al., 2016). Therefore, this study is focused on the Malaysian population.

Table 1.1 : Hip fracture incidence by age group (per 100,000) in Malaysia

Age	Male	Female	Overall
50-54	10	10	10
55-59	20	30	20
60-64	40	50	40
65-69	60	100	80
70-74	100	230	170
75+	320	640	510

Sources: Lee J-K, Khir (2007), ASM, ‘The incidence of hip fracture in Malaysians above 50 years of age: Variations in different ethnic groups’

1.2.4 Incidence of post menopausal osteoporosis

Post menopausal women PMW is a woman who is at risk for having osteoporosis. The dramatic decline in estrogen levels at menopause results in women experiencing low bone density. The incidence of osteoporosis among PMW was increase worldwide. The osteoporosis prevalence in Valencia Spain was greater than other studies (30%). The incidence of osteoporosis was 50.4% and 29.6% had osteopenia from a total of 115 postmenopausal women aged 49 at 85 years old (Reyes et al., 2005)

In Malaysia, there were 57 women (28.4 percent) from 201 postmenopausal women who met the inclusion criteria had osteoporotic bones (Fatemeh, Tengku Aizan, Mohd Nazri, Zanariah, and Rozi, 2011). Another study also found that, overall 42.1% and 11.1% postmenopausal and premenopausal were osteoporotic, a highly significant difference ($p < 0.0005$) (Shan, Bee, Suniza, and Adeeb, 2011). Therefore,

early identification and preventive measure should be started earlier for the purpose maintaining bones mineral density among postmenopausal women.

1.2.5 The increased risks for osteoporosis in postmenopausal women

Postmenopausal women have a significant risk of developing a number of chronic conditions, including osteoporosis, breast cancer, and cardiovascular disease. Chronic conditions such as osteoporosis, which occur more frequently in women after menopause, may impose a significant burden (Sasser et al., 2005). The decline of the bone mineral (BMD) in women accelerates particularly in year 5-10 after menopause. The decrease of hormone in the menopausal stage will make women in their elderly life to be at risk of developing osteoporosis. It is widely accepted that the accelerated rate of bone loss seen after menopause is mainly due to the uncoupling in bone turnover and the increase in bone resorption (Seibel, 2005). Suppression of estrogen production will result in significant increase in bone resorption markers and a suppression of bone formation markers (Khosla and Riggs, 2005).

In Malaysia, 42.1% from 514 population of postmenopausal women were found to have osteoporosis (Shan et al., 2011). Postmenopausal women are at high risk of osteoporosis and form a major admission to hospitals with fragility fractures (Shuid, 2014). Apart from the decreasing hormones in menopause, nutritional factor is also one of the major contributors to osteoporosis among women (Aggarwal et al., 2011). In general, women are neglecting the consumption of calcium in their daily nutritional intake. The average calcium intake of (426 mg/day) amongst postmenopausal women, which is lower than the required amount, has been associated with low bone density (Haron et al., 2010). Consequently, postmenopausal women are

the target population that contributes to the existing risk of osteoporosis, where they require attention and close monitoring to deal with their problem.

1.3 PROBLEM STATEMENT

1.3.1 The healthcare burden of osteoporosis and fragility fractures

An estimation of worldwide prevalence and disability related osteoporotic fracture accounted for 0.83 percent (9 million populations) of the global burden of non-communicable disease (Johnell and Kanis, 2006). The most significant medical problem associated with osteoporosis is fragility fracture. A retrospective study of incidence on hip fractures in Malaysia in 1996 and 1997 revealed that the overall incidence was 90 per 100 000 individuals among people above 50 years of age (Lee and Khir, 2007). A study done in Japan has shown a significant correlation between the annual bone mass reduction and decreased activities of daily living of the elderly population, especially women after menopause (Oka, Yoshimura, Kinoshita, Saiga and Kawaguchi, 2006).

The costs involved in the diagnosis and management of osteoporosis-related fracture is of another great concern affecting the health care policy planning. From a study conducted in Thailand, it was revealed that the cost that incurred from the diagnosis and management of hip fracture in one year was high, amounting to Thailand Baht 116,458.6, which is equivalent to Ringgit Malaysia (RM) 14,467.05 (Woratanarat, Wajanavisit, Lertbusayanukul, Loahacharoensombat, and Ongphiphatanakul, 2005). In Malaysia, the direct cost of hospitalization due to hip fracture in 1997 was estimated to be at RM 22 million (International Osteoporosis Foundation , 2015). This is a huge amount to be borne for most patients in the developing countries. The rising yearly incidence of osteoporosis will have a

significant impact on the healthcare financing system of a country. It is evident from all of the study that the consequences from osteoporotic bone do have a great impact on the society, requiring proper intervention to prevent this silent disease from affecting us.

1.3.2 Problem with the current treatment of osteoporosis in postmenopausal women

Current treatment modalities for osteoporosis are calcium and vitamin D supplementations, as well as the parathyroid hormone therapy (WHO, 2004). It was also found that the gold standard of treatment for post-menopausal women is the estrogen-replacement therapy (ERT) (Shuid, 2014). However, concerns were raised regarding the long-term use of ERT, based on reports linking its use to increased risk of cardiovascular disease and breast cancer (Stevenson, 2009; Dietel, 2010). Another accepted anti-osteoporotic agent, bisphosphonates, is inconvenient to administer, and is associated with several side-effects such as gastrointestinal irritation and osteomalacia (Shuid, 2014). Due to side effects that come with the treatment of osteoporosis, most women are influenced to discontinue their treatment, particularly the estrogen replacement therapy. On the other hand, strontium should be used with caution in patients with renal impairment, and its use has been associated with venous thromboembolism. The role of HRT and Selective Estrogen Receptor Modulators (SERMs) in the treatment of postmenopausal osteoporosis is restricted as a result of an increased risk of stroke, venous thromboembolism and breast cancer (McGreevy and Williams, 2011). Therefore, there is a need for a focus on preventive management strategies, in the management of osteoporosis.