LOURDES HOSPITAL & COMMUNITY HEALTH SERVICE
catholic healthcare

Outback Breast Cancer Related Lymphoedema Interventions:

Do we get the same lymphoedema outcomes?

Author: Brenda Svensson,
Occupational Therapist
Occupational Therapy Department,
Lourdes Hospital and Community Health Service,
PO Box 974 (80-110 Cobbora Rd)
Dubbo NSW 2839
Phone: 02 68418584
bsvensson@chcs.com.au

NSW Institute of Rural Clinical Services and Teaching
NSW HEALTH

Acknowledgements

The Author would like to acknowledge the input and assistance of:
Emma Webster, IRSCT Research Mentor
Aaron Thrift, Biostatistician
Professor Neil Piller, Clinical Mentor
Amy Hawkins, Occupational Therapist and proof reader

Abbreviations

AV- Arm volume
BCN – Breast Care Nurse
BCRL – Breast cancer related lymphoedema LLS – Lourdes Lymphoedema Service
CLT – Complex Lymphatic Therapy
LACM – Lymphoedema Arm Circumference Measurements
Lourdes – Lourdes Hospital and Community Health Service
MCP – Metacarpal Phalangeal
MLD – Manual Lymph Drainage
RFA – Risk Factor Assessment
SLD – Simple Lymphatic Drainage
SOAC – Sum of Arm Circumferences

Tables

Graphs

Table of Contents

Abstract

Aim:
The Lourdes Lymphoedema Service (LLS) provides limited assessment and treatment services to a large geographical area. As access to health services and health outcomes are generally poorer in rural and remote areas, a review of clients with or at risk of breast cancer related lymphoedema (BCRL) was completed to ascertain if distance from LLS, treatment program undertaken and service utilisation rates were associated with changes in affected arm volume (AV).

Method:
A Medical record review of all clients with or at risk of BCRL attending the LLS between 1 June 2006 and 30 June 2009.

Results:
Subjects with a diagnosis of lymphoedema experienced a reduction in affected AV over time (p=0.0032), subclinical subjects experienced no change in AV (p=0.5462) and treatment non-compliers experienced growth in AV (p=0.0313). There was no association between distance and treatment program undertaken (p=0.831). Evidence suggests a beneficial association between living 50+ km from LLS and lymphoedema outcomes, with greater reductions in AV and lower rates of lymphoedema diagnosis in this group (RR=0.70, p=0.0377). Clients living within 49 km of LLS accessed the service at shorter intervals than those living 50+ km away (p=0.02) but this was related to diagnosis rather than distance.

Conclusion:
Analysis has shown positive but not optimal changes in AV in the LLS BCRL client group. Mean reductions in AV at LLS were not equal to those documented in the literature due to inability to provide optimal treatment programs. Contrary to expectation distance did not have a detrimental effect on BCRL outcomes but it should still be considered during service provision. The results of this study mandate a focus on the education and monitoring of subclinical lymphoedema clients to enable early identification and treatment of new lymphoedema cases and supply of additional treatment programs to those with established lymphoedema.

Key Words

Lymphoedema, arm, measurement, breast cancer, rural.

Executive Summary

Aim
To review the clinical outcomes of clients with or at risk of breast cancer related lymphoedema (BCRL) attending the Lourdes Lymphoedema Service (LLS) and assess if distance or inability to supply "gold standard" treatment (CLT) has had an impact on their affected arm volumes (AV).

To make recommendations for future service provision for the main treatment groups: clients with BCRL and those with subclinical lymphoedema (or at risk), taking into consideration predicted increased in BCRL due to increasing rates of breast cancer in Australia.

Method:
A medical record review was completed for all clients with a diagnosis of breast cancer who have attended the LLS between 1 June 2004 and 30 June 2009. Seventy nine of a possible 160 clients were eligible for inclusion in the study. Bilateral AVs were computed from the routinely collected circumferential measurements for each of these clients. AV at Time 1 was calculated from measurements taken at initial assessment and AV at Time 2 was calculated from measurements taken at the last intervention prior to 30 June 2009.

Analysis of change in affected AV (in comparison to the non affected arm) between Time 1 and Time 2 was calculated. Analysis of change in AV was also reviewed for the different diagnostic (lymphoedema, subclinical lymphoedema and treatment non-compliers), treatment (CPT, garment, SLD and monitoring) and distance groups (less than 49km and 50+km from Dubbo) within the cohort.

Results:
Analysis of the entire group revealed no evidence to suggest that the affected AV of clients attending the LLS had changed over the study time (p=0.129). Analysis of diagnostic groups showed those with a diagnosis of lymphoedema experienced a reduction in affected AV (p=0.0032), subclinical lymphoedema experienced no significant change (p=0.5462) and treatment non-compliers experienced a growth in affected arm volume (p=0.0313). These results were replicated across the two distance groups.

There was no difference in treatment programs undertaken by lymphoedema subjects in the two distance groups (p=0.831). Service utilisation rates of the two distance groups were different (p=0.0193) with the under 49km group accessing the service more regularly than the 50+km group , this difference appears to be related to the dissimilar rates of subclinical/lymphoedema in each group. However the impact of distance on service utilisation can not excluded as there was a higher rate of once only assessments in the 50+km group.

There was evidence to suggest that subclinical lymphoedema subjects living 50+km from the LLS experienced a greater reduction in affected AV than those living within 49km (-55ml compared to growth of 11ml). The possible beneficial aspect of distance appears to be replicated across the diagnostic groups with lymphoedema subjects in the 50+km group experiencing greater mean reduction (94ml to 67 ml) and non–compliers experiencing smaller growth in mean affected arm volume (211ml to 254ml) than the under 49km group. The 50+km group were significantly less likely to have a diagnosis of lymphoedema than the under 49km group (RR=0.70, p=0.0377).

Conclusion:
Broad analysis of all included subjects has shown that there is no change in affected AV. This is an artificial positive result that does little to inform the service planning process of the LLS. When broken into treatment groups, the small cohort of clients who underwent CLT experienced reductions in affected AV that were similar to those documented in the literature. The largest treatment group which encompassed 65% of those with a diagnosis of lymphoedema, the "garment" treatment group did not achieve equivalent reductions to those in the literature. The small group of treatment non-compliers experienced growth in affected arm volumes as expected in the literature. A review of the treatment programs and protocols available to clients with lymphoedema is required to ensure optimal treatment outcomes.

Distance did not impact treatment program undertaken as each distance group was equally unable to access intensive treatment programs for subjects with excess affected arm volume of 200ml. The lack of capacity to provide intensive treatment and achieve optimal treatment outcomes is a challenge to be addressed in future service planning. This may require procurement of additional funding and physical resources to complete CLT. Alternative and creative avenues through which to supply CLT will be required to meet the needs of clients living at a distance from the service.

Service planning must address the needs of clients who have lymphoedema but also encompass strategies to reduce the need for intensive treatment in the future (address the needs of those with subclinical lymphoedema). Implementing an early identification and intervention program for clients in the initial stages of lymphoedema may limit progression of the lymphoedema (10,14,36,50) and costs associated with intensive treatment for the LLS. Early identification requires regular monitoring of clients during the period of highest lymphoedema development – the first

three years following surgery (21,25,31). Pre breast cancer surgery assessment of limb volume would inform the diagnostic process, allowing diagnosis of lymphoedema at the earliest time (28).

Distance (50km+) appeared to have a beneficial effect on affected AV and development of lymphoedema. This trend was the reverse of what was expected at the commencement of this study. The reason for this is unknown and further investigation is warranted to ascertain if the beneficial effect can be transferred to other groups.

Approximately one half of the breast cancer subjects attending the LLS during the study period were excluded from this study. Forty one of these subjects were excluded from the study as they had attended the LLS on only one occasion. The literature documents that the average rate of development of BCRL is 20% to 30% and as such it is predicted that between eight and 13 of these "once only" subjects will develop lymphoedema and could re-present at the LLS at some time in the future with established or advanced lymphoedema. The monitoring systems and processes for subclinical (at risk) subjects must to be considered in future service planning. Early identification and treatment of lymphoedema is essential to reduce the impact of lymphoedema development on the client and the additional treatment burden of advanced lymphoedema on the LLS. Training of lymphoedema practitioners in motivational interviewing may assist this process.

Implications for practice:

- The LLS needs to develop a focus on early intervention and treatment due to resource and distance issues that limit capacity for intensive treatment programs. This requires the development of a precise and accurate lymphoedema diagnostic tool.
- Changes are required to treatment practices for clients with lymphoedema to ensure that maximum reductions are achieved, limiting likelihood of progression of lymphoedema and associated health problems.
- Avenues of funding and alternate sources of intensive treatment for clients with established lymphoedema are required to treat existing and future clients with lymphoedema.
- Strategies need to be developed to ensure appropriate monitoring of subclinical/at risk clients to increase service ability to catch expected cases of lymphoedema.
- Additional funding for compression garments is required to reduce reliance on public generosity for this essential treatment.

Introduction

The Lourdes Lymphoedema Service (LLS) is a relatively new program providing education, assessment and treatment to persons with or at risk of lymphoedema. LLS provides lymphoedema services to clients from a large geographical area, with some clients travelling up to 400 km one way to obtain intervention. A variety of interventions are available to clients but the LLS is generally unable to provide intensive treatment in the form of complex lymphatic therapy (CLT) due to limited time and resources. Some compression garments are available free of charge through the LLS as a garment assistance scheme has been established with donations from the general public.

Persons with a history of breast cancer make up the majority of users of the LLS. Persons with or at risk of Breast Cancer Related Lymphoedema (BCRL) can be divided into two main service groups: clients with a diagnosis of lymphoedema and those with subclinical or latent lymphoedema. These two groups have significantly different service needs that require a different focus of intervention for each group, resulting in different treatment intensity, service utilisation and costs of intervention.

This study has reviewed the clinical outcomes of people with or at risk of BCRL attending the LLS. This review has been completed to assess the impact of the service provision issues of distance, time and resources on BCRL client outcomes. Recommendations for future service planning have been made as a result of this study and are outlined at the end of the report. These recommendations take into consideration the needs of the two service groups and expected growth in service demand that will result from increasing rates of breast cancer (all cancers) in Australia.

Significance

Lymphoedema is a progressive type of swelling (1, 2) that develops when there is a problem in the lymphatic system, such as a lack of lymph vessels, a blockage in or removal of part of the lymph system. It usually manifest as swelling of one or more limbs and may include the corresponding trunk quadrant (2). Lymphoedema is the end result of an overload of the lymphatic system, where the transport capacity of the system is overwhelmed by the volume of lymph to be transported (3). Once developed, lymphoedema is usually a progressive disease that continues to progress (1,49) as the reduced transport capacity leads to a build up of macromolecules (including protein) in the interstitial spaces (4) which in turn increases the oncotic pressures of the tissues, producing more oedema (3).

The development of lymphoedema can cause distress and be a life altering event for the sufferer (3,5). It can impact everyday activities (6) and affect quality of life (5). There is no cure for lymphoedema (1, 2, 7, 8) and as such it requires a lifetime of ongoing management (9). Lymphoedema can have a significant impact on the individual, their family and health services, but it is often unrecognised and under diagnosed (10). However early detection may reduce the risk of long term lymphoedema developing and enable early intervention of prophylactic measures preventing progression to a chronic condition (50).

Treatment of lymphoedema is aimed at the containment (slowing of progression) or reduction of the oedema so as to prevent limb enlargement and deformity, skin changes, discomfort, infections, physical disability, difficulties with everyday activities and psychological and body image issues that can occur as a result of the condition (1,3,11). Delays in identification and treatment, or inappropriate treatment can exacerbate the swelling (12) compounding problems already being experience by the sufferer (5). Treatment for established lymphoedema can be time consuming and expensive, it can also interfere with self care, leisure and work pursuits. Early identification and appropriate intervention is advisable (1,12) as failure to treat swelling can make it difficult to manage (2). Increases in swelling directly influences one's capacity to complete their activities of daily living (6).

Lymphoedema can be either primary or secondary (acquired) in nature. Primary lymphoedema is classified according to age at onset: congenital (before the age of 2 years), praecox which is the most common form of primary lymphoedema (at puberty) and tarda (after the age of 35 years) (13). Secondary lymphoedema is the most common form of lymphoedema and is the result of disruption or obstruction of the lymphatics from disease, injury or surgery (or radiotherapy). Filariasis is the primary cause of secondary lymphoedema worldwide (13). The ratio of primary to secondary lymphoedemas is approximately 1:10.

In the Western world, breast cancer and its treatment are the leading cause of secondary lymphoedema (10). Lymphoedema of the ipsilateral arm has been recognised as a common and potentially serious complication of breast cancer treatment (14) since it was first described in the literature by Halsted in the early 1920s. Even with advancements in medical procedures since this time it continues to be a significant concern for breast cancer survivors (5).

All patients who have undergone axillary surgery have a lifetime risk of developing lymphoedema (5,9). It is widely documented that the threat of developing lymphoedema is one of the most dreaded sequela of breast cancer aside from recurrence of cancer itself (3,15,16,17). Unlike a mastectomy, arm swelling associated with BCRL is difficult to hide, it is a public display of one's diagnosis of breast cancer that draws attention and curiosity. BCRL is an ever present

reminder that can affect the sufferer's entire life, till the end of their life, affecting body image, choice of clothing, home, work and leisure pursuits (3,9).

The Australian Institute of Health and Welfare and the National Breast and Ovarian Cancer Centre (2009) report that the rate of breast cancer in the Australian population is increasing, with 1 in 9 women expected to develop breast cancer before they reach the age of 85. By 2015 the number of new breast cancer cases among women is projected to be 22% higher than in 2006, with 75% of women diagnosed with breast cancer being diagnosed before their 70th birthday (average age of first diagnosis being 60 years). In Australia the five year survival rates for breast cancer has also improved and reached 88.3% in 2006 (18). Average life expectancy of women in Australia has risen to 83.5 years (19).

The increasing incidence of breast cancer and improved survivorship will continue to make lymphoedema a significant consequence of breast cancer treatment (4) irrespective of new treatment techniques that appear to reduce the incidence of BCRL. Secondary lymphoedema poses a significant and potentially growing public health problem (20,21), placing an emphasis on prevention of the condition where possible (22), early detection of new cases and treatment.

It is clear from the literature that not all women who undergo breast cancer surgery will develop lymphoedema. Reported rates of BCRL following breast cancer interventions vary significantly between studies with rates between 2% to 83% (3,23,24) being described, some report that BCRL is under estimated and that the true rate is unknown (21,25). The vast range of BCRL incidence rates may be the result of different measurement techniques, diagnostic definitions and criteria, the timing of the BCRL assessment, duration of client follow up, varying number of study cases, small study sizes and surgical procedures performed (20,22,28). It appears that studies that follow subjects for longer periods generally found the length of time since breast cancer surgery is associated with a higher incidence of BCRL in the population (higher incidence rates) (3,28). Similarly studies with the shorter follow-up periods report lower incidence of BCRL (3). Differing rates of BCRL have also been consistently reported for axillary dissection surgery versus sentinel node biopsy with varying rates of incidence within each group (29, 30). General consensus suggests that the rate of BCRL development lies somewhere between 20% and 30% (26,27).

The onset of lymphoedema following breast cancer treatment is unpredictable, it often begins insidiously, sometimes years after surgery (3,25). The National Breast and Ovarian Cancer Centre reported in their 2008 review of research evidence on secondary lymphoedema that 70-80% of patients with long term lymphoedema presented within 12 months of surgery(21). This is supported by Norman et al (2009) who conducted a five year study that found 80% of women with lymphoedema were diagnosed within the first two years (rising to 89% by three years) (31). The Petrek et al (2001) 20 year study of women with breast cancer that reports 77% of those who had developed lymphoedema did so within the first three years and the women who developed lymphoedema after the three year mark, did so at a rate of 1% per year until the 20 year period ended (25).

The exact aetiology and pathophysiology of BCRL is unclear with Lane et al (2005) reporting it is not simply a stop cock effect (32) of lymph glands removed therefore lymphoedema develops. It has been proposed by others that the onset of lymphoedema is mainly related to the removal of the lymph nodes and the clients congenital pre-disposition (22) towards lymphoedema i.e. their lymph system did not work effectively prior to surgery making them more likely to develop lymphoedema.

Many factors have been linked to the development of BCRL in the literature and their effect and relevance varies between studies. These factors can be patient, treatment or behavioural in character and range from type and extent of surgery, radiotherapy, number of lymph nodes removed, size of the tumour through to age, physical activity, ethnicity and socioeconomic status (21,33). Body mass index (BMI), weight gain since breast surgery, ipsilateral arm infection and to a lesser extent arm injury, appear to be emerging as modifiable or contributing risk factors for the development of lymphoedema (6,25,30). However it is generally accepted that the predisposing factors for lymphoedema remain unclear and are multifactorial (33) due to the inconsistent relationships between the patient, treatment and behavioural characteristics (21).

There are multiple diagnostic criteria and measurement techniques for BCRL outlined in the literature (34), with most attempting to measure the volume of the affected limb rather than directly measuring the oedema. Complicating the measurement and volume estimation process is the natural variations of limb volume that occurs as a result of hand dominance, which can be 3% in healthy subjects (35).

Objective measures that can be used in the diagnosis of BCRL include circumferences, perometry, tonometry, ultrasound, water displacement, lymphoscintigraphy, lymphaniography, and bioimpedance spectroscopy (21,36). Within these objective measures there are multiple criteria to diagnose BCRL, ways of reporting and analysing the results, each with varying levels of specificity and sensitivity. Not all measures have clinical and research relevance or applicability. Only those that are related to this research project will be discussed further.

Water displacement involves quantifying water overflow volume when the affected limb is placed in a water filled container (14). Water displacement has been regarded as the sensitive and accurate "gold standard" for volume measurement (28) in BCRL as it allows measurement of volume in irregular areas such as the hand (14). A 200ml increase from the preoperative difference in volume between the arms (22) indicates a diagnosis of BCRL. However in the clinical setting water displacement is seldom used due to its being cumbersome, messy (28,30), inappropriate to use with open wounds (28) and presenting infection control issues related to cleaning.

Arm circumference measurements that are taken at one or more points along the affected arm and then compared to the non affected arm (to reduce the impact of hand dominance and weight gain) are the most commonly used objective measurement in the clinical setting (10,30). A two cm difference between the arms at any point being the most often used diagnostic criteria for BCRL (3,20). The circumferences of each arm can be summed and a diagnosis made where a difference of five cm or ten percent exists (20). Arm circumferences can be used to diagnose lymphoedema at a single point in time or monitored for change over time indicating growth in volume of the affected arm (a diagnosis of lymphoedema). Arm circumferences can also be used to calculate limb volume (where the 200ml criteria applies).

Arm circumferences are widely used in the clinic as they are a relatively simple and inexpensive measure, however control of intra- and inter-rater reliability is difficult (28). Where multiple measurement points are used the circumferential method is time-consuming and requires considerable experience to ensure replicable measurement techniques (28). Hayes et al (2008) found that the sum of arm circumferences method had the potential to under diagnose BCRL (20) and a two cm difference at a single point has the disadvantage of possibly not being clinically significant in a heavy arm, yet severe in a thin arm (3).

Stout et al (2008) propose that the existing classification systems for lymphoedema fail to recognise a sensitive diagnostic threshold for subclinical lymphoedema (36). This is supported by Armer et al (2003) who report that the diagnostic criteria of 200 ml or two cm difference between the affected and non affected arms over looks the latent-stage lymphoedema when early intervention may be most effective in reversing swelling (10). A limb difference of one cm (but less than two cm) in at least one point or a difference of three percent have been suggested as alternative diagnostic criteria for picking up subclinical or latent lymphoedema (36,37). Bland et al (2003) recommend that a five percent change in circumference or a one cm growth at any point on the affected arm indicates the need for referral to lymphoedema specialist for assessment (5).

Biompedance Spectroscopy is a relatively new advance that has been shown to be a direct, accurate and reliable measure for lymphoedema diagnosis that is more sensitive to change than other objective measures (20). However its sensitivity to diagnose lymphoedema in the absence of preoperative measures has not been proven. Cost can also put it beyond the reach of reach of most practitioners working in a mixed caseload such as clinicians working in rural areas.

Self reported symptoms of lymphoedema have been addressed in a number of studies. Few studies have found significant relationships between self reported symptoms and lymphoedema diagnosis as there are many symptoms in common between the general breast cancer population and the BCRL population (10). However the symptoms heaviness and swelling are reported to correspond with two cm or greater changes in limb girth among women treated for breast cancer (10).

There are a number of studies that have documented conflicting findings regarding the value of each of the various objective measurements when comparing them against each other. Tewari et al (2008) report that there is a significant correlation between volume estimation using arm circumference measurement and water volume displacement (38) while Chen et al (2008) found water displacement and circumference measurement (not volume calculation) are reliable techniques for assessing lymphoedema in clinical practice (14). Hayes et al (2005) raised questions about the use of circumferences as the choice of measurement for lymphoedema in both research and clinical settings and suggest Bioimpedance as a potential alternative (16). Box et al (2002) found that sum circumference difference and Bioimpedance methods failed to detect lymphoedema in up to 50% of women who demonstrated an increase of at least 200ml in the volume of the operated arm compared to the un-operated arm (40). Anecdotal reports from the clinical setting suggest that no one method can adequately diagnose lymphoedema and that the objective criteria put forward are not sensitive or specific enough to diagnose all BCRL seen in the clinical setting.

Armer et al (2005) conclude that in the absence of a gold standard we can only say that different lymphoedema definitions are not equivalent and that it is impossible to state which criteria is closest to the true incidence of lymphoedema (28). The sensitivity and specificity issues surrounding each of the measurement procedures and criteria mean it is likely that these objective measures are under-diagnosing BCRL (21).

In addition to the lack of definitive measurement and diagnostic criteria there is also no definitive treatment for lymphoedema (14). Many studies have been devoted to investigating the effect of various types and combinations of treatment. The main treatments for lymphoedema include complex lymphatic therapy (CLT), manual lymph drainage (MLD), compression bandaging and garments, limb exercise and pneumatic pumps (41). Only those therapies that are related to this research project will be discussed in further detail.

CLT (also know as complex physical therapy, complex decongestive therapy) is often seen as the gold standard in lymphoedema treatment in both the public (42) and professional arenas (12). In Australia, CLT is taught in intensive post graduate workshops developed to guidelines established by the Australasian Lymphology Association (43). During these workshops the focus of education is the main skills associated with CLT: MLD and compression bandaging, with three quarters of the program being devoted to the demonstration and development of practical skills (43).

Patients undergoing CLT participate in an intensive course of manual lymph drainage massage (MLD), multi layer compression bandaging (followed by compression garments), exercise, skin care and education provided five days (or more) per week over a period of two to six weeks (11,41), with each daily session taking between 60 and 90 minutes.

- Manual lymph drainage is the use of various light massage techniques to encourage the removal of excess interstitial fluid, increase lymphatic transport and soften fibrotic induration (41). MLD is performed at areas adjacent to the affected limb before moving to the limb root and distal sections of the limb (41). Simple Lymphatic Drainage (SLD) is a modified, simpler version of MLD completed by the patient or a family member (2).
- Compression bandaging involves the application of two to three layers of low stretch bandages over padding material, applied along the length of the limb (41). Bandages are primarily used during the reduction phase of treatment and are only removed for self care activities. Compression garments work on a similar principle, applying greatest compression at the distal end of the limb and least at the proximal end (41). Compression helps to decrease the amount of interstitial fluid formation (reducing the amount of fluid to be transported), prevents lymph backflow and enhances the muscle pump action by providing a surface for the muscle to work against (41).
- Exercises prescribed for BCRL are aimed at maintaining affected shoulder range of motion and stimulating lymphatic functions (41). Exercises can range from deep breathing through to range of motion and resistive exercises.
- Skin care and education is primarily aimed at reducing trauma to the affected limb and maintaining optimal skin condition. Historically education has consisted of a number of precautionary guidelines given to at risk persons on the basis of theoretical or anecdotal evidence.

Where once CLT was seen as the first choice of treatment for BCRL, CLT and it's components (MLD, exercises, skin care education and compression bandaging) are increasingly coming under scrutiny with somewhat inconsistent results (21). CLT uses multiple modalities to treat oedema and there is no definitive evidence confirming whether it is the combination of modalities or if one of the modalities is responsible for volume change that is experienced during treatment. The physical resources and time involved on behalf of both the therapist and client make this treatment costly and intrusive. A successful course of CLT requires significant commitment on the part of the patient due to its impact on everyday activities.

Moseley et al (2007) in their literature review reported that in five CLT studies, reductions in affected limb volume ranged from 298 to 652 ml (18.7 to 66%) (41). Karadibak et al (2009) reported reductions in excess limb volume of 87% in those with mild BCRL, 56% in moderate BCRL and 30% in severe BCRL (44). Ramos et al (1999) found subjects who had an excess affected limb volume of less that 250 ml achieved a better result than those who had a volume difference greater than 250ml (45). Dayes et al (2009) reported in the DELTA trial that complex decongestive therapy (CLT) provides a modest additional reduction when compared with compression sleeve alone, with benefits being greater in lymphoedema of longer duration (over one year) (46).

Moseley et al (2007) found that MLD alone has been found to produce a reduction of between 104 to 156 ml, with the greatest reduction being 48% (41). However there is no evidence as to whether this reduction is maintained after MLD is stopped. Andersen et al (2000) reported that in early lymphoedema (under 30 % difference) MLD did not contribute significantly to the reduction of oedema volume when compared with compression garment, exercises and information about lymphoedema and skin care (47). MLD combined with compression appears to result in larger reductions of 47 to 260 ml (7 to 84%) than MLD alone (41).

The National Breast and Ovarian Cancer Centre (2008) review of the literature reports that long term use of compression is effective in reducing and/or controlling limb swelling and may be an essential component of combined physical therapies (21). To obtain best results with compression therapy it is important to start compression treatment in the early stages of lymphedema (47). The Moseley et al (2007) literature review found that compression alone (through bandaging or garments) has been shown to produce volume reductions of between 20 to 49 ml (4-8%). Greater reductions in volume were noted when compression was combined with other modalities such as limb exercise or self massage (24-60%) (41). Compression with self massage (simple lymphatic drainage) resulted in a reduction of 24.4% (41).

Moseley et al (2007) concluded that therapies that are administered by trained health professionals yield the larger percentage volume reductions, maintenance therapies which are completed by the client yielded generally smaller percentage reductions (41).

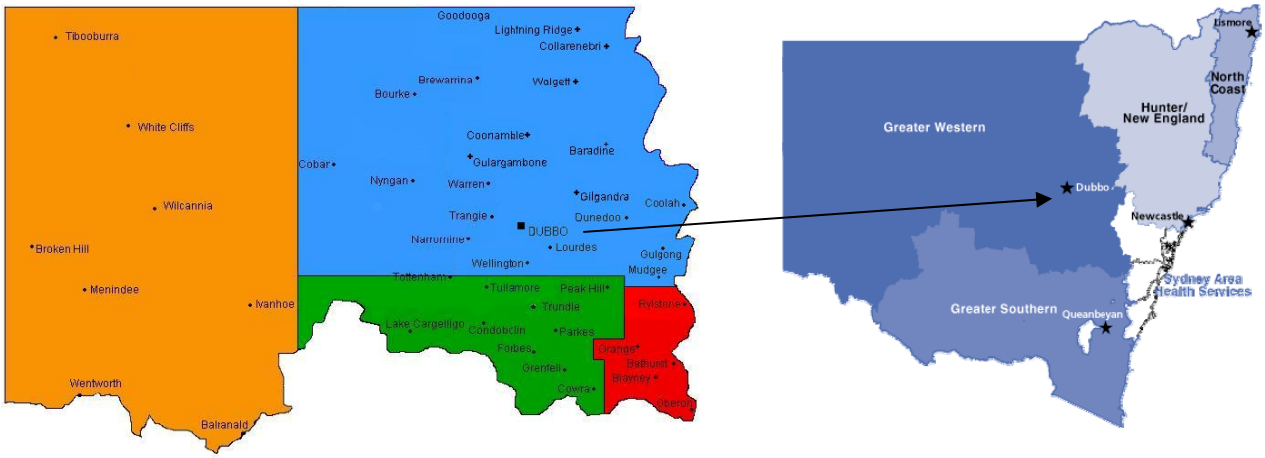
Background

The lymphoedema service of the Occupational Therapy Department at Lourdes Hospital and Community Health Service (Lourdes) commenced in 1994, however it was not until January 2006 that funding for the Lourdes Lymphoedema Service (LLS) was received and half an Occupational Therapist position was dedicated to providing lymphoedema related interventions. The LLS provides services to persons with or at risk of primary and secondary lymphoedema and clients are able to access the LLS through self referral or referral from health professionals.

Approximately two thirds of the clients accessing the LLS have or are at risk of BCRL. The majority of these clients were initially referred by the Breast Care Nurse (BCN) Program. Since July 2004 the BCN program has used a modified version of a Risk Factor Assessment (RFA) Form developed at Flinders University to screen for referral to the LLS (moderate or above risk are referred). This ensures that clients who require lymphoedema intervention are being referred to and offered intervention at the LLS. However not all clients who are referred to the service by the BCN program choose to participate in lymphoedema assessment and education (i.e. do not accept an appointment when offered one). The BCN program provides information about lymphoedema and the LLS to all its' clients with breast cancer regardless of the clients' lymphoedema risk as determined by the RFA.

The LLS is based in Dubbo and provides services to a large geographical area, covering from Wellington in the south, north to the Queensland boarder, west to Cobar and east to Mudgee (Northern Cluster of the Greater Western Area Health Service indicated in sky blue in the map below). Services are generally provided on an outpatient basis at Lourdes with some clients travelling up to 400 km one way to attend the LLS. The service has provision for outreach clinics to be held in areas of high need but Dubbo based service demands limit opportunity for this to happen.

GWAHS – Northern Cluster



Anecdotal reports from the LLS indicate that clients who live further than 50 km from Dubbo are less likely to travel to the LLS to participate in daily complex lymphatic therapy or MLD massage due to time and costs associated with travel and accommodation. Clients living further than 50 kms also appear less likely to make a "special trip" to the LLS for appointments; rather they appear to combine lymphoedema appointments with other activities in Dubbo, resulting in lymphoedema interventions occurring at times of convenience rather than clinical need.

The extensive waiting list and service demands of the LLS combined with the large geographical area in which clients live, has resulted in less than eight percent of clients with BCRL attending the LLS undergoing a course of CLT. Of the clients who have undergone a course of CLT, 50% lived in Dubbo and were able to undergo a full course of treatment (four weeks), 50% lived at a distance and had to stay with family/friends or in rented accommodation in Dubbo while they underwent CLT. The clients who lived at a distance participated in shortened courses of CLT (only 1 to 2 weeks rather than 4 weeks). CLT, when available at LLS is usually completed in the cooler months between April and October to improve comfort and compliance with the compression bandaging.

Lymphoedema intervention available in the LLS includes:

- Education regarding lymphoedema, risk factors, skin care, precautionary strategies and treatment.
- Clinical assessment of signs, symptoms and objective measurements (at initial assessment and reviews).
- Treatment programs including CLT, MLD massage and training of client/family in self treatment.
- Self-management programs including simple lymphatic drainage massage, compression garments, exercise and skin care.
- Garment prescription, fitting and review.

The intervention pattern for a typical client with or at risk of BCRL at the LLS includes: education, initial clinical and physical assessment, ongoing monitoring and reviews, client self-management programs of varying intensity and garment prescription and fitting if required.

Service Delivery Issues

The LLS is a relatively new service but is experiencing a number of complex service delivery issues that could impact client care and outcomes. These service issues include:

- The LLS is unable to provide the "gold standard treatment" (CLT) to all clients who require it (either those living in Dubbo or those living further away)
    - ⇒ Is this having a negative impact on the clinical outcomes (arm volume) of clients who have or are at risk of BCRL accessing the LLS i.e. are their affected arm volumes growing?
    - ⇒ Are clients with or at risk of BCRL in the LLS service area experiencing lymphoedema outcomes similar to those documented in the scientific literature (which are usually metropolitan based)?
- It appears that clients with or at risk of BCRL who live further away from Dubbo are not coming to the LLS regularly for review at LLS.
    - ⇒ Is this a significant trend in intervention patterns? And if it is,
    - ⇒ Is there a difference between the clinical outcomes of women with BCRL who live within 50km of the LLS (Dubbo) and those who live further than 50km from the LLS?
- For clients who live further away from the LLS, access to the LLS is more difficult in terms of costs, distance to be travelled and travel time,
    - ⇒ Is this causing a difference in the treatment programs undertaken by clients with BCRL who live within 50km of the LLS and those living further than 50 km from the LLS?

As the LLS covers a large geographical area much of which is rural and remote, it is necessary to establish if distance or other modifiable factors have an impact on the Lymphoedema Arm Circumference Measurements (LACM) of persons with or at risk BCRL so that these can be addressed in future lymphoedema service planning.

Method

This is a longitudinal, retrospective medical record review of clients with or at risk of BCRL who have attended the LLS between 1 June 2004 and 30 June 2009.

Study Time Period

The study time period start date 1 June 2004 was chosen as the BCN Program started using the RFA form as the basis for referral to the LLS in June 2004. Study completion on 30 June 2009 was a date of convenience. It is acknowledged that as only moderate and high risk clients are referred by the BCN program, the client population being researched has rates of lymphoedema that are higher than the average breast cancer population. This has not impacted the integrity of this research project as it has reviewed LACM outcomes rather than rates of lymphoedema development.

Changes in LACM were assessed over the total time that the client was known to the service. For example, where a client seen during the study period frame was first seen in 1995, the measurements taken at the initial assessment in 1995 will be used as the Time 1 measurements. This allows for the maximum time period over which to gauge LACM change. Time 2 measurements were the last recorded measurements prior to 30 June 2009.

Data Collection and Analysis

A medical record review was used to gather relevant data from information routinely documented during BCRL assessment and treatment interventions. All client medical records were handled according to Lourdes medical record policies and procedures and client confidentiality was maintained. Relevant information from the medical record was recorded on data collection sheets, de-identified and then entered into an Excel spreadsheet where it was analysed for trends and associations. Data collection sheets were housed in a locked filing cabinet, the Excel spreadsheet was stored in password protected computer file.

Wilcoxon Signed-Rank Test, Mann-Whitney U analysis, Pearsons Correlation and Fishers' Exact test used in data analysis were performed using Graphpad Software's Instat version 3.10.

Diagnosis criteria used in the study

Due to the absence of a "gold standard" criteria for the diagnosis of lymphoedema (28) the LLS uses an eclectic approach for lymphoedema diagnosis. A clinical diagnosis is made at initial assessment and then reviewed at each intervention with the client. This eclectic approach is also used to guide treatment decisions, assess the success of treatment interventions and monitor and review client status over time.

As has been discussed previously, objective measurements alone may not be the most reliable indicator of clinically significant lymphoedema (30), with a tendency to under diagnose lymphoedema (20) due to sensitivity and specificity issues. As a result the LLS eclectic diagnostic approach includes a visual and physical assessment of both the affected

and non affected arms for signs of oedema, followed by the collection of objective measures including circumferential measurements of both arms. The LLS also takes into consideration client reported symptoms which, even though not strongly associated, may be an indicator of lymphoedema development (10,48). Armer et al (2003) support an approach using symptoms in combination with the objective measures of inspection, palpation and volume estimation over time to diagnose, treat and monitor lymphoedema (10).

Clients are diagnosed as "at risk of lymphoedema", having "subclinical lymphoedema" or "lymphoedema" after the completion of the following four assessment components:

1. Symptoms assessment include client reports of swelling or puffiness, heaviness, fullness, tightness, aching or pain, redness or warmth, stiffness, numbness, pins and needles or tingling or other related symptoms as identified by the client.
2. Visual examinations completed in the clinic include a comparison of skin on both the affected and non affected arms. This includes skin tightness, presence/absence of wrinkles, visibility of blood vasculature, skin texture, defined or generalised areas that appear oedematous or misshapen when compared to the unaffected limb.
3. The Palpation assessment includes assessing any differences in texture of the affected and unaffected arms. This includes pitting oedema, fullness, thickness, boggy/spongy, floppy/loose tissues or firmness.
4. Objective measurements include sequential circumferential measurements taken of each arm. A description of how these measurements are taken will be described elsewhere. Size difference at one point, sum difference and changes in these over time is used to assist diagnosis.

Diagnostic criteria

At risk of lymphoedema: A diagnosis of being at risk of lymphoedema is made where there are no definitive or measurable signs of lymphoedema and the client does not report any of the symptoms outlined above.
Subclinical lymphoedema: A diagnosis of subclinical lymphoedema is made where there are no definitive or measurable signs of lymphoedema but the client reports at least one of the symptoms outlined above.
Lymphoedema: A diagnosis of lymphoedema is made where there is a combination of findings in two or more of the assessment areas: symptoms, visual observation, palpation and objective measurements.

Objective Measurement Protocol

Even though arm circumference measurements are not a definitive diagnostic tool, they have been found to be a reliable and accurate measure to quantify and monitor lymphoedema over time in the clinical setting (36,38,39). As discussed above the LLS routinely records circumferential arm measurements for both the "unaffected" and "affected" arms for all BCRL clients as this approach reduces the impact of weight gain or loss and natural asymmetry of the arms (3,30). The arm circumference measurements are recorded to a standard format and have generally been taken by the same experienced measurer over time to control issues related to inter and intra-observer reliability (28,38). Due to local constraints, preoperative measurements are not available for analysis in this study.

The standard format for measuring the affected and unaffected arm in the clinic is as follows:

- The arm position is demonstrated and then the client is instructed to place their arm in a position that is perpendicular position to their body, with the shoulder in 90 degrees forward flexion, elbow in extension, forearm pronated, wrist in neutral, fingers extended. Clients who are unable to independently maintain this position for the duration of the measurements have been excluded from the study.
- Measurement points are marked on the clients arm using a water-soluble pen. The mid point of the ulnar styloid process is marked and used as the zero point for the other circumferential measurements up the arm. The arm is then marked at ten centimetre intervals from the zero point to approximately the axilla. Intervals are marked using a solid ruler rather than tape measure to reduce incorrect measurement length.
- A one cm wide, nylon retractable tape is used to take the measurements. The tape is placed around the arm on the proximal side of the marked points on the arm. The tape is pulled to be snug but not tight on the clients arm, the skin and tissues are not compressed during the measurement process and care is taken to ensure the tape is perpendicular on the arm. The measurement is read on the distal side of the tape. The client's trunk position is observed to ensure that the arm remains perpendicular to the body.
- Measurements are taken at proximal to the Metacarpal Phalangeal (MCPs) joints of the hand CPS, wrist just distal to the ulnar styloid process, 10, 20 30 and 40 cm (50cm if a long arm) from the mid point of the ulnar styloid process (zero point). Note: the hand measurement taken at the MCPs is not included in the analysis of measurements in this study due to calculation of volume issues.
- The measurements are recorded for both the affected and unaffected arms and recorded on a table in the clients' medical record.
- The circumferential measurements of each arm are summed and this number is recorded. Change (up or down) in the sum of the arm circumferences (SOAC) of the each arm is monitored over time.
- The difference between the SOAC measurements of the affected and unaffected arm is calculated at each intervention and monitored over time. The Sum Difference (sum diff) is calculated by subtracting the

unaffected arms' SOAC from the affected arms' SOAC. An increase in sum diff (for example from 2 cm to 5 cm) would indicate that the affected arm is growing in comparison to the unaffected arm.

In the clinic, SOAC and sum diff are clinically expedient and relevant lymphoedema outcomes. However these measures are not often reported in the literature. As a result volume of the arm (AV), a measure that is regularly reported in the literature will be calculated and used as the lymphoedema outcome measure in this study.

There for: The LACM outcome of each arm in this study is the volume of the arm (minus hand) calculated using the circumferential measurements of the arm. A truncated cone volume formula will be used to calculate the volume of each ten cm segment of the arm from the styloid process to the 40cm marked point is as follows–

$$V = \frac{h \times (C^2 + Cc + c^2)}{(\pi \times 12)}$$

where V = the volume of the segment of the arm
h = difference between the two measures
C = the proximal circumference
c = the distal circumference

Total volume of the arm is computed through summing the four 10cm segments of each arm.

Inclusion criteria

For inclusion into this research project the client has:

- A Breast cancer diagnosis with either a lumpectomy/mastectomy and axillary clearance/axillary node sampling with at least two lymph nodes removed.
- Circumferential arm measurements taken by the same therapist using the same measurement technique.
- Been seen at least once within the study period 1 June 2004 to 30 June 2009 and will have at least two sets of LACM documented in their medical record.
- Two sets of LACM that are more than three months (90 days) apart. The period between the first set of LACM and last set of LACM taken for each client will be known as the intervention period).
- Been known to the service for at least three months.

Exclusion criteria

Factors that excluded clients from the lymphoedema outcomes research project include:

- A recurrence of disease or designation as palliative within the intervention period.
- A decreased range of motion or deformity in either arm preventing measurements being taken in the standard protocol.
- Oedema in either arm that is a result of a cause other than lymphoedema e.g. blood clots, infection at the time of measurement.
- Bilateral axillary clearance/node sampling.
- Clients experiencing an accommodation change from within 50 km to further than 50 km from Dubbo (or reverse) during the intervention period will be excluded from the analysis related to distance.
- Clients who are referred to the LLS but refuse service.
- Clients who have only one set of LACM recorded in their medical record (seen only once by the service).

Ethics

Ethics approval was obtained from the Human Research Ethics Committee of the Greater Western Area Health Service.

Results

Sample description

There were 160 persons (159 women and one man) who attended the LLS between 1 June 2004 and 30 June 2009 who had a diagnosis of breast cancer. Of these, 79 were included in the study and 81 were excluded.

Inclusions

The included cohort consisted of 79 women with an average age when first seen of 61 years (range 34 to 84 years). Of these clients 54 had undergone a mastectomy (five with sentinel node sampling, 49 with axillary node clearance), 25 had undergone a lumpectomy (one with sentinel node sampling, 24 with axillary node clearance).
At initial assessment, 39 clients had lymphoedema, 37 were classified as having subclinical lymphoedema and three were classified as at risk. During the intervention period, 12 clients progressed from subclinical lymphoedema to lymphoedema and four clients with clinically evident lymphoedema regressed to subclinical lymphoedema with no further need to wear compression. The three clients classified as at risk of lymphoedema remained in that category

during the intervention period. The average number of days between Time 1 and Time 2 measurements for clients with a diagnosis of lymphoedema was 967 days and for clients who were subclinical or at risk was 654 days.

Forty one of the included subjects live within 49 km of the LLS location in Dubbo, 38 live 50km or more from the LLS. No clients moved from one location to another during the course of their intervention with the LLS. Six clients who were diagnosed with lymphoedema either chose not to treat their lymphoedema or were unable complete their recommended treatment program (i.e. did not seek further treatment or did not wear compression sleeves as required).

Table 1: Volume difference at Time 1

Diagnosis at beginning of Study		Affected arm Smaller than unaffected	Affected arm 0 to 99 ml larger than unaffected	Affected arm 100 to 199 ml larger than unaffected	Affected arm over 200 ml larger than unaffected	Total
At risk	Under 49km	0	0	0	0	0
	50+km	3	0	0	0	3
Sub clinical lymphoedema	Under 49km	7	6	3	1	17
	50+km	7	7	6	0	20
Lymphoedema	Under 49km	1	4	4	15	24
	50+km	1	4	3	7	15
Total		19	21	16	23	79

Exclusions

The excluded cohort consisted of 80 women and one man with an average age when first seen of 60 years (range 38 to 86 years). Twelve of the excluded clients passed away during the study time period and no further information was available as their medical records had been sent to storage. Fifty one of the remaining 69 excluded clients had undergone a mastectomy (two with sentinel node sampling, 49 with axillary node clearance), 18 had undergone a lumpectomy (two with sentinel node sampling, 16 with axillary clearance). Twenty three excluded clients had lymphoedema and 46 were classified as subclinical or at risk. All clients who underwent sentinel node sampling where diagnosed as subclinical or at risk. Thirty one of the 69 excluded persons live within 49 km of the service location at Dubbo, 38 live 50km or more from the service location at Dubbo.

Table 2: Reason for exclusion from Research

Reason for exclusion from Study	Under 49 km from LLS	50+km from LLS	Unknown distance	Total
Bilateral nodes removed	1	5	0	6
Active cancer	2	3	0	5
Deceased during study	0	0	12	12
Different therapist taking measurements	1	2	0	3
Known to service less than 3 months	7	3	0	10
Once only intervention	18	23	0	41
Recurrence of cancer	0	2	0	2
Unable to take measures	2	0	0	2
Total	38	31	12	81

Variable Analysis

A number of the variables have been identified in the literature as being predictive of or having an effect on lymphoedema that could have an association and possible confounding effect on changes in AV over time in this study. The variables that were reviewed in this study include: age, hand dominance, side involved, radiotherapy, delay between onset of symptoms and intervention, lymphoedema stage and time between surgery and first intervention with LSS.

Univariate associations were examined; the Wilcoxon Signed-Rank test was used to compare intragroup differences. Intergroup differences were analysed by the Mann-Whitney U test. A P-value of less than 0.05 was considered statistically significant. None of these variables were found to be significant in this analysis.

Research Aims, Hypothesis and Statistical Analysis

Evaluation of arm volume change over the study time will be completed by subtracting the volume difference of the arms at Time 1 (Vdiff1) from the volume difference at Time 2 (Vdiff2). Vdiff1 is subtracted from Vdiff2 as where lymphoedema is untreated/uncontrolled it is expected that volume will increase over time.

Volume difference of the arms (Vdiff1 and Vdiff2) is calculated by subtracting the volume of the non-affected arm (Vna) from the volume of the affected arm (Va) at each time. The non affected arm is subtracted from the affected arm as when lymphoedema is present, it is expected that the affected arm will be larger than the non-affected arm.

As a result of this analysis process: an increase in AV difference over time indicates an increase in affected AV (lymphoedema developing or worsening) and a decrease in AV difference over time indicates a reduction in affected AV (lymphoedema improving).

Vdiff1= Va1 – Vna1 (excess volume of the affected arm at Time 1)
Vdiff2 = Va2 – Vna2 (excess volume of the affected arm at Time 2)
Vdiff2 -Vdiff1= Excess volume change in affected arm over time

Where:
Time 1 = Initial assessment of the client at the LLS.
Time 2 = Last time the client was seen at LLS prior to 30 June 2009.
Va1 = volume of affected arm at Time 1
Vna1 = volume of the non-affected arm at Time 1
Va2 = volume of the affected arm at Time 2
Vna2 = volume of the non-affected arm at Time 2

Hypothesis 1

Aim: To describe the AV outcomes of clients with or at risk of developing BCRL who have attended the LLS.

Hypothesis a. Due to issues affecting service provision at the LLS it is expected that there will be an increase over time, in affected AV outcomes of clients with BCRL attending the LLS.

Null Hypothesis: There is no change over time in affected AV outcomes of clients with BCRL attending the LLS.

All subjects
An examination of all subjects found a mean arm volume difference (AVdiff) at Time 1 of 136ml (median 100ml) and 111ml (83ml) at Time 2. There was no evidence to suggest that affected AV in all subjects attending the LLS had changed over the study period (p=0.129, Wilcoxon Signed-Rank test).

Diagnostic group - lymphoedema
An examination of only women diagnosed with lymphoedema found the mean AVdiff of the lymphoedema diagnostic group at Time 1 was 223 ml and Time 2 was 189 ml, with the mean (median) change in AVdiff during the study being a reduction of 34 ml (22 ml). There is no evidence to suggest that when looking at only those women diagnosed with lymphoedema that their affected AV has changed over the study period (p=0.1705, Wilcoxon Signed-Rank test).

Diagnostic group – Subclinical (or at risk)
An examination of only women diagnosed with subclinical lymphoedema (or at risk) found the mean AVdiff of the subclinical lymphoedema (or at risk) diagnostic group at Time 1 was -23ml and Time 2 was -31ml, with the mean change in AVdiff during the study being a reduction of eight ml (four ml). There is no evidence to suggest that when looking at only those women with a diagnosis of sub clinical lymphoedema (or at risk) that their affected AV has changed over the study period (p=0.5462 Wilcoxon Signed-Rank test).

Review of the subjects with a diagnosis of lymphoedema revealed that there were six women who did not participate in the recommended lymphoedema management programs or did not seek treatment when lymphoedema was present. These six women experienced an average increase of 10% (range 4% to 16%) AVdiff over the study period. The mean AVdiff of these six subjects at Time 1 was 164ml (146ml) and Time 2 was 458ml (404ml) with the mean change in AVdiff during the study being an increase of 293ml (239ml). There is evidence to suggest that there was a statistically significant increase in affected arm volume in this group over the study period (p=0.0313 Wilcoxon Signed-Rank test).

The magnitude of the increase in affected AV in these cases appears to be skewing the analysis of lymphoedema subjects. These subjects will be classified as non-compliers and removed from the analysis of subjects with a diagnosis of lymphoedema. The removal of non-compliers does not affect the group of women diagnosed with subclinical lymphoedema or at risk of lymphoedema

Diagnostic group – lymphoedema minus non compliers
An examination of the women with lymphoedema (minus non-compliers) found the mean AVdiff of the subgroup at Time 1 was 231ml (165ml) and Time 2 was 153ml (116ml), with the mean change in AVdiff during the study being a reduction of 77ml (45ml). There is strong evidence to suggest that when looking at only those women with lymphoedema (minus non compliers) that their affected AV has experienced a statistically significant reduction over the study time (p=0.0032 Wilcoxon Signed-Rank test).

Table 3: Arm Volume Difference for Diagnosis Groups

Group tested	Subjects	P Value	Mean AVdiff Time 1	Mean AVdiff Time 2	Mean AVdiff change over time	Median AVdiff change over time	Range
All subjects	79	0.1294	136.34	111.34	-25.00	-9.00	-545 to 589
Lymphoedema all	51	0.1705	223.90	189.75	-34.157	-22.00	-545 to 589
Subclinical	28	0.5462	-23.143	-31.464	-8.321	-4.00	-187 to 165
Non compliers	6	0.0313	164.50	458.00	293.50	239.50	178 to 589
Lymphoedema minus non compliers	45	0.0032	231.82	153.98	-77.844	-45.00	-545 to 207

Hypothesis 2

Aim: To compare the AV outcomes of clients attending the LLS to those documented in the literature.

Hypothesis b. Due to service issues experienced at the LLS there will be a difference in the AV outcomes of clients with BCRL who have attended the LLS and those documented in the literature.

Null Hypothesis: There is no difference between the AV outcomes of clients attending the LLS to those documented in the literature

Treatment groups to be compared include: CLT, Garment (with or without SLD), SLD alone and monitoring. The non compliant cases have been removed from this analysis.

CLT group

There were four clients with lymphoedema who underwent CLT treatment. The mean reduction in AVdiff for these clients was nine percent of total arm volume (nine percent reduction in affected arm volume). Mean AVdiff of the CLT group at Time 1 was 828 ml (854ml) and Time 2 was 489 ml (481ml), with the mean change in AVdiff during the study being a reduction of 339ml (344ml). These reductions are very clinically significant.

Garment group

There were 33 lymphoedema clients in the garment treatment group. The mean change in AVDiff was a reduction of two percent of total arm volume (two percent reduction in affected arm volume). Mean AVdiff of the garment group at Time 1 was 183ml (165ml) and Time 2 was 132ml (116ml), with the mean change in AVdiff during the study being a reduction of 51ml (6.00ml). A Wilcoxon Signed–Ranked test showed these results were not significant (p=0.1753) and there is no evidence that affected AV of the garment treatment group changed over time.

SLD alone group

There were six clients with lymphoedema who underwent the treatment of SLD alone. The mean reduction in AVdiff was three percent of the total arm volume (three percent of affected arm volume). Mean AVdiff of the SLD group at Time 1 was 117 ml (112 ml) and at Time 2 was 55 ml (50ml), with the mean change in AVdiff being a reduction of 62ml (63ml). A Wilcoxon Signed–Ranked test showed these results were significant (p=0.0313). However, while there is evidence to suggest that there has been change in the affected AV of the SLD treatment group over time, these results are of little clinical value due to the screening of clients in this treatment group. Only clients not requiring comprehensive treatment can be placed in this group and the results achieved may be the result of a regression to normal rather than treatment effect.

Monitoring group

There were only two women who underwent monitoring only during the study period. One experienced a reduction of 87ml, the other an increase of 2ml.

Table 4 – Arm Volume Difference for Treatment Groups

Group tested	Subjects	P Value	Mean AVdiff Time 1	Mean AVdiff Time 2	Mean AVdiff change over time	Median AVdiff change over time	Range	Mean % volume reduction over time	Total volume change range
CLT treatment group	4	n/a	828.00	489.00	-339.00	-344.00	-468 to -200	9%	7.2% to 16.2%
Garment treatment group	33	0.1753	183.94	132.82	-51.12	-6.0	-545 to 207	2%	-20% to 12%
SLD treatment group	6	0.0313	117.00	54.50	-62.50	-63.00	-78 to -45	3%	-4% to -2%

Hypothesis 3

Aim: To establish if there is a difference between the AV outcomes of clients with BCRL who live within 50km of the LLS and those who live further than 50km away.

Hypothesis c: Of the clients with BCRL who have attended the LLS there will difference in the AVdiff over time of those who live within 50 km and those who live further than 50 km away

Null Hypothesis: Of the clients with BCRL who have attended the LLS there is no difference in the AVdiff over time of those who live within 50 km and those who live further than 50 km away from the service.

This analysis will be completed by dividing the study cohort into two groups:

- Group A - live in Dubbo or within 49 km of Dubbo,
- Group B - live 50 km or more from Dubbo

An evaluation of change within each group (Wilcoxon Signed–Rank test) and between groups will be made (Mann-Whitney test). Each group and subgroup will be analysed in turn.

All subjects

The analysis of all subjects living within 49km of Dubbo shows the mean AVdiff at Time 1 was 157ml (113.0ml) and Time 2 was 143ml (121ml), with the mean change in AVdiff during the study being a reduction of 13ml (0 ml). There is no evidence to suggest that affected AV in subjects living within 49 km of Dubbo has reduced over the study time ($p = 0.5276$, Wilcoxon Signed-Rank test).

The analysis of all subjects who lived 50 or more km from Dubbo shows the mean AVdiff at Time 1 was 114ml (74ml) and Time 2 was 76ml (29ml), with the mean change in AVdiff during the study being a reduction of 37ml (15ml). There is weak evidence to suggest that affected AV in all subjects living 50+ km from Dubbo reduced over the study time ($p = 0.0954$, Wilcoxon Signed-Rank test).

A Mann-Whitney test was used to analyse whether there was a difference between the change over time in AVdiff experienced by the group living within 49 km of Dubbo and the group living 50km or more from Dubbo. No evidence was found to suggest that there is any difference between the affected AV change over time experienced in the two groups ($p=0.5015$).

Distance has also been analysed in the diagnostic groups previously analysed: lymphoedema minus non-compliers, subclinical and at risk and non-compliers.

Lymphoedema subjects (minus non-compliers)

An analysis of the women diagnosed with lymphoedema (minus non-compliers) who live within 49 km of Dubbo reveals that the mean AVdiff of the subgroup at Time 1 was 227ml (207ml) and Time 2 was 160ml (139ml), with the mean change in AVdiff during the study being a reduction of 67ml (38ml). There is evidence to suggest that when looking at only those women with lymphoedema (minus non compliers) who live within 49 km of Dubbo that their affected AV has experienced a statistically significant reduction over the study time ($p=0.0214$ Wilcoxon Signed-Rank test).

An analysis of the subgroup of women diagnosed with lymphoedema (minus non-compliers) who lived 50 or more km from Dubbo shows the mean AVdiff at Time 1 was 238ml (153ml) and Time 2 was 143ml (96 ml), with the mean change in AVdiff during the study being a reduction of 94ml (56.0ml). There is weak evidence to suggest that affected AV in lymphoedema subjects living 50+ km from Dubbo reduced over the study time ($p = 0.0638$ Wilcoxon Signed-Rank test).

A further review of the women diagnosed with lymphoedema (minus non-compliers) who live 50+ km from Dubbo showed that there was one subject who experienced a 207ml growth in the volume of her affected arm (compared to non affected) due to infection and further surgery to that arm during the intervention period (there was no infection present when measurement were taken so the client was not excluded from the study). If this subject is removed from the analysis, the lymphoedema 50+km subgroup experiences a mean reduction of 113 ml which is significant ($p=0.0182$, Wilcoxon Signed-Rank test).

A Mann-Whitney test was used to analyse if there was a difference between the change over time in AV experienced by the lymphoedema group living within 49 km of Dubbo and the lymphoedema group living 50km or more from Dubbo (including subject with infection). No evidence was found to suggest that the affected AV change over time experienced in the two distance groups is different ($p=0.6993$).

Subclinical and at risk subjects

An analysis of the women diagnosed with subclinical lymphoedema (or at risk) who live within 49 km of Dubbo reveals that the mean AVdiff of the subgroup at Time 1 was -15ml (4ml) and Time 2 was 11ml (18ml), with the mean change in AVdiff during the study being an increase of 27ml (30ml). There is no evidence to suggest that when looking at only those women with subclinical lymphoedema (or at risk) who live within 49 km of Dubbo that their affected AV has changed over the study time ($p=0.2754$ Wilcoxon Signed-Rank test).

Analysis of the women diagnosed with subclinical lymphoedema (or at risk) who live 50 or more km from Dubbo found the mean AVdiff at Time 1 was -27ml (-31ml) and Time 2 was -55ml (-50ml), with the mean change in AVdiff during the study being a reduction of 28ml (15ml). There is weak evidence to suggest that affected AV in subclinical lymphoedema (or at risk) subjects living 50+ km from Dubbo reduced over the study time ($p = 0.0665$ Wilcoxon Signed-Rank test).

A Mann-Whitney test was used to analyse if there was a difference between the change over time in AV experienced by the subclinical lymphoedema (or at risk) group living within 49 km of Dubbo and the subclinical lymphoedema (or at risk) group living 50+ km from Dubbo. There is evidence to suggest that the affected AV change over time experienced in two groups is different (p=0.0439), with the group living 50+km from the LLS experiencing larger AVdiff change (reductions in affected AV).

Non- Compliers
Of the six subjects who were non compliant with treatment, 3 lived within 49 km of Dubbo and 3 lived 50+ km from Dubbo. Both groups experienced growth in their affected arm volume.

The mean increase in AVdiff for the clients living within 49km of Dubbo was 10.8% (range 3.8 to 16.2) of total arm volume (10.8% growth in affected arm volume). Mean AVdiff of the group at Time 1 was 71ml (113ml) and Time 2 was 427ml (367ml), with the mean change in AVdiff during the study being an increase of 356ml (254ml). These increases are very clinically significant and larger than the three percent limb variance due to dominance (35).

The mean increase in AVdiff for the clients living 50 km of more from Dubbo was 9.9% (range 7.2 to 14.4) of total arm volume (9.9% growth in affected arm volume). Mean AVdiff of the group at Time 1 was 257ml (158ml) and Time 2 was 488ml (439ml), with the mean change in AVdiff during the study being an increase of 231ml (211ml). These increases are very clinically significant and larger than the three percent limb variance due to dominance (35).

It was not possible to accurately analyse if the two distance groups experience different rates of change over time due to small sample size. However the group living within 49km of Dubbo exhibited a greater mean increase in affected AV (245ml) than those living further away, even though the group living 50+km (211ml) from Dubbo started out with a larger mean and median AV at Time 1.

Table 5: Arm Volume Difference for Distance Groups

Group tested	Subjects	P Value	Mean AVdiff Time 1	Mean AVdiff Time 2	Mean AVdiff change over time	Median AVdiff change over time	Range
Distance ≤49km (all diagnosis)	41	0.5276	157.05	143.49	-13.561	0.00	-468 to 589
Distance 50+ km (all diagnosis)	38	0.0954	114.00	76.658	-37.342	-15.00	-545 to 304
Compare ≤49km and 50+km groups change in AV over time (all diagnosis)	41/38	0.5015	na	na	na	na	na
Distance ≤49km, lymphoedema minus non compliers	28	0.0214	227.93	160.14	-67.786	-38.00	-468 to108
Distance 50+ km lymphoedema minus non compliers	17	0.0638	238.24	143.82	-94.412	-56.00	-545 to 207
Distance 50+ km lymphoedema minus non compliers and subject with infection/trauma	16	0.0182	238.25	125.00	-113.25	-56.50	-545 to 73
Compare ≤49km and 50+km lymphoedema minus non compliers groups change in AV over time	28/17	0.6993	na	na	na	na	na
Distance ≤49km, subclinical	10	0.2754	-15.80	11.60	27.40	30.50	-124 to 165
Distance 50+ km subclinical	18	0.0665	-27.222	-55.389	-28.167	-15.00	-187 to 45
Compare ≤49km and 50+km subclinical groups change in AV over time	10/18	0.0439	na	na	na	na	na
Distance ≤49km, non compliers	3	na	71.667	427.67	356.00	254.00	225 to 589
Distance 50+ km non compliers	3	na	257.33	488.33	231.00	211.00	178 to 304
Compare ≤49km and 50+km non compliers groups change in AV over time	3/3	0.4000	na	na	na	na	na

Hypothesis 4

Aim: To establish if there is a difference in the treatment programs undertaken and LLS utilisation patterns of clients with BCRL who live within 49 km of the LLS and those who live 50 km or more away.

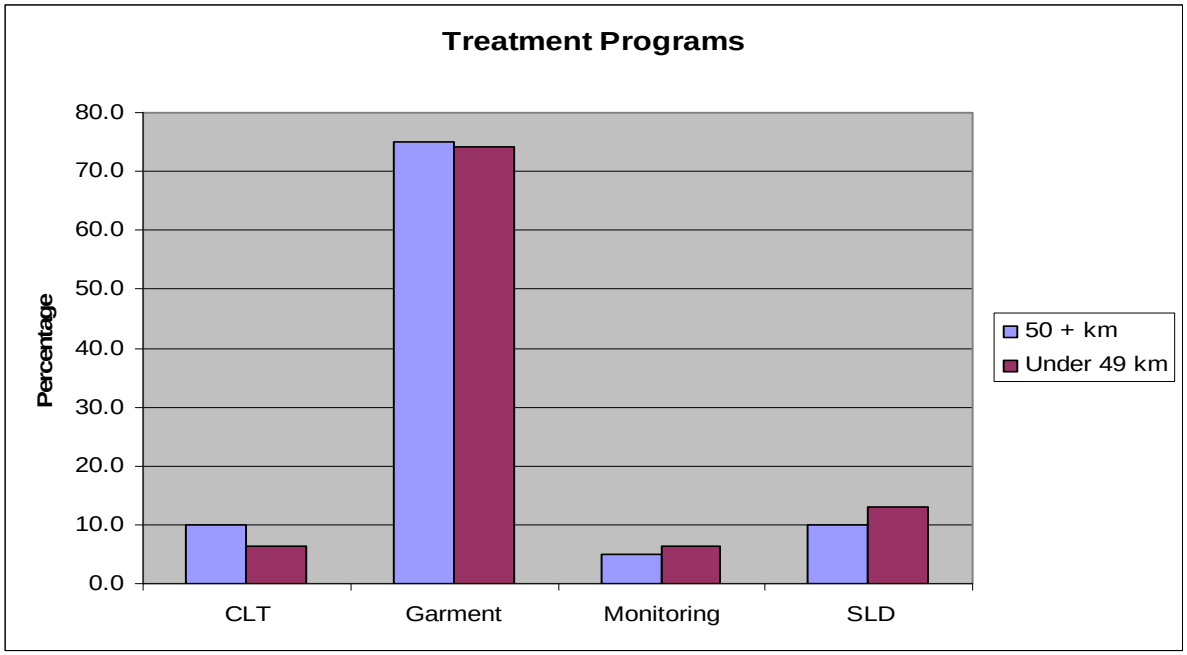
Hypothesis d: Of the clients with BCRL who have attended the LLS there will be a difference in the treatment programs undertaken and utilisation patterns of those who live within 49 km and those who live 50km or further away from the service.

Null Hypothesis: Of the clients with BCRL who have attended the LLS there is no difference in the treatment programs undertaken and LLS service utilisation patterns of those who live within 49 km and those who live 50 km or further away from the service.

Variables of interest will include:

1. Treatment program undertaken - lymphoedema diagnosis only,
2. Service utilisation rates i.e. how often the client has accessed the LLS (average number of days between intervention)

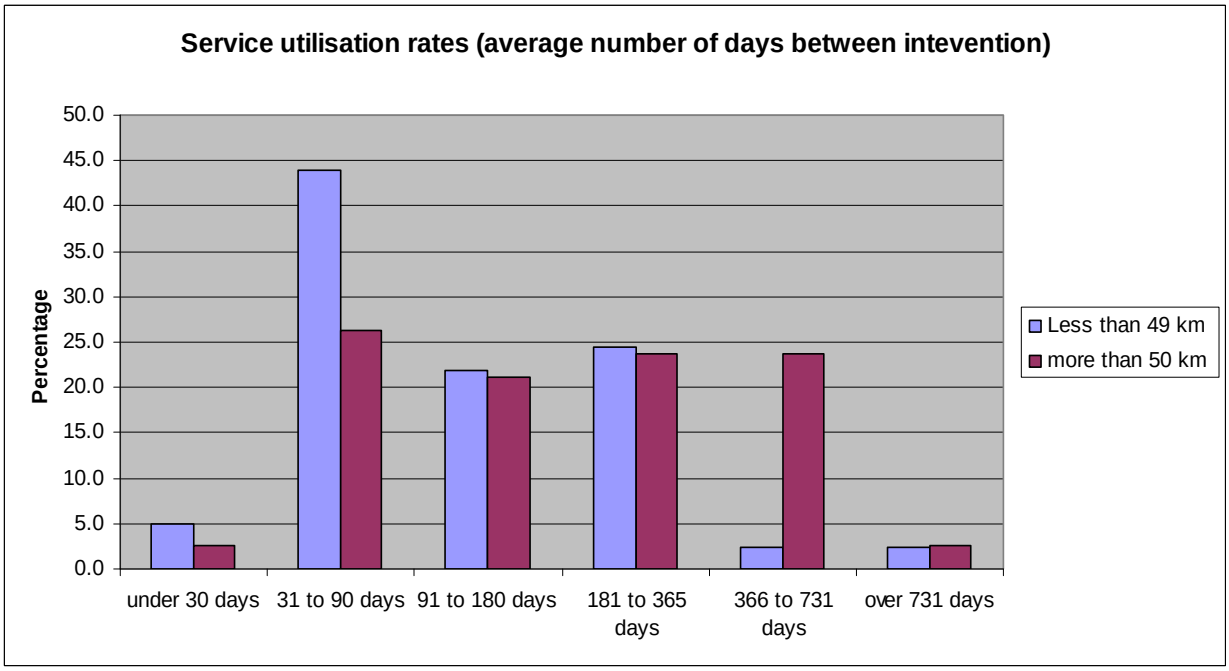
Graph 1: Treatment Programs Undertaken and Distance from Lourdes Lymphoedema Service



It appears from the Graph 1 that there are similar percentages of lymphoedema subjects undertaking each treatment program type, regardless of where they live (within 49 km or 50 km or more from Dubbo).

A chi-squared test found that there is no association between distance from LLS and treatment program undertaken (chi-square=0.876, p=0.831). There is no evidence to suggest that there is a difference in the treatment programs undertaken by both distance related groups.

Graph 2: Service Utilisation Rates and Distance from Lourdes Lymphoedema Service



It appears from the Graph 2 that rates of service utilisation are similar for both distance groups, except in the:

- 31 to 90 days category, which exhibits a higher percentage of clients from the 49 km distance group (43.9% to 26.3%) and
- 366 to 731 days category, which exhibits a higher percentage of clients from the 50km distance group (23.7% to 2.4%)

An examination of service utilisation rates of the subjects living 49km or less and 50+km from Dubbo found that on average subjects living ≤49km accessed the LLS once every 157 days (median 91 days) and subjects living 50+ kms from Dubbo once every 248 days (176 days). There is evidence to suggest that the service utilisation rates of the two distance groups attending the LLS was different during the study period (p=0.0193, Mann-Whitney Test).

This difference in service utilisation rates could be the result of different rates of subclinical and lymphoedema diagnosis subjects within each group (subclinical/lymphoedema rates: ≤49 group is 10/31 and the 50+ group is 18/20). As when examining the service utilisations rates of only those subjects with a diagnosis of lymphoedema in the two distance groups there is no evidence to suggest that there is a difference between the two groups (p=0.1426, Mann-Whitney Test).

An additional examination of service utilisation rates of subjects with lymphoedema compared to subjects with subclinical lymphoedema (or at risk), regardless of distance found subjects with lymphoedema on average accessed the LLS once every 167 days (median 98 days) and subjects with subclinical lymphoedema (or at risk) every 262 days (213 days). There was evidence to suggest that subjects with lymphoedema is significantly more often than those with a subclinical (at risk) diagnosis (p=0.0130, Mann-Whitney Test).

Table 6 - Service Utilisation Rates and Distance from Lourdes Lymphoedema Service

Group tested	Subjects ≤49 km	Subjects 50+ km	P Value	Mean ≤49 km	Median ≤49 km	Mean 50+ km	Median 50+ km
Compare utilisation rates of all clients in distance groups	41	38	0.0193	157.98	91.00	248.34	176.00
Compare utilisation rates of lymphoedema diagnosis in distance groups	31	20	0.1426	130.23	81.00	225.90	120.50
Compare utilisation rates of subclinical (at risk) diagnosis in distance groups	10	18	0.4719	244.00	116.50	273.28	259.50
Group tested	**Subjects Lymphoedema**	**Subjects Subclinical (at risk)**	**P Value**	**Mean Lymphoedema**	**Median lymphoedema**	**Mean Subclinical (at risk)**	**Median Subclinical (at risk)**
Compare utilisation rates of Lymphoedema and Subclinical (at risk) diagnostic groups	51	28	0.0130	167.75	98.00	262.82	213.00

Additional Analysis

Distance and diagnosis

The different rates of lymphoedema and subclinical (or at risk) diagnosis within the distance groups (≤49 km and 50+ km) were analysed using Fisher's Exact Test which found the 50+km groups were significantly less likely to have lymphoedema than the under 49km group (RR=0.70; p=0.0377). Age which has been found to have a significant relationship with diagnosis in this study (RR=1.5; p=0.0184, Fisher's Exact Test) did not impact these results as there was no evidence to suggest that there was a difference in the mean age of either group (p=0.1032, Mann-Whitney Test).

Discussion

This research project has reviewed the outcomes of BCRL interventions at LLS and whether the service issues; inability to provide intensive treatment (CLT) and distance, impact client AV outcomes. A possible 160 subjects with a history of breast cancer attended the LLS during the study period and of these, 81 subjects who were excluded and 79 included in the study.

Review of the subjects excluded from the study reveals that 41 had attended the LLS on only one occasion and then were lost to the service (see Table 2). While it is not possible to analyse the lymphoedema outcomes of this group it is reasonable to assume that this population will experience lymphoedema development rates similar to those outlined in the literature; 20% to 30% of patients develop BCRL following breast cancer intervention (26,27). Therefore is expected that between eight and 13 of these clients will develop lymphoedema. The LLS needs to address the loss of clients in its subclinical lymphoedema monitoring systems and procedures. Early identification and treatment of lymphoedema is essential to reduce the impact of lymphoedema development on the client and the additional treatment burden of advanced lymphoedema on the LLS. Training of lymphoedema practitioners in motivational interviewing may assist this process.

The broad analysis of the 79 included subjects has shown that there is no significant change in the AV of persons with or at risk of BCRL attending the LLS. This in itself can be considered a positive outcome as it has been reported that untreated lymphoedema is likely to grow (1,49), implying a lack of significant growth in AV indicates that there is an effective (but not necessarily optimal) treatment is being completed. However this broad analysis is of little clinical value to service planning in the LLS.

Review of the three primary diagnostic groups within the included subject sample: non compliers (with a diagnosis of lymphoedema), lymphoedema and subclinical lymphoedema (including those diagnosed of at risk of lymphoedema) shows varied results, with the non-compliers experiencing a statistically significant increase in AV (p=0.0313), the lymphoedema subjects experiencing a statistically significant reduction in AV (p=0.0032) and the subclinical

lymphoedema group experiencing no significant change in AV (p=0.5462). These results appear logical as neglecting to treat lymphoedema results in an increase in volume (1,49) and the absence of lymphoedema in the subclinical group should result in no significant change in AV (similar to that found in the normal population).

The clinically significant reduction in AV for the lymphoedema diagnostic group is a positive result for this client group but does not infer that optimal treatment effect (reduction) has been achieved by attendance at the LLS. Twenty two clients with a diagnosis of lymphoedema presented at Time 1 with excess affected AV of over 200ml (see Table 1), indicating the need for intensive intervention, however only four of these clients were able to undergo a course of CLT. If all of these clients had been able to participate in higher intensity treatment programs, greater reductions in affected AV could reasonably be expected.

Treatment Related Service Issues

Lymphoedema diagnosis clients were allocated to treatment group according to the most intensive treatment undertaken. The treatment groups reviewed were CLT, garment, SLD and monitoring. Each treatment group often incorporated the less intensive treatments below it, for example the CLT group wore garments and often completed SLD, the garment group often were prescribed SLD and all groups were monitored.

Treatment results achieved by these groups were compared to those documented in the literature and it was found that the:

- CLT treatment group experienced reductions similar to those documented in the literature (339ml or 9% of total AV at LLS compared to reductions of 298 to 652 ml reported in the literature)(41).
- Garment treatment group experienced non-significant mean reduction of 51ml which is similar to those documented in the literature (20 to 49 ml) (41). However the garment group did not achieved similar percentage reductions, as LLS only averaged a two percent reduction where the literature reported four to eight percent reductions. The garment group was often prescribed SLD in combination with garment use and the mean two percent reduction in affected arm volume was considerably below those for combined modalities documented in the literature (24-60%) (41). These non-significant reductions indicate the need for review of the treatments being provided to this group. This may include the need to encourage changing of compression garments at shorter intervals, regular attendance at the LLS for review and commencement of more intensive treatment where AV growth or significant AV difference is found.
- SLD (patient version of MLD) treatment group did achieve a significant sustained reduction of 52.5 ml but this is not equivalent to those documented in the literature, where 104 to 106 ml (41) reductions were achieved with MLD (though not sustained). This significant reduction is not an indicator of the clinical value of SLD as a primary treatment as only a limited number of clients can undergo this type of therapy alone (i.e. only those with minimal or transient swelling can undertake this treatment, it is not applicable to those with established lymphoedema). This significant reduction in AV may be the result of affected AV regressing to normal rather than treatment effect.

Distance Related Service issues

The effect of distance on AV was analysed by breaking the subjects into two groups, those living within 49 km of the LLS in Dubbo and those living 50+ km from Dubbo. A broad analysis of subjects in these two groups shows no significant difference in AV change over time experience between the two distance groups (p=0.5015). There was no significant difference in AV experienced within the ≤49 km group (p=0.5276) and weak evidence to support a reduction in affected AV in the 50+km group (p=0.0954). Once again this macro analysis was of limited clinical value to the LLS and the results were further analysed in diagnostic groups.

The analysis of the subjects with lymphoedema within the two distance groups produced results similar to those found for all lymphoedema subjects outlined above. Both lymphoedema distance groups experienced significant reductions and there was no evidence to suggest a difference between the AV change experienced in each distance group (refer to Table 5). However it is interesting to note that the 50+ km lymphoedema group experienced greater mean and median reductions in affected AV over time as this is opposite to what was expected.

Analysis of the subclinical lymphoedema group produced results that were different to those found for all subclinical lymphoedema subjects as outlined above. The subclinical ≤ 49km distance group experiencing a non significant increase in AV and the 50+ km subclinical group experiencing a reduction in AV (see Table 5). This distance related difference in AV change over time was found to be significant, implying once again that clients living 50+km from the LLS experience greater affected AV reductions over time than those living nearer the LLS.

Analysis of the non-compliers distance groups also appears to support the emerging concept that distance from LLS is associated with better AV outcomes, with those living at a distance experiencing smaller increases in arm volume than those living closer to the service (see Table 5).

The concept of better AV outcomes for those living 50+ km from the LLS is the opposite of what was expected at commencement of this research project. Additional analyses were completed to see if this effect carried over to diagnosis of lymphoedema and excess AV development. It was found clients living at a distance from the LLS were

significantly less likely to be diagnosed with lymphoedema (RR=0.7, p=0.0377) and the group of lymphoedema clients living 50+ km from the LLS had a lower percentage of clients with an excess AV 200+ ml (32% in the 50+km group compared to 68% in the ≤49km group) at Time 1.

The reason for the trend of better BCRL outcomes being experienced by the clients living 50+ km from the LLS is not known, but could be related to activity levels or proactive approach to care of one's own health (in the absence of health services) within the 50+km distance group. Further investigation of this trend is warranted to establish whether the effect can be transferred to other areas.

Treatment programs and distance
An analysis of the treatment programs undertaken by the two distance groups showed that there was no significant difference between the groups (p=0.831). This analysis could indicate that distance does not affect treatment programs undertaken or the more likely cause, that treatment options are equally limited for all subjects, regardless of distance from LLS.

Service utilisation and distance
Analysis of the service utilisation rates of the two distance groups has shown a significant difference (p=0.0193) between the two groups, with the ≤ 49 km distance group accessing the LLS at shorter intervals (more regularly) than the 50+ km distance group. This difference is most probably the result of dissimilar rates of lymphoedema and subclinical (at risk) diagnosis in each distance group. The ≤49km distance group has a greater rate of lymphoedema subjects and the 50+ km distance group has a greater rate of subclinical (at risk) subjects. Service utilisation across diagnostic groups is significantly different (p=0.0130) with lymphoedema subjects accessing services more regularly (mean 167 days) than subclinical subjects (262 days).

The effect of distance on service utilisation within the lymphoedema diagnosis group and total BCRL group can not be completely discounted. Even though there was no evidence to support there being a difference between utilisation rates of the two distance lymphoedema groups (p=0.1429), there was a 95 day difference between the mean service utilisation of the ≤ 49km distance group (130 days) and 50 + km distance group (225 days). This 95 day difference could result in delayed identification of increases in AV or overdue compression garment changes. This could explain why the lymphoedema group who live 50+km from the LLS did not have strong evidence of reduction in AV when a significant change was experienced in the ≤ 49km distance group. Analysis of the clients who were excluded from the study found that the 41 who had attended the LLS on only one occasion were more likely to be from the 50+km group (56%) than the ≤ 49km (44%). Distance must still be taken into consideration in service planning to address the needs of clients with lymphoedema and subclinical lymphoedema.

Conclusion

This study has reviewed the AV outcomes of clients with or at risk of BCRL attending the LLS. The analysis of included subjects has shown that only those clients who were non-compliant with treatment experienced significant increases in AV. Most lymphoedema subgroups experienced significant reductions in AV which is a positive but not necessarily optimal result. Greater reductions could have been achieved if a course of CLT was available to all clients who required it. Additional capacity to supply intensive treatment is required to meet current lymphoedema service demands at the LLS.

Due to the weak evidence for reduction achieved by lymphoedema subjects living 50+ Km from the LLS, ongoing review of these clients is required to assess if the weak result is a trend or the effect of a single client. Alternative and creative avenues to supply CLT to clients living 50+km from the LLS are necessary to adequately meet the treatment need in rural and remote areas. The apparently beneficial effect on BCRL outcomes of living 50+km from the LLS also requires further investigation to ascertain if the effect can be transferred to other groups.

In addition to treating clients with lymphoedema, the LLS provides intervention to clients at risk of developing BCRL (or subclinical lymphoedema). Effective assessment and monitoring, including the early initiation of treatment where indicated, has been shown by some studies to slow or reverse the progression of lymphoedema (10,14,36,50). The limited capacity to provide intensive treatment combined with distance issues encountered by the LLS highlights the need to implement a regular assessment and early intervention focus. This focus will enable identification and cost effective treatment of lymphoedema before it reaches a level requiring CLT, reducing time and costs associated service provision. Early diagnosis of lymphoedema would be substantially enhanced through the implementation of preoperative assessment (10) as this would reduce time delay in diagnosis (28).

Reliable methods to diagnose and monitor lymphoedema in the clinical setting are critical to the early detection and accurate monitoring of the condition (14). In the absence of gold standard diagnostic criteria (28) the LLS employs an eclectic diagnostic approach used by experienced lymphoedema practitioners to make a diagnosis of lymphoedema. This diagnostic practice has found lymphoedema in the absence of a 200ml excess volume or two cm size discrepancy (objective measures which have been found to under diagnose lymphoedema) (21,25). The absence of defined,

objective criteria for diagnosis may be a limitation of this study and validation of the approach used at LLS would ensure consistency of diagnosis, assessment and treatment effect monitoring. .

Due to the impact of uncontrolled lymphoedema on activities of everyday living and quality of life (1,3,5,6,11) increasing cases of lymphoedema over time (28), increasing public health burden of BCRL (20,21) and underestimation of BCRL (25) in the milieu of financial, time and distance constraints experienced in rural health, additional ongoing funding for the lymphoedema service is required to meet current and expected increases in service demands. However, alternate models of service provision that do not rely exclusively on lymphoedema practitioner implemented treatment programs are required where distance and time effect access and service provision.

Recommendations

As a result of the findings of this research project, the following recommendations are made for service planning within the LLS:

1. Due to reduced resources and distance issues that limit capacity for CLT, the LLS should develop a focus on the early identification and treatment of lymphoedema. This can be facilitated through:
    a. Establishing intervention procedures that encourage regular client contact with the LLS, such as promoting best practice intervention patterns and making future appointments while the client is at the LLS rather than relying on the client phoning to make appointment,
    b. Implementation of pre breast cancer surgery assessment of AV,
    c. Regular (bi yearly) outreach clinics in areas of service need,
    d. Validation of the LLS diagnostic practices used to diagnose and monitor lymphoedema in the absence of a gold standard diagnostic criteria,
    e. Active monitoring of clients identified with subclinical lymphoedema for three years following surgery in line with best practice (reduce the incidence of once only assessments to ensure adequate monitoring and identification of expected cases of lymphoedema)
    f. Education of lymphoedema practitioners in techniques that encourage clients to actively monitor their risk of lymphoedema or treat lymphoedema when diagnosed (motivational interviewing).
2. Sourcing of ongoing funding for compression garments (which are the primary treatment used at LLS) due to the current reliance on public generosity to supply compression garments to clients.
3. Investigate alternate avenues for funding and physical capacity to supply CLT to those clients who experience increased affected AV (in both Dubbo and the region) to improve AV outcomes.
4. The weak evidence supporting reductions in clients with lymphoedema who live 50+ km away from LLS should be monitored to establish if this is a trend or the effect of a single client.

Future Research Opportunities

1. Further investigation of the positive association of distance and BCRL outcomes is required to establish if the effect found in this study is anomaly or trend.
2. Development a diagnostic tool is required to enable diagnosis and monitoring of lymphoedema by rural practitioners in the absence of gold standard diagnostic procedure and resources to purchase expensive diagnostic equipment.

Limitations of this study

Limitations of this study include:

- Lack of a universal definition and criteria for diagnosis of lymphoedema resulting in this study relying on diagnosis by experienced therapist,
- AV does not include measurement of the hand,
- Number of subjects in some analysis preventing more precise statistical estimates,
- The formula used to calculate volume assumes that the arm is a number of truncated cones which is not always the case (38).

Search Criteria

Search engines used in this study: EMBASE, Psych Info, Cinhal, Medline, Google Scholar
Search words: Lymphoedema, Arm (upper limb etc), Prognosis, Progression, Breast cancer, Measurements, Diagnosis.

References

1. Gary DE. Lymphedema diagnosis and management. Journal of the American Academy of Nurse Practitioners. 2007 Feb;19(2):72-8.
2. Lymphoedema Framework. Best Practice for the Management of Lymphoedema. International Consensus. London: MEP Ltd; 2006.
3. Petrek JA, Heelan MC. Incidence of breast carcinoma-related lymphedema. Cancer.1998;83(12 Suppl American):2776-81.
4. Golshan M, Smith B. Prevention and management of arm lymphedema in the patient with breast cancer. The Journal of Supportive Oncology. 2006;4(8):381-6.
5. Bland KL, Perczyk R, Du W, Rymal C, Koppolu P, McCrary R, et al. Can a practicing surgeon detect early lymphedema reliably? American Journal of Surgery. 2003;186(5):509-13.
6. Swenson KK, Nissen MJ, Leach JW, Post-White J. Case-control study to evaluate predictors of lymphedema after breast cancer surgery. Oncology Nursing Forum. 2009;36(2):185-93.
7. Cheville AL, McGarvey CL, Petrek JA, Russo SA, Taylor ME, Thiadens SRJ. Lymphedema management. Seminars in Radiation Oncology. 2003 Jul;13(3):290-301.
8. Loudon L, Petrek J. Lymphedema in women treated for breast cancer. Cancer Practice: A Multidisciplinary Journal of Cancer Care. 2000 Mar-Apr;8(2):65-71.
9. Harmer V. Breast cancer-related lymphoedema: risk factors and treatment. British Journal of Nursing. 2009;18(3):166-72.
10. Armer JM, Radina ME, Porock D, Culbertson SD. Predicting breast cancer-related lymphedema using self-reported symptoms. Nursing Research. 2003 Nov-Dec;52(6):370-9.
11. Mondry TE, Riffenburgh RH, Johnstone PAS. Prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy. 2004 Jan-Feb;10(1):42-8.
12. Neese PY. Management of lymphedema. Lippincott's Primary Care Practice. 2000;4(4):390-9.
13. Rockson S. Lymphedema. The American Journal of Medicine. 2001;110(March):8.
14. Chen Y, Tsai H, Hung H, Tsauo J. Reliability study of measurements for lymphedema in breast cancer patients. American Journal of Physical Medicine & Rehabilitation. 2008;87(1):33-8.
15. Petrek JA. Commentary: prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy. Cancer Journal. 2004 Jan-Feb;10(1):17-9.
16. Hayes S, Cornish B, Newman B. Comparison of methods to diagnose lymphoedema among breast cancer survivors: 6-month follow-up. Breast Cancer Research & Treatment. 2005 Feb;89(3):221-6.
17. Collins LG, Nash R, Round T, Newman B. Perceptions of upper-body problems during recovery from breast cancer treatment. Supportive Care in Cancer. 2004;12(2):106-13.
18. Australian Institute of Health and Welfare and National Breast and Ovarian Cancer Centre. Breast Cancer in Australia: An overview, 2009. Cancer Series no 50 [serial on the Internet]. 2009; Cat.no. CAN 46(29/10/09): Available from: http://www.aihw.gov.au/publications/can/can-46-10852/can-46-10852.pdf.
19. Australian-Government. Life Expectancy. Online information: Australian Institute of Health and Welfare; 2009 [updated 29/10/09; cited 2009 29/10/09].
20. Hayes S, Janda M, Cornish B, Battistutta D, Newman B. Lymphedema secondary to breast cancer: how choice of measure influences diagnosis, prevalence, and identifiable risk factors. Lymphology. 2008;41(1):18-28.
21. National Breast and Ovarian Cancer Centre. Review of research evidence on secondary lymphoedema: Incidence, prevention, risk factors and treatment. Surry Hills, NSW: NBOCC; 2008.
22. Boccardo FM, Ansaldi F, Bellini C, Accogli S, Taddei G, Murdaca G, et al. Prospective evaluation of a prevention protocol for lymphedema following surgery for breast cancer. Lymphology. 2009;42(1):1-9.
23. Erickson V, Pearson M, Ganz P, Adams J, Kahn K. Arm edema in breast cancer patients. Journal of the National Cancer Institute. 2001 Jan 17;93(2):96-111.
24. Clark B, Sitzia J, Harlow W. Incidence and risk of arm oedema following treatment for breast cancer: a three-year follow-up study. Qjm. 2005;98(5):343-8.
25. Petrek JA, Senie RT, Peters M, Rosen PP. Lymphedema in a cohort of breast carcinoma survivors 20 years after diagnosis. Cancer. 2001 Sep 15;92(6):1368-77.
26. Franks P, Williams A, Moffatt C. A Review of the Epidemiology of BCRL. 2006.
27. Hayes SC, Janda M, Cornish B, Battistutta D, Newman B. Lymphedema after breast cancer: incidence, risk factors, and effect on upper body function. Journal of Clinical Oncology. 2008;26(21):3536-42.
28. Armer JM, Stewart BR. A comparison of four diagnostic criteria for lymphedema in a post-breast cancer population. Lymphatic Research & Biology. 2005;3(4):208-17.
29. Armer J, Fu MR, Wainstock JM, Zagar E, Jacobs LK. Lymphedema following breast cancer treatment, including sentinel lymph node biopsy. Lymphology. 2004;37(2):73-91.
30. McLaughlin SA, Wright MJ, Morris KT, Giron GL, Sampson MR, Brockway JP, et al. Prevalence of lymphedema in women with breast cancer 5 years after sentinel lymph node biopsy or axillary dissection: objective measurements. Journal of Clinical Oncology. 2008;26(32):5213-9.
31. Norman SA, Localio AR, Potashnik SL, Simoes Torpey HA, Kallan MJ, Weber AL, et al. Lymphedema in breast cancer survivors: incidence, degree, time course, treatment, and symptoms. Journal of Clinical Oncology. 2009;27(3):390-7.

32. Lane K, Worsley D, McKenzie D. Exercise and the lymphatic system: implications for breast-cancer survivors. Sports Medicine. 2005;35(6):461-71.
33. Herd-Smith A, Russo A, Muraca MG, Del Turco MR, Cardona G. Prognostic factors for lymphedema after primary treatment of breast carcinoma. Cancer. 2001 Oct 1;92(7):1783-7.
34. Stanton A, Badger C, Sitzia J. Non-invasive assessment of the lymphedematous limb. Lymphology. 2000 Sep;33(3):122-35.
35. Gebruers N, Truijen S, Engelborghs S, De Deyn PP. Volumetric evaluation of upper extremities in 250 healthy persons. Clinical Physiology & Functional Imaging. 2007;27(1):17-22.
36. Stout Gergich NL, Pfalzer LA, McGarvey C, Springer B, Gerber LH, Soballe P. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. Cancer. 2008;112(12):2809-19.
37. Meek AG. Breast radiotherapy and lymphedema. Cancer. [Review]. 1998 Dec 15;83(12 Suppl American):2788-97.
38. Tewari N, Gill PGMF, Bochner MAMF, Kollias JMF. Comparison of Volume Displacement Versus Circumferential Arm Measurements For Lymphoedema: Implications For The SNAC Trial. ANZ Journal of Surgery October. 2008;78(10):889-93.
40. Box RC, Reul-Hirche HM, Bullock-Saxton JE, Furnival CM. Physiotherapy after breast cancer surgery: results of a randomised controlled study to minimise lymphoedema. Breast Cancer Research & Treatment September. 2002;75(1):51-64.
41. Moseley AL, Carati CJ, Piller NB. A systematic review of common conservative therapies for arm lymphoedema secondary to breast cancer treatment. Annals of Oncology. 2007;18(4):639-46.
42. Pincock S. Swollen limbs show risk of cancer surgery. The Australian; 2007.
43. Australasian Lymphology Association. ALA Guidelines For Level 1 Lymphoedema Training Courses. Australasian Lymphology Association; 2004 [16 November 2009].
44. Karadibak D, Yildirim Y, Kara B, Saydam S. Effect of complex decongestive therapy on upper extremity lymphedema. Fizyoterapi Rehabilitasyon. 2009;20(1):3-8.
45. Ramos SM, O'Donnell LS, Knight G. Edema volume, not timing, is the key to success in lymphedema treatment. American Journal of Surgery. 1999 Oct;178(4):311-5.
46. Dayes I, Whelan T, McNeely M, Pritchard S, Parpia B, Mackinnon D, et al. The DELTA Trial: Early results of a randomised trial of decongestive lymphatic therapy for lymphoedema following treatment for breast cancer 22nd International Congress of Lymphology; Sydney Australia: International Society of Lymphology.
47. Andersen L, Hojris I, Erlandsen M, Andersen J. Treatment of breast-cancer-related lymphedema with or without manual lymphatic drainage--a randomized study. Acta Oncologica. 2000;39(3):399-405.
48. Kosir MA, Rymal C, Koppolu P, Hryniuk L, Darga L, Du W, et al. Surgical outcomes after breast cancer surgery: measuring acute lymphedema.[erratum appears in J Surg Res 2001 Apr;96(2):304]. Journal of Surgical Research. [Research Support, Non-U.S. Gov't]. 2001 Feb;95(2):147-51.
49. Casley-Smith JR. Alterations of untreated lymphedema and it's grades over time. Lymphology. 1995;28(4):174-85.
50. Rockson S. Bioimpedance Analysis in the Assessment of Lymphoedema Diagnosis and Management. Journal of Lymphoedema. 2007;2(1):44-8.