Full Title: Walking the boundaries – using the six-minute walk test for accurate assessment of the level of fitness in breast clinic outpatients.

Short Title: Fitness in breast cancer patients.

Type of manuscript: Original Article

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Word count (abstract): 240

Word count (text): 4600

No. of Figures: 3

No. of Supporting Information: 13

Keywords:

Breast cancer, Quality of life, six-minute walk test (6MWT), six-minute walk distance (6MWD), Physical activity, Level of fitness

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1111/ans.15637](https://doi.org/10.1111/ans.15637)

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Abstract

Backgrounds: Healthy levels of physical activity and improved fitness have shown better quality of life outcomes and improved survival in women with breast cancer. There is a lack of baseline data for fitness levels in breast cancer outpatients in Australia.

Methods: A single centre cross-sectional study was performed to provide a snapshot of the fitness levels of women attending the Surgical and Oncology Breast Outpatient Clinic at Western Health in Melbourne. 200 women (aged 18-85) were surveyed and six-minute walk test (6MWT) was performed. Single and multiple linear regression analyses were performed.

Results: The mean six-minute walk distance (6MWD) was 486.6m (95%CI±12.8m), which was comparable with reference ranges. The mean age of participants was 47.5 years. 97 (48.5%) participants had diagnosis of breast cancer. Breast cancer diagnosis had a negative effect on 6MWD of -33.6m walked ($p=0.010$). However, multiple regression analysis showed that only age (-2.6m walked per year older; $p<0.001$), body mass index (BMI) (-4.2m walked per unit of BMI increase; $p<0.001$) and presence of comorbidities (-56.9m walked; $p<0.001$) had statistically significant negative effects on 6MWD. Self-reported exercise tolerance correlated significantly with 6MWD (walking: $p<0.001$ and stairs: $p=0.014$).

Conclusion: 6MWT was easily performed within outpatient environment to accurately assess baseline level of fitness in breast cancer clinic outpatients. This indicates that 6MWT can be used

as a valuable adjunctive tool to assess the level of fitness in breast cancer patients to make therapeutic recommendations in improving breast cancer outcomes.

Introduction:

Breast cancer is the most commonly diagnosed cancer in women and the second most diagnosed type of cancer overall in the world (1). Breast cancer is also the most common cause of cancer death among women worldwide (522,000 deaths in 2012) (2). Despite its increasing prevalence, new diagnostic tools that allow early detection and technological advances in anti-cancer treatments have been credited as the main factors for increased longevity seen in breast cancer patients (3, 4).

Many studies have now demonstrated the increased physical activity and level of fitness as one of the beneficial factors on breast cancer survival (5-7), as well as on quality of life of cancer patients (8). One of the simple fitness assessment tools is the six-minute walk test (6MWT), which was developed and officially introduced by the American Thoracic Society in 2002 (9). The 6MWT is a sub-maximal exercise test that assesses the aerobic capacity and endurance of patients using the distance walked over a time period of six minutes. The aim of our study was to evaluate the feasibility of using the 6MWT in the outpatient setting to accurately assess the level of fitness of our patients, which we then envisaged to use as valuable adjunctive tool to make therapeutic recommendations to the patients.

Methods:

A single centre cross-sectional study was performed to provide a snapshot of the fitness levels of women attending the Surgical and Oncology Breast Outpatient Clinic at Western Health (Melbourne), using the 6MWT. The long corridor at the rear of the clinic (Figure 1) with a continuous uninterrupted length of 40m and width of at least 1.5m was used as the site for conducting the 6MWT. The ethics approval was obtained from the hospital ethics committee.

A total of 200 women were recruited into the study from June 2017 to June 2018. Men, underage patients, those with significant mobility issue (e.g. wheelchair-bound), and pregnant women in their third trimester were excluded from the study.

Informed consent was obtained from all participants and all data collected were de-identified. Patients were first surveyed on their general health status and details of treatments for those with a breast cancer diagnosis. Various medical data from patients were collected, including the height

and weight (to establish BMI) prior breast cancer history and treatment, smoking status, and presence of significant comorbidities, and self-reported exercise tolerance for distance walked and flights of stairs climbed.

The 6MWT was then performed on a 30m walking track, where participants were measured on their distance walked in six minutes. A Modified Borg Dyspnoea Scale (S1) was then used to measure the participants' level of breathlessness (scale of 1-10) immediately after participation in the 6MWT. Statistical analysis using SPSS (Statistical Package for the Social Sciences) program, including single and multiple linear regression models, was performed with analysis of variance.

Results:

Basic demographics were compiled (S2). The mean six-minute walk distance (6MWD) was 486.6m (95%CI $\pm$ 12.8m). The mean age of participants was 47.5 years (range 18-85). The mean BMI was 27.4 (range 17.5-49.9).

Age had a negative effect on 6MWD of -2.6m walked per year older (SE=0.4m, $p<0.001$) (S3). BMI had a negative effect on 6MWD of -4.2m walked per unit of BMI increase (SE=1.0m, $p<0.001$) (S4). Those in the obese category had the lowest mean 6WMD (S5).

N=97 (48.5%) participants had a diagnosis of breast cancer. Breast cancer diagnosis had a negative effect on 6MWD of -33.6m walked (SE=12.8m, $p=0.010$). The average 6MWD of patients who

have had breast cancer was lower than those without (Figure 2). Sub-categorisation of breast cancer to its stages also showed differences, with stage 4 being the biggest difference (Figure 3).

Patients with presence of single broad category comorbidities had lower mean 6MWD. Each single category comorbidity correlated negatively with 6MWD to varying degrees including cardiovascular disease (-55.1m walked, SE=22.5m, $p=0.015$) (S6), type 2 diabetes (-87.8m walked, SE=30.9m, $p=0.005$) (S7), respiratory disease (-53.4m walked, SE=20.1m, $p=0.009$) (S8), peripheral vascular disease (-49.3m walked, SE=31.3m, $p=0.117$) (S9) as shown by linear regression. The presence of any of the abovementioned comorbidities also had a negative effect on 6MWD (-56.9m walked, SE=14.7m, $p<0.001$). This difference (S10), albeit smaller, was also confirmed to be statistically significant in multiple regression analysis (-31.5m walked, SE=14.4m, $p=0.030$) when controlling for other variables.

Multiple regression analysis showed that only age (-2.03m/year, SE=0.47m, $p<0.001$), BMI (-2.2m/BMI unit, SE=1.0m, $p=0.029$) and presence of comorbidities (-31.5m, SE=14.4m, $p=0.030$), but not breast cancer (+2.1m, SE=13.2, $p=0.876$), had statistically significant negative effects on 6MWD. Smoking was not associated with a statistically significant difference in 6MWD.

The mean self-reported exercise tolerance for walking was 3000m (95%CI $\pm$ 0.33m) and for stairs was 4.5 flights (95%CI $\pm$ 0.74) (S2). Self-reported exercise tolerance correlated significantly with 6MWD (walking: $R^2=0.14$, $0.014\text{m}\pm 0.0025$, $p<0.001$ and stairs: $R^2=0.03$, $3.0\text{m}\pm 1.2$, $p=0.014$), but there is a high degree of variance between all of the reported values which is reflected in the low R^2 values (S11).

A combination of age, BMI and self-reported exercise tolerance in walking had the highest correlation with 6MWD ($R^2=0.28$, $0.011\text{m}\pm 0.002\text{m}$, $p<0.001$). The mean Modified Borg Dyspnoea Score was 2.24 (95%CI ± 0.23) (S2). There was no difference between Breast Cancer patients and non-Breast Cancer patients in terms of the average Modified Borg Dyspnoea Score (S12). Regression analysis showed Modified Borg Dyspnoea Score had a low inverse correlation with 6MWD ($R^2=0.08$, $-14.4\text{m}\pm 3.9\text{m}$, $p<0.001$) (S13).

Discussion:

The risk factors for developing breast cancer are categorised into non-modifiable and modifiable factors. Non-modifiable factors include age, genetic predisposition, family history of breast cancer, and breast density, and modifiable factors include alcohol consumption, smoking, obesity, and lack of physical activity (10). A number of studies have shown statistically significant reduction in breast cancer risk amongst the most physically active when compared to the least active women

(11).

Not only does physical activity reduce the risk of developing breast cancer, other studies have also demonstrated an association between physical activity and reduction in mortality amongst breast cancer survivors; a meta-analysis of 16 studies on breast cancer survivors who increased their physical activity by any level following diagnosis showed a statistically significant decreased total mortality risk (12). A meta-analysis by Lahart et al of 22 studies also concluded that a higher lifetime and more recent pre- and post-diagnosis recreational activity was significantly associated with a lower risk of all-cause and breast cancer-related death and breast cancer events. Post-diagnosis physical activity was found to significantly reduce the risk of both all-cause death and breast cancer-related death (13). Numerous potential biologic mechanisms have been proposed to explain the observed apparent beneficial effects of physical activity on breast cancer, which include reduced exposure to oestrogen and androgens, insulin-related factors, cytokines, adipokines and inflammation that is achieved with physical activity (11).

Healthy levels of physical activity and improved fitness have also shown better quality of life outcomes in women with breast cancer in various domains (12-14), including body image, self-esteem, emotional well-being, sexuality, sleep disturbance, social functioning, anxiety, fatigue, pain, and specific concerns about breast cancer (8). A review by Carmichael et al (15) on North American and Norwegian studies suggested that the beneficial effect of physical activity as demonstrated in many observational studies could potentially be added to the spectrum of adjuvant therapies which could provide a tremendous opportunity to enhance treatment of breast cancer and enhance survival.

Physical activity is defined as any bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above a basal level (16). One form of objective test to measure one's level of physical activity and level of fitness receiving more attention in the literature is the 6MWT, which has been shown to be safer, easier to administer, better tolerated, and better reflects level of fitness and physical activity than other walk tests (such as the shuttle walk test), and has proven to be reliable, inexpensive test for measuring fitness in various studies (9, 17, 18). Moreover, the 6MWT has also demonstrated validity as a fitness test for cancer patients (19). Patients differ in their ability to recall information in self-reports or questionnaires asking "how many flights of stairs can you climb?" or "how many blocks can you walk?" and as a result it may over- or underestimate the patient's true physical capacity. Therefore, the authors propose that 6MWT can be used in the outpatient setting as a practical and objective tool for accurate assessment of patients' level of physical capacity that is superior to self-reports or questionnaires (20).

Currently, there is a lack of 6MWT data to assess the fitness levels of patients living with breast cancer in Australia. There have also been no studies looking at whether the introduction of exercise intervention will improve the overall health outcome including quality of life and mortality outcome in our population. Hence, our study aimed to use the 6MWT to establish a baseline and assess the overall fitness levels of patients attending our institution.

The mean six-minute walking distance (6MWD) of 486.6m in our study was comparable with 6MWD data from reference ranges (460-540m) that the American Thoracic Society has issued as guidelines for the 6MWT (9). However, a review by Casanova et al (21) of the reference standards

of healthy individuals undertaking the 6MWT from seven countries showed that the 6MWD was 571m. The 6MWD was also inversely proportional to age, and male participants walking on average 30m more than female participants (21).

As expected, age and BMI correlated negatively with 6MWD in our study, suggesting fitness levels decrease with increasing age and obesity. Weight gain is very common during the first year after patients are diagnosed with breast cancer. Those who were more overweight had greater reductions in their physical activity, implying a greater potential for weight gain amongst those already overweight (14). A number of reasons for post-diagnosis weight gain in patients with breast cancer have been suggested, which include adjuvant therapies, such as chemotherapy and endocrine therapy, decreased physical activity and increasing caloric intake (22-24). A study of patients diagnosed with stage I or II breast cancer demonstrated a significant reduction in physical activity levels during chemotherapy from pre-treatment levels (22). Thus, maintaining or increasing physical activity levels after diagnosis of breast cancer would help to minimise the post-diagnosis weight gain because physical activity is associated with maintenance of body weight in healthy women (25, 26).

The presence of single broad category comorbidities had a negative effect on 6MWD with type 2 diabetes having the greatest effect. Multiple regression analysis also validated the statistical significance of the presence of any one of the major comorbidities having a negative influence on fitness levels. Although linear regression indicated that breast cancer diagnosis correlated negatively with 6MWD (-33.6m walked), multiple regression analysis revealed that this difference disappeared once age, BMI and comorbidities were accounted for. One possibility to account this

is the demographics of our institution's breast cancer population, which tends to consist of older, less fit females. Another possibility is that the majority of our patients (74.3%) were either under surveillance or had past treatment hence not being as negatively affected by chemotherapy to adversely affect their fitness levels. Although univariate analysis was performed for each individual breast cancer stage, which suggested negative correlation with 6MWD, there was insufficient number of patients in each subcategory to generate data of sufficient statistical significance, indicated by the high standard errors. A potential future project would aim to collect 6MWT data from a population of older, less-fit females without a diagnosis of breast cancer and compare them to our cancer population.

Self-reported exercise tolerance as "distance walked before you feel tired" and "flights of stairs you can climb before feeling tired" were generally poor predictors of 6MWD. The supplementary figure 11 (S11) models a sharp rise in 6MWD (outside the shaded area) on the left followed by tapering (similar 6MWD at 5km and 10km). Although the overall dataset correlated significantly with 6MWD, this result may be clinically irrelevant due to the high degree of variance between any single reported value. This is well reflected in the high standard error and low R^2 values. Therefore caution should be taken in an outpatient clinic setting when asking patients how fit they think they are, as patients often suggest inaccurate level of their fitness.

A limitation to our current study design was that the questionnaire survey as a means for collection of data to determine patient's cancer status. Tumour size, presence of nodal disease, prior and current treatments, including surgery, chemo-radiotherapy, hormonal or biological therapies were all reported to the experimenter by participants (which relied on accuracy of their recall). The stage

of breast cancer was manually calculated in each case. An improvement to this study design could have been to utilise the current breast cancer database for more accurate determination of breast cancer stage. Another limitation was that the current study did not look into means of assessing preoperative fitness for surgery as most breast surgery is relatively well tolerated with minimal perioperative complications. However, for those patients having breast reconstructions, especially with autologous abdominal reconstruction, which is more extensive surgery, preoperative assessment of fitness may be useful, and assessment using the 6MWT could identify those patients that would benefit from prehabilitation. A larger dataset would also be expected to improve the reliability of 6MWT to predict fitness in various phases of breast cancer treatment.

A number of practical limitations were also encountered during implementation of the 6MWT. Patients sometimes had a lack of comfortable walking shoes (e.g. high heels) precluding them from meaningful participation. Approximately 10% of patients refused to participate due to one reason or another. We noticed there was a general lack of effort in walks despite participants being given clear instructions to walk briskly and with effort. In these patients, low dyspnoea scores were also quite common. This is modelled by the quadratic in supplementary figure 13 (S13), showing a tapering of 6MWD at low dyspnoea scores. No test or trial walks were administered prior to a final walk test to reduce recruitment time. Minor interference from doctors, allied health staff and interpreters in the shared hallways during clinic was inevitable, resulting in slightly reduced 6MWD in some instances. These practical limitations are avoidable and easily rectified; these include a revised protocol with strict rules for footwear, clear walking instructions with increased supervision, a dedicated and uninterrupted walking track.

One of the unintended benefits of this study was that it raised an overall awareness of the importance of physical activity and fitness amongst both breast cancer patients and clinicians. The study acted as a reminder to the clinicians to promote physical activity. More patients expressed interest in participating in the hospital and external exercise programs. Exercise programs such as those proposed by Rogers et al (27) have demonstrated significant improvements to physical activity, fitness and quality of life with benefits continuing 3 months following intervention. Their results showed that those from the treatment group were significantly more likely to adhere to their exercise by meeting the physical activity recommendations and have improved fitness. A similar program proposed by Travier et al (28), called Physical Activity during Cancer Treatment (PACT), running over 18-weeks, which offered early routine care during adjuvant breast cancer treatment showed positive effects on physical fatigue, submaximal cardiorespiratory fitness and muscle strength. They have since recommended exercise during early treatment of breast cancer. We believe that 6MWT could easily be repeated before and after exercise program interventions to demonstrate their effectiveness in improving fitness of patients. Future studies aimed at incorporating exercise programs to measure the effect on physical activity and fitness in breast cancer patients would find the 6MWT a useful tool. The 6MWT could also be extended to look at fitness levels of cancer patients in other surgical cohorts and incorporated into multicentre studies.

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Figure legends

Figure 1: Western Health Sunshine Hospital outpatient clinic Six-minute walk test set-up area.

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Figure 3: Six-minute walk distance against Breast Cancer Stages.

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Date:

2020-06-01

Citation:

Ying, L., Yahng, J. -M. J., Fisher, M., Simons, K. & Nightingale, S. (2020). Walking the boundaries: using the 6-min walk test for accurate assessment of the level of fitness in breast clinic outpatients. ANZ JOURNAL OF SURGERY, 90 (6), pp.1141-1145. <https://doi.org/10.1111/ans.15637>.

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