

Compression
systems for treating
venous leg ulcers
nursing essay



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The Evidence-Based Medicine (EBM) is defined as " the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of Evidence-Based Medicine means integrating individual clinical expertise with the best available external clinical evidence from systemic research . By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice ". (Sackett, 1996 cited in: <http://www.ex.ac.uk/stloyes/extract.htm>).

Other types of Evidence-Based Practices include the Evidence-Based Health Care, and Evidence -Based Nursing.

Evidence-Based Health Care is: " The conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. Current best evidence is up-to-date information from relevant , valid research about the effects of different forms of health care , the potential for harm from exposure to particular agents , the accuracy of diagnostic tests , and the predictive power of prognostic factors"(<http://www.ex.ac.uk/stloyes/extract.htm>).

The Evidence-Based Nursing (EBN) is defined as " the process by which the nurse makes clinical decision using the best available research evidence, their clinical expertise and patient preferences ". (Kathleen R. Steven, 1999).

History and importance of Evidence-Based Practice

The EBP began its life in health care as EBM. This was based on the concept of shifting health care away from basing decisions on opinion and past

practices. The earliest documented example of EBP was the development of aseptic technique in the nineteenth century, following observations of cross infection. These issues made the doctors review their performance and ask questions regarding their application of the measures that should prevent spread of infection. Since then, it became clear that no aspects of nursing practice for health, whether in the community, home or hospital, should be “safe” from the concept of Evidence-Based Practice.

The importance of considering the EBP in the scientific field now became clear. Things are changing very fast in this era and the continuous studies and researches lead to new results which should change some of the old practices. Getting the right evidence and applying it into practice would definitely help improving people’s experiences of illness and health care and thus, a good nursing practice will be established and patients will get better care services.

The Evidence-Based Practice is about incorporating research use, professional judgment and knowledge together with individual patient characteristics and preferences in formulating clinical decisions (Dubouloz et al, 1999). It is, accordingly, about the interaction between the clinician and the client. Although it is expected that clinical practice will be based upon the systemic application of rigorous scientific methods to the evaluation of the effectiveness of health care interventions (Booth, 1996).

In this research, we tried to find out whether compressions applied to venous ulcers were truly effective or not.

During the whole period of our working experience we came across lots of situations in which patients will develop a type of leg venous ulcer (open ulcers : like the heel bed sores in elderly patients , or internal , closed ones such as varicose veins , phlebitis and DVT) . In all of these cases, we used to advice our patients to apply a compression bandage or a stocking over the site of the ulcer believing it is useful. But as we noticed in the hospital setting , our elderly patients did not really have their heel bed sores healed with the use of these compressions although we applied them to the sore sites for a prolonged period of time .

This made us ask our question: Whether these compression bandages are really beneficial or only we practice applying them due to routines and habits?! .

Is there any clinical, recent evidence that proves this practice is based on? science?? .

We asked the question and went on searching.

Formulation of question

The issue or problem

“ Venous leg ulcer is an open sore in the skin of the lower leg due to high blood pressure in the leg veins”(www. bad. org. uk) .

Epidemiology: Large-scale studies in both of UK and Europe suggest that 1-2 % of the population develops a leg ulcer . The problem increases and reaches up to 4-5 % in older people (Tonbridge, 2004. pg. 610).

The underlying cause of the venous ulcer is a venous hypertension which results from where the leg calf muscle fails to pump the blood to the heart due to incompetent valve in the deep, perforating or superficial vein.

Leg ulcer can reduce the patient's quality of life. Patients with venous leg ulcers will experience high level of anxiety, depression and pain. In addition, their performance of activity of daily living will be highly affected. In a study about the socio-economic aspect of chronic leg ulceration found that this condition interferes with work and leisure activities to a moderate or a severe degree.

The venous ulcers require external compression bandages to apply controlled pressure to the leg venous system. This will improve venous return and enhance the leg blood circulation and healing.

Clear question:

Do applications of compression bandages fasten the healing rates of venous leg ulcers in patients suffering from venous leg ulcers?

Population: Patients suffering from venous leg ulcers.

Intervention: Application compression bandages.

Comparison: Compared with no application of compression bandages.

Out come: Fasten the healing rates of venous leg ulcers.

Importance of formulating question:

We formulated this question to direct our search and to get a scientific answer that could possibly prove, or disprove our practice. Also, to have an opportunity to search for scientifically based evidence regarding the effectiveness of using compression bandages for the patients suffering from venous leg ulcers. We are going to discuss the search findings with the ward supervisor and other nurses to apply the search result findings on the patients. This will aid in better healing for their venous leg ulcers in order to minimize patients' sufferings and save the budget which is spent in treating venous leg ulcer, and which is considered of a relatively high amount.

Searching the literature:

Searching strategies:

We have used different resources to get the related researches regarding our formulated question.

First, we started searching in Cochrane Database.

Second, we searched in Proquest Database.

Third, we searched in Pub-Med Database.

Fourth, we searched through e-journal.

Fifth, we searched in Google.

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Sixth, hand journals search.

Key words used in searching strategies;

Venous leg ulcer and compression and healing

Venous leg ulcer and compression

Venous leg ulcer and bandage or bandages

Venous leg sore and compression and healing

Venous leg sore and bandage and healing

Venous leg sore and healing

Venous leg sore or venous leg ulcer and compression

Venous leg ulcer

From all the researches we have found, we came across lots of new information with important details, statistically and clinically. For example, we knew that the heel bed sores is the 2nd fast developing in the immobile patients who would - usually - be incontinent and have dry skin and difficulty in turning in bed. We also found an abstract stating that 41% of geriatrics' bed sores are the ones of heel. This significant percentage (research done in July 2004) lead us to further searching, especially that we know much is the development of sore is costly to treat and most important, reduces the quality of life of elderly patients.

As for the clinical details and results, we came across researches with variable statements and conclusions. And also, with completely opposite outcomes. But all of them, of course, agreed on the scientific facts about venous ulcers (the 2 types of it). Some of the researches discussed the type and manufacturer of the bandages used. Others discussed the layers of compression applied and others merely discussed the fact of the compression being of a good benefit or only a “harmless” one!.

However, a better research in this issue is believed to discuss all other circumstances that could be playing a role in the healing of the ulcer other than the applied compression. For example: patient's general health and nutritional status, patient's age and the size and number of bed sores a patient is having additional to the degree of the sore. All of these factors were important to include in a research done about such highly, interrelated issue. Although, many researches didn't give it the deserved attention.

Other facts about the venous ulcers and which stimulated us more to investigate about it is the fact that in 45 to 60 % of cases the ulcerations of the lower extremities would be a form of a venous origin (approx. 1% of adult population , including the orderly's " open sores ") . In addition, we have found that compression was the most widely used treatment for venous leg ulcers and it is being used for over than 300 years now although the mode of its action is not yet clearly understood. It's some how assumed that that application of external pressure reduces the superficial venous pressure and thus , improves venous return leading to a reduction in superficial venous hypertension and edema which , in turn , allow healing of ulcers to take place .

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Due to the variable outcomes and considerations in each research we have found, we excluded some of them:

Literature: 3 Layer Paste Bandages Were More Effective than 4 Layer Bandages for Healing Venous leg Ulcer: Excluded because it discusses the force of pressure used rather than the principle of compression being useful or not.

Literature: Is Compression Bandaging Accurate? The Routine Use Of Interface Pressure Measurements In Compression Bandaging Of Venous Leg Ulcers : This is also excluded because it is mainly discussing a type of low cost , portable and battery - powered pressure monitor which is invented to be placed under the pressure bandage .

Literature: Dressing For Healing Venous Leg Ulcers: This also discussed and compared types of dressings applied beneath the compression (not the compression itself) so, it was excluded.

Critical Appraisal 1:

The researches we finally agreed to study are attached behind as references, and discussed in details in the following tables:

Research 1:

Efficacy and Tolerability of an Ulcer Compression Stocking for Therapy of Chronic Venous Ulcer compared with a Below-Knee Compression Bandage published in October 2004.

Author / Researcher

M. Junger, U Wollina, R Kohnen, E Rabe.

Objectives

To investigate possibility of improving healing rates in ulcers cruris venosum by using an ulcer compression stocking (U stocking) as compared to compression bandages. The general concept aimed at showing non-inferior efficacy of U-stocking compared with bandages (the standard therapy in this condition).

Study Design

Prospective, multicenter, open labeled, randomized, active controlled study with blinded assessment of primary endpoint.

Outcome Measures / Instruments

Therapy with the U stocking produced a significant higher rate of complete healing of venous ulcers.

Result / Findings

Complete healing rate reveals U-stocking use is helpful.

Conclusion

The U-stocking was superior to bandages in compression therapy for venous ulcer. It is also of significance in regard with the long term therapy, as well as the prevention of recurrence of the ulcer.

Strengths

Study done in 2000-2002 , variables considered , tolerability evaluated , dropped out patients were followed , time of healing considered and analyzed as well as the degree of ulcer healing (assessed by planimetry)

Limitations

Some patients dropped out of the study for other reasons than complete healing so final sample size was about to be prematurely terminated. (Recalculation of the size saved it). Other factors which influence healing rate were not considered.

Comments

This result might not be that accurate as a compression therapy was being applied to patients prior to the study implemented.

Research 2:

A Systemic Review of Compression Treatment for Venous Leg Ulcers published in September 1997.

Author

Alison Fletcher, Nicky Cullum, Trevor A Sheldon.

Objectives

To estimate the clinical & cost effectiveness of compression system for treating venous leg ulcers.

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Study Design

Systemic review of research.

Outcome Measures

Rate of healing \propto portion of ulcers healed with in a time period.

Results / Findings

24 randomized controlled trials were included in the review. 5 discussed in details and all of them agreed that compression systems enhance the healing of venous leg ulcers.

Conclusion

Compression system improves the healing of venous leg ulcers & should be used routinely in uncomplicated venous ulcers. Insufficient reliable evidence exists to indicate which system is the most effective.

Strengths

The quantity of the studies evaluated in this systemic review gives results some weight and reliability. Also the selection of the studies with no restrictions regarding the date of their publications or the language enhances the reliability on the results reported.

Limitations

The research evidence was quite weak: Many trials had inadequate sample size \geq generally, poor methodology. The same system applied by different staff

under different circumstances may result in the attainment of widely differing pressures, making interpretation difficult.

Comments

The quality research in this area is generally poor: Trials are often too small, follow up is short, recurrence of ulcers is rarely considered, & sometimes multiple ulcers are incorrectly regarded as independent ulcers. Several papers do not report the method of bandage application, the experience of staff, and other aspects of bandaging, & patient's mobility, which all affect healing. The same system applied by different staff under different circumstances may result in the attainment of widely differing pressures; making interpretation difficult. This issue rarely comes into the minds of researchers.

Research 3:

A Systemic Review of Compression Therapy for Venous Leg Ulcers published in 1998.

Author

Simon . J Palfreyman , Rona Lochiel & Jonathan A Michaels.

Objectives

To determine the relative effectiveness of compression therapies used in the treatment of venous leg ulcers.

Study Design

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Systemic review of randomized controlled trials (RCT).

Outcome Measures

Quality of trials was determined using proforma based on CONSORT statement and Cochrane collaboration checklists.

Result / Findings

Results vary in each study according to the compared compressions. Most studies take for granted that compression is effective in healing venous leg ulcers and base their studies on this information.

Conclusion

More high - quality trials are required & more emphasis should be placed on economic & quality of life data to try to ascertain the cost- effectiveness & utility of the treatment options available.

Strengths

Gives very specific & detailed prescriptions about the chosen samples & the way of randomizing & blinding them. Time and year of the included studies were not restricted. Also no restrictions on the country of origin of the trials.

Included very detailed literatures and pays attention to every small detail which is very necessary for judgment of the quality of the researches.

Limitations

Search was limited to English language articles or articles that provided sufficient details in English . Quality of the studies were very mixed with majority of trials being of relatively short duration & small sample size.

Omission of a specific description of the method of randomization or blinding made the research's reality doubtful (They only stated that the participants were randomized but not offered convincing details about " how " did they randomize them!).

Short durations (between 4 weeks & 18 months) is questionable as it is not a sufficient long enough period to detect the number of ulcers healed , nor it could prospect or determine the recurrence rates for any of the interventions

A study that evaluated compression versus non-compression was found but it had the same (methodological) problem. In addition, the generalizability of it to UK is also questionable, since the use of the mentioned type of bandage there (in UK) is limited!

Comments

Compression therapy is widely used in the treatment of venous leg ulcers but this is not necessarily based on the amount of evidence available to justify the practice.

There's a clear need for larger, high quality trials to confirm the benefits of compression therapy.

Research 4:

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Higher Compression Elastic Bandages show no Significant Advantage in the treatment of Venous Leg Ulcers published in 2002.

Author

Anonymous

Objectives

To compare time to total healing using two compression bandage regimens.

Study Design

Randomized trial.

Outcome Measures

Complete healing of ulcers

Result / Findings

There was no statistically significant difference between the healing times of the two groups with different types of bandages (elastic and inelastic bandages). Healing was significantly slower for large ulcers than it is for the small ulcers.

Conclusion

There's no appreciable benefit in adding higher compression to speed ulcer healing.

Strengths

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Exactly describes the way bandages were applied in order to prevent variations & inaccuracy of the results.

Limitations

Some patients were excluded & some withdrawn but fortunately, number of patients from the 2 groups was equivalent and so, results were unaffected.

Comments

Critical Appraisal 2:

Research 1:

Efficacy and Tolerability of an Ulcer Compression Stocking for Therapy of Chronic Venous Ulcer, Compared with a Below-Knee Bandage

Study design:

Prospective, multicenter, open labeled, randomized, active controlled study with blinded assessment of primary endpoint.

Population / sample:

Patients with chronic venous ulcers in the leg (121 patients)

Inclusion / exclusion criteria:

134 patients with venous ulcers were first chosen, patients with infected ulcers or obesity were excluded later on.

Finally, 121 patients were eligible.

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Time frame of study:

From October 2000 to October 2002

Time frame of interventions:

Applying U-Stocking for 12 weeks for at least 8 hours daily

Outcomes measures / interventions:

U-Stocking or bandages applied for at least 8 hours per day and up to 12 weeks. Primary endpoint was healing rate after 12 weeks assessed by planimetric measures. Secondary outcome variables were: Time to healing, changes in ulcer size (planimetry), experience of use and patient's compliance.

Data collection:

Not mentioned

Data analysis:

General concept aimed at showing non-inferior efficacy of U-Stocking compared to bandages (the standard therapy). Primary desired outcome is complete ulcer healing after 12 weeks.

(The non-inferiority margin was set as 15% of the healing rate).

Secondary target variables:

Comparison of time to complete healing: analyzed with long-rank test.

Planimetry: defined degree of ulcer healing presenting it as a percentage remission of ulcer surface and evaluated with Mann-Whitney U-tests.

Experience of use (in part of patient).

Satisfaction of nursing staff.

Patient's compliance.

Time needed to apply the U-stocking or compression bandage.

Comparisons performed with the two sample tests and interpreted in an exploratory manner.

Results / findings:

Primary endpoint analysis: Complete ulcer healing which reveals that U-Stocking is more significant and superior to bandages with healing rate of 47.5% opposed to 31.7%.

Limitations:

Other factors which have an impact on patients' healing rates (e. g.: high protein diet) were not considered. Also long pre-treatment period (usage of compression therapy for prolonged period before the study) was not given any attention.

Conclusion of study:

U-Stocking might be effective. But the former compression therapy is still considered the best therapy. This study result is not totally the effect of the

U-Stocking since the previous use of the compression therapy by the patients might have interfered with it.

Our comments:

We think this study has covered lots of important details and considered other factors which are not - in most of the times - put in to attention while researching about the ulcers' healing . However, it is mainly focusing on a one type of pressure appliance (and that is the U-Stocking) and assuming from the beginning that the compression therapy is - for granted - useful. It eventually and clearly says that “ some evidence can be found in the literature of the efficacy of compression bandages in venous leg ulcers ” but they only wanted to prove the effectiveness of the U-Stocking in comparison with it.

Research 2:

A Systemic Review of Compression Treatment for Venous Leg Ulcers

This study done by the researcher Alison Fletcher and his group (we came across their names quite a lot in our searching for this issue) , done to estimate the clinical and cost effectiveness of compression system for treating leg ulcers .

Study design:

Systemic review of research.

Population:

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Varies in each involved study.

Sample:

24 randomized controlled trials included. Researchers admit that the researches' evidence was weak due to the inadequate sample size and the poor methodology.

Inclusion / exclusion criteria:

Not mentioned

(Systemic reviews do not conduct studies but only analyze the found literatures and assess the related studies to a chosen issue).

Time frame of the study:

Used publications that are published at any time with out restrictions.

Time frame of treatment:

Not applicable.

Interventions:

Comparisons of previous researches in the same issue with involvement of different and specific details.

Data collection:

Structured guidelines were used: electronic search of 19 specialist databases including Medline, CINAHL, and EMBASE. Hand searching also used scrutiny

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of citation and contact with relevant manufacturers and original authors.

Data collected with no restrictions on publications status, dates (as previously mentioned) or languages.

Data analysis:

24 relevant randomized controlled trials were identified. Five were discussed and they are:

Compression Versus No Compression :

3 trials: 2 showed higher proportion of healed ulcers when compression used, the remaining one showed a non-significant healing rate with “ Unna’s Boot “ specifically.

Another 3 studies compared different forms of compression (short stretch, 2 layer and 4 layer bandages) with treatments using no compression and this, showed that healing improved with compression.

Elastic Multilayer Higher Compression Bandages Versus Inelastic Compression :

This study showed an overall significant increase in healing with the use of the higher compression bandages.

Comparisons between different medium and high compression systems: This reported no significant difference in outcomes of both compared types.

Compression Hosiery Versus Compression Bandages :

This study reported complete healing of those patients whose ulcers were treated with short stretch bandages in a period of 3 months.

Intermittent Pneumatic Compression Treatment :

This is a small study, reported the benefit of adding an intermittent pneumatic compression to the compression stockings from time to time. It, also, reveals an increase in healing rates with the help of this intermittently added compression.

Results / findings:

Results of all the reviewed literatures almost agreed that healing rate of venous leg ulcers is enhanced by the usage of bandages and thus, suggest possible better results with higher layers compressions. However, the different types of compression systems themselves when compared together in a trial (for example: multilayer and short stretch bandages, Unn's Boot, etc ...) show no difference in effectiveness.

Intermittent pneumatic compression, in contrast, seemed to report a significant benefit when added, from time to time, to these compression systems.

Conclusion of studies:

The review concluded that compression systems improve the healing of venous leg ulcers and recommended the use of of them routinely, as long as arterial diseases are proved to be absent.

Limitations:

The review admitted the poor methodology of the involved studies. Their small sample sizes and the short term of follow up. Also, the recurrence of the ulcers was not considered and some patients with multiple ulcers were incorrectly regarded as independent ulcers and this was misleading the results.

Other limitations already shown in the table, in this research's first critical appraisal.

Our comments:

According to us , we found it's a bit difficult to agree with all of this since the review which is based on poor and weak studies make us wonder how strong would be the evidences they provided us with , and if they were only an advertisal studies that markets for specific manufacturers !!? .

Also , we thought that if the principle of application of pressure is , basically , the concept , then the increase in pressure should , definitely , be of significance in treatment , and that is what the included studies had varied to state it ! .

Research 3:

A Systemic review of Compression Therapy for Venous Leg Ulcers

Study design:

A systemic review of randomized controlled trials (RCT).

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Population / sample:

Each included study varies.

Inclusion / exclusion criteria:

Suitability to be included in this systemic review was decided upon a critical appraisal of key determinants of the quality of the trials.

Trials that included patients with mixed ulcer etiologies were excluded.

Time frame of study:

Included studies were not restricted regarding the date and year.

Time frame of intervention:

Not applicable.

Interventions:

After excluding the other studies, remaining trials which had met the inclusion criteria underwent a critical appraisal (a performa based on CONSORT statement and Cochrane collaboration checklists). This determined the quality of the trials and graded them by assessing: method of randomization and blinding, analysis of results, completeness of follow up, blinding and objectivity of outcomes, appropriateness of statistical analysis of the results.

Other researches with less than 50 participants were included after specifically considering these outcomes : complete ulcer healing (which is

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considered as a definite , measurable endpoint) , time to complete ulcer healing , recurrence rates with in 12 months , complications and morbidity , compliance with treatment , patient's satisfaction and quality of life , economic analysis .

Data collection:

Eight electronic database were searched (including Medline, Embase and CINHAL), conference proceedings and hand searching key journals, citations within papers.

Extracted data were synthesized quantitatively and qualitatively.

Data analysis:

Some excellent trials (8 of them) were regarded as high-quality trials at the time of data extraction but while reviewing, unfortunately, were found to lack a very important detail regarding the blinding of outcome assessment and methods of randomization. Similarly, other trials had no possibility of pooling the results for the meta-analysis and so, these, and the former mentioned trials, all were excluded giving a chance for only 4 studies. Analysis was carried out using DerSimonian and Laird random effects methods.

Researches analyzed and their outcomes are mentioned in the following point.

Results / findings:

Research 1: Unna's Boot versus Other Therapies

Analysis showed no statistically significant differences between Unna's Boot compared with other therapies.

Research 2: Pneumatic Compression:

More patients healed in treatment with pneumatic compression. But result is not

that accurate since the sample size was insufficient to make judgment.

Research 3: Compression versus No Compression:

Only 1 trial found where compression was compared with no compression at all.

With in this trial there was no clear benefit statistically detected! .

Research 4: Multilayer versus Single layer Compression Bandages:

This is only one study and it showed that multilayer compression bandages were

Associated with a greater number of ulcers healed than single layer bandages.

Research 5: Elastic versus Non-Elastic Bandages:

A trial showed that odds of healing were greater with elastic bandages when compared with non-elastic bandages.

Conclusion of the studies:

Compression therapy seems to be used widely in the treatment of venous leg ulcers not because of the strong evidences available in its regard, but, because of its prolonged period of practice that made it as a “ routine ” work! (Used since more than 300 years).

Limitations:

Quality of the study was very mixed. Majority of the trials were of relatively short durations (4 weeks - 18 months) and small sample size. Other, high-graded researches were excluded just because they missed a small and a very important detail (method of randomization and blinding of allocation and assessment).

Only 2 studies gave the exact method of randomization and the rest just “ stated” that their participants were “ randomized”!

Only 1 study evaluated compression versus no compression, but it had a methodological problem as the unit of randomization was the ulcer, not the patient. Besides, generalizability of study to U. K made the study questionable as the compression of Unna’s Boot (used in the study) is not widely used in that country.

Another point of limitation is that some studies stated a complete healing of ulcers with in only 4 - 6 weeks which is unbelievable as such a period is no