Quantitative study of the subcutaneous needle drainage of lymphoedema in advanced malignancy

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Key words

Lymphoedema, palliative care, subcutaneous needle drainage

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Abstract

Background: Lymphoedema is an often-neglected symptom of advanced malignancy. Subcutaneous needle drainage is a procedure that drains the fluid externally in refractory lymphoedema. It has the potential to improve quality of life but little objective data exist about its efficacy or adverse outcomes. This study used validated tools to objectively assess subcutaneous lymphoedema drainage. **Methods:** The drainage procedure followed a prescriptive protocol. A lymphoedema quality-of-life questionnaire was completed before the procedure, immediately following the procedure and approximately 2 weeks later. **Results:** Sixteen patients were assessed as suitable for the procedure. The average length of drainage was 5.4 days (1–10 days) with volumes drained ranging from 102 ml to 15.2 L. Within 1 week both function (3.3 versus 2.7, $p<0.05$) and appearance (2.9 versus 2.7, $p<0.05$) improved, with a sustained effect at 2 weeks post-procedure. Adverse events did occur, with 19% developing cellulitis. **Conclusion:** Subcutaneous needle drainage of the lower limb is a potential treatment for patients with refractory symptoms. It appears to be effective for patients in the areas of function and appearance. Overall quality of life trended towards improvement but the improvement was not statistically significant.

Lymphoedema is a build-up of lymph fluid in the subcutaneous tissues (Rockson, 2001; Caban, 2002; Kerchner et al, 2008). It can be primary or secondary in nature. Secondary lymphoedema is usually due to damage or obstruction to a specific part of the lymphatic system, for example after surgical procedures such as the removal of lymph nodes in breast cancer or pelvic surgery, and damage from radiation, trauma and infection (Ohba et al, 2011; Abu-Rustum et al, 2006). Intra-pelvic tumours may compress lymphatic structures or invade regional lymph nodes, causing obstruction and/or increased back pressure in the lymphatic system, with lymphoedema often being the consequence.

Associated with the development of lymphoedema are diminishing function, substantial psychosocial distress, pain and overall impaired quality of life (Passik et al, 1988; McWayne and Heiney, 2005; Morgan et al, 2005; Elumelu-Kupoluyi et al, 2013; Fu et al, 2013). Mobility is often significantly affected, with patients experiencing a decreased ability to perform activities of daily living. Lymphoedema can also be linked to increased anxiety, body image issues, loss of confidence and relationship stresses (Frid et al, 2005; Fu et al, 2013). This is even more apparent in patients facing the end of their lives. In palliative care, lymphoedema appears to be a neglected area, with little knowledge or understanding of the condition and its management among the majority of health professionals (Williams et al, 2005; Renshaw, 2007).

The incidence of lower limb lymphoedema in advanced cancer patients is reportedly between 25% and >80%, depending upon the primary malignancy (Keeley et al, 2010). Real et al (2016) recently published a study looking at all patients referred to a specialist palliative care service. Over 90% of their patient population had malignancy and 10.5% of all referrals had a diagnosis of lymphoedema.

There are a variety of possible treatments for lymphoedema, including surgery, manual lymphatic drainage, bandaging and compression garments (Preston et al, 2004; Todd, 2009; Clemens et al, 2010; Hewitt et al, 2010). In end-stage palliative care, however, such options are not always appropriate and interventions aimed at symptom relief and comfort should be the focus.

Subcutaneous needle drainage is a technique first described by Clein and Pugachev in 2004. They outlined eight patient experiences of the procedure after conventional treatments had failed, reporting a reduction in oedema. They concluded that the procedure was cost-effective and valuable. Four small case studies were later published outlining similar procedures (Faily et al, 2007; Lam et al, 2009; Bar-Sela et al, 2010; Jacobsen et al, 2011). A subsequent review concluded that the procedure was potentially effective in those with advanced malignancy but that none of the studies had objective measures of outcomes, had reported on any adverse outcomes or published a generalisable protocol (Beck et al, 2012). The aim of this study was to determine the

Table 1. Demographic data of patients in the study (n=16).

Demographic	Number
Age (mean (standard deviation, range))	67.1 (12.4, 49–81)
Sex (male/female)	5/11
Ethnicity	
New Zealand European	10
New Zealand Maori	1
European other	4
Missing data	1
Type of malignancy	
Breast	2
Melanoma	3
Prostate	2
Gynaecological	2
Colon	3
Kidney	1
Hepatocellular	1
Bladder	1
Mesothelioma	1

effect of subcutaneous needle drainage of lower limb oedema on quality of life in patients with advanced cancer, and record complication rates.

Methods

A prospective non-randomised observational study was conducted using purposive sampling to assess the outcomes of subcutaneous needle drainage using objective measurements. The study was approved by the Nurse Maude Association Ethics Advisory Group and all patients gave written informed consent. All participants resided within the Canterbury area, the second largest District Health Board in New Zealand, and had been referred to the Nurse Maude Hospice Palliative Care Service with advanced and incurable malignancy.

To be included in the study, the participants needed to be competent to give consent, over the age of 18 years and English-speaking. Exclusion criteria included patients undergoing chemotherapy, the presence of neutropaenia and/or thrombocytopaenia, active cellulitis or an acute concurrent illness. Patients who were immunosuppressed, anticoagulated or had unexplained fever were evaluated by a medical professional before the drainage commenced. The procedure was offered if conventional treatments such as compression garments, bandaging or manual drainage were no longer effective or possible.

Following written consent, demographic data including age, gender and diagnosis were collected. The participants' characteristics are summarised in *Table 1*. Quality of life was measured using the lymphoedema quality-of-life (LYMQOL) questionnaire designed by Keeley. It is the only validated measure for quality of life in patients with lymphoedema (Keeley et al, 2010). This tool was utilised in this study despite not being developed for the palliative population. It asks respondents to rate their function, appearance, symptoms and emotions on a four-point scale, as well as an overall quality of life measure rated from nought to ten, with higher numbers being more favourable.

A mobility measurement tool (see *Figure 1*) was developed by the author (MT), and was adapted from the Accident Compensation Commission assessment tool. The Accident Compensation Commission is a New Zealand government organisation that provides funding to treat and rehabilitate those recovering from an accident. The author's mobility tool asks the participant to choose three activities of importance to him/her and rank them from nought to ten, with higher numbers correlating with greater function.

The LYMQOL questionnaire and mobility measurement were completed immediately prior to the procedure (baseline), the day the needles were removed (time point 1) and 2 weeks after the procedure (time point 2). The final data collection at time point 2 was performed by a research assistant over the telephone.

The Nurse Maude Hospice staff were asked to record any complications related to the lymphoedema drainage procedure during the intervention and until the patients were discharged from the hospice. The community palliative care team monitored patients for 2 weeks after they had returned home.

Procedure protocol

A protocol for the drainage procedure, see *Box 1*, was adapted from Koso (2008). It had been extensively used on patients previously at the Nurse Maude Hospice and found to be replicable. All patients who consented to participate were admitted to the Nurse Maude Hospice for the duration of the procedure. The needles were placed by a medical professional experienced in the procedure. The needles remained *in situ* until drainage had stopped or was minimal, the patient wanted the needles removed, or there was any sign of infection.

Patients were generally discharged after the needles were removed and there was no further leakage from the sites. After-procedure care was important to prevent infection and possibly maintain the effect of drainage for longer. Adverse events were reported by the medical staff or the community team once the patient had returned home.

Statistical analysis

Data were collected in an electronic database (MS-EXCEL, Redmond, WA). The LYMQOL questionnaire has a suggested scoring system grouping the original 27 questions into four domains: function, appearance, symptoms and emotions. The mean changes for each domain were compared between the pre-assessment and time points 1 and 2 using paired t-tests. A two-tailed p-value >0.05 was taken to indicate statistical significance.

Results

The recruitment of participants occurred between May 2013 and October 2014. Sixteen patients met the criteria and agreed to participate. The most common reasons for not being selected for the trial were poor functional status and rapid deterioration. The most common diagnoses were melanoma and colon cancer.

Drainage took an average of just over 5 days per patient (1–10 days) and volumes obtained ranged from 102 ml to 15.2 L, with an average of >6 L. One patient had an unsuccessful procedure and there was no drainage from the needle sites. This patient was able to return home from the hospice immediately.

Approximately 12 months after the procedure, 12 of the patients had died. They died in a period of between 5 days and 8 months. As these patients were referred to the palliative care service with a life-limiting illness, prognosis was often limited. The other four patients are still alive, and two of them did not have recurrent lymphoedema.

LYMQOL questionnaire and mobility tool

All 16 participants managed to complete the baseline LYMQOL questionnaire and 13 of them selected three activities for the mobility measurement. Three of the participants deteriorated due to their underlying illness either during the procedure or immediately following, and did not complete any subsequent assessments. Only nine patients completed the time point 2 LYMQOL questionnaire and mobility tool.

Subcutaneous needle drainage was associated with statistically significant improvements in function and appearance. Of the five domains of the LYMQOL questionnaire, function was scored the worst before the intervention, with an average of 3.3 on a four-point scale, see *Table 2*. Immediately following the procedure there was an improvement (3.3 versus 2.7, $p<0.05$) that was sustained at 2 weeks. Appearance also improved significantly (2.9 versus 2.7, $p<0.05$). All of the domains trended towards improvement, including quality of life.

Participants documented a range of activities important to them on the mobility measurement tool. These included activities such as walking, climbing stairs, getting into bed, putting on shoes, cooking and going to the toilet. Seven patients with more than one mobility measurement showed improvement in at least two of their self-selected activities.

Adverse events

Eleven of the 16 patients (69%) did not have any complications or unexpected adverse events.

In two of the patients there was a diagnosis of cellulitis with no sequelae, requiring oral antibiotics only. This was probably related to the subcutaneous needle drainage procedure. Neither patient had a fever and the diagnosis was made based on erythema of the legs. One of the patients died of renal failure 9 days after the start of the drainage procedure. She was already known to have renal impairment and her deterioration was unlikely to be related to the intervention.

One of the participants developed significant renal impairment 3 days after the drainage commenced and died 5 days later. The renal failure or death was possibly related to the procedure although he had been deteriorating rapidly.

Another patient developed bilateral cellulitis and was put on oral antibiotics at the start of symptoms. She required an admission to the acute hospital, however, for intravenous antibiotics. It was highly likely that the infection was secondary to the procedure.

MOBILITY MEASURES

PATIENT STICKER

Evaluation

A) Initial Assessment
I am going to ask you to identify three important activities that you are unable to do or are having difficulty with as a result of your lymphoedema.

B) Follow-up Assessment
When I assessed you previously you told me that you had difficulty with the activities listed below. Today, do you still have difficulty with these?

Scoring Scheme

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before problem

Initial Assessment								
Y		Y		Y		Y		
M		M		M		M		
D		D		D		D		

ACTIVITY	Rate Performance Ability from 0-10			
Calculate rating for each column and put average score here.				

Figure 1. The mobility measurement tool developed to assess mobility in patients with lymphoedema attending the Nurse Maude Hospice.

Discussion

In this study patients with advanced malignancy were offered subcutaneous needle drainage for their intractable lower limb lymphoedema as a last resort to improve quality of life. Improvement in function, appearance, symptoms, emotions, and ultimately quality of life, were measured using a validated tool (LYMQOL questionnaire) and a patient-centred mobility instrument. Function and appearance improved significantly, however there were some adverse outcomes. Subcutaneous needle drainage shows value for those with this often-neglected symptom, but some potential modifications to the protocol are required.

Lymphoedema in advanced malignancy is not uncommon (Real, 2016). There are multiple treatment options available to patients; however, for many people the conventional treatments become too burdensome or stop being effective. Needle drainage may be one option for selected patients. Of the five published studies on

Box 1. Subcutaneous needle drainage protocol.

1. View and approve a full blood count taken within the past 2 weeks
2. Explain the procedure to the patient and give him/her the patient information sheet. Obtain a signed consent form
3. Identify the site(s) for drainage
4. If appropriate, wash hands and apply local anaesthesia (Emla Cream containing lignocaine and prilocaine or 1% lignocaine) to selected needle sites and apply Tegaderm over each site (this hastens effectiveness of the local anaesthesia but must be removed after 30 minutes and the skin cleansed with a BD Persist Plus swab). The use of local anaesthetic is optional
5. Wash or sanitise hands. Wear gloves for the procedure
6. Insert a 19G butterfly needle (bevel down) into the subcutaneous tissue and secure it with Tegaderm
7. If lymph is flowing, thread the butterfly needle tubing into the hole of a stoma bag and fold it in half to form a closed system
8. Place the bag flat and below the limbs to allow for gravity drainage. If the patient is mobile, it may be appropriate to strap the bag to a leg
9. Consider prescribing prophylactic antibiotics
10. Record patient drainage volumes an accumulative way three times a day

the use of needle drainage in end-of-life lymphoedema patients (Clein et al, 2004; Faily et al, 2007; Lam et al, 2009; Bar-Sela et al, 2010; Jacobsen et al, 2011), Beck et al (2012) concluded that there were no objective measures of outcomes and little had been reported on complication rates. Our study systematically quantified the improvements in function and appearance and collected information on adverse events.

Patients with lymphoedema experience pain, heaviness, bloating and a feeling of clumsiness (Frid et al, 2005; Clement et al, 2010; Elumelu-Kupoluyi et al, 2013). The condition also has an impact on social well-being, body image and mobility, potentially leading to distress, depression and anxiety (Passik et al, 1988; McWayne and Heiney, 2005; Fu et al, 2013). One qualitative study exploring the experiences and perceptions of cancer patients with lower-limb oedema in the late palliative stage found that it was the least severe consequence of a patient's illness. The participants reported that it was difficult to distinguish this aspect of their life from the whole picture (Frid et al, 2005). It is almost impossible to tease out any improvement in one aspect of life, such as lymphoedema, from health as a whole, particularly as deterioration is also occurring. This possibly explains why the patients in our study did not show a great improvement in their overall quality of life measure. It was also difficult to be certain that the reported positive effects were not attributable to the supportive hospice environment.

Jacobsen et al (2011) highlighted the lack of knowledge about infection rates with which to counsel patients about the risks of needle drainage. Cellulitis is potentially life-threatening in this population and was a significant adverse outcome for one patient in our study. Two other participants were diagnosed with infection, but this needs to be taken in context: skin changes happen as a consequence of the increased interstitial fluid causing pigment changes and lymphangitis; it can therefore be difficult to differentiate between this and true infection. Further research needs to be undertaken to develop and validate a tool to assess for cellulitis in individuals with lymphoedema. It is a recommendation from this study that everyone undergoing needle drainage is put on prophylactic antibiotics. Monitoring of renal function may also need to be incorporated into further studies.

This study had several potential weaknesses. Recruitment was not randomised and there was no control arm. It did not control for any demographic factors that may have influenced any of the domains or quality of life scores. There was a significant attrition rate as patients deteriorated or died, which impacted on the follow-up questionnaire completion rate. Overall there was a small sample size, although this study is the largest reported to date. The LYMQOL questionnaire used in this study was validated in chronic lymphoedema but not the palliative population. It asked a question about occupation that was usually irrelevant and could be removed in any subsequent studies. This may, however, change the validity of the questionnaire.

Our study has addressed some important questions regarding this procedure, including effects on quality of life and mobility. It has a number of strengths, including being undertaken at a single site with medical personnel experienced in carrying out the procedure in a standardised manner. The patients were also able to nominate their own mobility measure, making the outcomes individualised.

Conclusions

This is an effective procedure in an extremely vulnerable population of patients. It appears to improve function and appearance. Two changes to the protocol are recommended for ongoing research: the addition of prophylactic antibiotics and the development of a cellulitis grading tool. The drainage procedure may not have an impact on total quality of life, but may influence various aspects of the illness.

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Table 2. Lymphoedema quality of life questionnaire at baseline, immediately post procedure (time point 1), and 2 weeks later (time point 2).

Domains	Mean scores		
	Baseline	***Time point 1***	***Time point 2***
	n=16	n=12	n=9
Function	3.3	2.7*	2.6
Appearance	2.9	2.7*	2.4
Symptoms	2.5	2.1	2.2
Emotions	2.0	1.9	1.6
Quality of life (11 point scale)	4.0	4.3	4.4

*$p<0.05$