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Clinical Innovation Accelerator – Health Economic Insight Report

Intermittent Pneumatic Compression (IPC) therapy on the thigh of an ulcerated limb to promote lower leg wound healing in patients.

1. What is a clinical innovation health economic Insights Report?

The Clinical Innovation Accelerator's (CIA) health economic Insight reports are economic reviews of clinical innovations, which are available to all stakeholders: Welsh enterprises, Health Boards, GP Clusters, Welsh Government, Third Sector, etc.

The reports are written in a similar style to articles in the Economist Magazine for readers who may not have any training in economics, but who are interested in an economics perspective. They are part of a series of CIA health economics reports.

The topic of intermittent pneumatic compression (IPC) therapy for wound healing was suggested by Dr Jane Davies, Clinical Support Manager at Huntleigh Healthcare Ltd and Dr Ceri Morris, CIA senior innovation fellow.

Note: Cyflymu Accelerate was established in 2018 with funds from Welsh Government and the European Regional Development Fund to support clinical innovation in Wales.

2. What is an Intermittent pneumatic compression (IPC) device?

Intermittent pneumatic compression (IPC) therapy has been described and reviewed in numerous clinical studies ⁽¹⁾. However, for the reader who is not familiar with IPC devices, they produce an inflating and deflating movement that supports the circulation of blood in patients' bodies. The devices are used to support patients' recovery for several conditions, such as deep vein thrombosis and leg ulcers (open sores). The therapy is used in conjunction with standard treatments and the devices can be worn when patients are resting in bed or sitting in a chair.

3. How is IPC therapy used for lower limb ulcers?

IPC therapy for lower limb ulcers can be used in conjunction with standard treatments, such as compression bandages or hosiery (stockings) to promote wound healing for patients at home. A Cochrane Review in 2014 reported that there was some limited evidence that IPC may improve healing when added to compression bandages ⁽²⁾. Although, the location of an IPC device close to the ulcerated area often causes pain to patients and so few choose to use it.

However, in 2019 and 2020 two small studies reported improved clinical effectiveness from applying an IPC device to the thigh of an ulcerated limb, instead of the wound site (3) (4). These studies indicated the potential benefits of locating an IPC device near to (proximal to) lower limb ulcers. A major benefit of proximal IPC devices is that patients report that they do not cause them pain and are comfortable to fit and operate.

Earlier this year in February 2021, 'Wounds UK' published a consensus document from a group of experienced UK clinicians on the benefits of using IPC as a means of improving lower leg wound management, with specific emphasis upon the use of proximal IPC applied solely to the thigh with no direct contact with lower leg wounds or their surrounding skin (5). Whilst the group reviewed a number of studies on IPC it made clear that their discussion was not intended to reflect a systematic review of IPC.

Note: the clinicians considered an IPC device that has been developed specifically to provide proximal IPC therapy. For more information see the WoundExpress website (6).

As matters stand, there are several indications that proximal IPC therapy could offer the potential for improved clinical effectiveness in treating lower limb ulcers. The main outcome would be shorter treatment duration, or put another way, a faster time to recovery for patients. What is required is conclusive evidence from a large clinical trial.

In March 2021 an international, multi-site, large randomised controlled trial (RCT) of using proximal IPC in conjunction with standard treatment started. It will use the WoundExpress device. The study findings should be published in 2022.

Disclaimer: the clinical innovation accelerator (CIA) is providing support to the Welsh arm of the RCT via a Welsh Life Sciences enterprise, Huntleigh Healthcare Ltd.

4. What is the prevalence of lower limb ulcers?

Lower limb ulcers mainly occur in older people and are often associated with diseases that affect a patient's circulatory system, and chronic diseases, such as diabetes.

National data on the prevalence of lower limb ulcers is not routinely collected across the UK or Germany or Sweden. However, estimates of prevalence can be derived from the findings of academic studies.

Gray et al (2018) surveyed eight community services in five Northern England NHS Trusts (sample size = 3179) (7). They reported the community prevalence per 10,000 patients to be:

- Venous leg ulcers: 612 (6.1%)
- Diabetic foot ulcers: 488 (4.9%)
- Pressure ulcers: 348 (3.5%).

5. What are the key issues in the demand and supply of treatments?

National data sets on the demand from people seeking treatment of lower limb ulcers are also not routinely collected across the NHS in the UK, or Germany or Sweden. However, since prevalence and the demand for treatment are associated with demographics and chronic diseases, it is likely that demand is increasing due to aging populations and more people having chronic diseases, such as diabetes.

National data sets on the provision of treatment for lower limb ulcers are available indirectly through workforce statistics for community nurses, who provide most of the care and treatment in the UK, Germany and Sweden.

A report on UK district nursing by the Queen's Nursing Institute and Royal College of Nursing (RCN) in 2019 identified that the district nursing workforce is getting smaller and not enough nurses are being recruited to replace those who leave district nursing or retire (8). Note: data from Germany and Sweden has yet to be identified.

From an economic perspective, the main issue is that demand for treatment is increasing at the same time as the supply of district nurses who provide treatments is getting smaller. In practice, patients with lower limb ulcers who require urgent treatment will still receive it. However, this prioritisation means that patients with less urgent needs will experience difficulties accessing nursing services.

In economic terms, the widening gap between the supply and demand for treatment for lower limb ulcers is most likely producing a growing "spill over effect" on patients who need to access district nursing services with other health needs.

6. What are the health economic insights?

First, a key assumption in health economics is that healthcare resources (clinician time, etc.) are relatively scarce when compared to all the needs of patients. Often there are not enough resources to do everything you want to do. As a result, choices must be made about how to use efficiently the resources that are available.

When health economists talk about efficiency, they mean maximising the overall benefits and health gains for patients from available healthcare resources. Economists further split this concept into:

- Allocative efficiency, which can be defined as achieving the optimal use of healthcare resources (healthcare budgets, clinician time, etc.) when there are alternative ways it could be used for the benefit of patients; and
- Technical efficiency, which can be defined as achieving an objective/health gain for the least resource cost (therapeutic interventions, clinician time, etc.).

Second, when economists talk about costs, they mean ‘Opportunity costs’, and not financial costs. An opportunity cost is the value of the next best use of a resource.

This is an important distinction. This report makes no attempt to estimate the monetary cost impact for health care systems in the UK, Germany and Sweden. Instead, it explains how proximal IPC therapy for lower limb ulcers could potentially improve the economic efficiency with which patients are managed by community nursing services.

For example, should proximal IPC therapy result in faster recovery and fewer appointments with nurses to change and dress wounds, then this change would not save the average financial cost of these appointments. Instead, it would allow the appointments and nurses’ time and expertise to be made available for other patients.

The full cost-effectiveness / cost-utility analysis at the end of the clinical trial will compare the costs and patient health outcomes of a standard treatment for lower limb ulcers with or without proximal IPC therapy. However, a key factor for healthcare budget holders will also be the trade-off between the nursing resource costs saved (avoided) due to fewer nurse appointments being required versus the price/cost of the IPC device which produces faster recovery times.

From a health economics perspective, NHS, Swedish and German healthcare funding bodies would be offered the option of paying more to get faster clinical outcomes and to free up their scarce nursing resources to do other things (treat other patients, etc.).

Note: data estimates on both the impact on nursing resources and the opportunity costs of other patients being able to access treatment from the freed-up nursing resources will be determined and included in the forthcoming CIA health economic rationale.

7. How could proximal IPC therapy lead to greater economic efficiency?

First, should proximal IPC therapy for lower limb ulcers be shown to be cost-effective, then patients could be treated at less cost compared to the standard treatment. In economic terms, it would demonstrate that the proximal IPC technique is more economically cost-efficient than the standard treatment. [Technical Efficiency.]

Second, should it be shown to produce faster health outcomes and be cost-effective, then any saved/avoided nurse appointments could be made available to treat other patients. In economic terms, it would demonstrate that the proximal IPC technique can free-up nurses to treat more patients. [Allocative efficiency.]

Third, improved patient health outcomes could be assessed using quality adjusted life years (QALYs). A cost-utility analysis could then determine whether the cost per QALY of proximal IPC is lower than standard treatments. [Technical efficiency.]

Fourth, the combined effects of improved allocative and technical efficiency would demonstrate improved economic value overall and enable healthcare organisations in the UK, Germany and Sweden to demonstrate increased value for their stakeholders. This might be viewed as an example of ‘value for money’ or ‘value-based healthcare’.

8. What about patient health outcomes?

Patient health outcomes will be assessed using QALY measures as part of the cost-utility analysis at the end of the clinical trial. In addition, patient reported experience measures (PREMs) will be used to assess patient feedback on treatment with or without proximal IPC therapy.

9. Conclusion.

There is growing clinical interests in the use of proximal IPC therapy in treating lower limb ulcers. Many clinicians, academics and health policy makers are taking an interest in the large international clinical trial that has started and whose findings should be published later in 2022.

In closing, should the clinical trial demonstrate that proximal IPC therapy using WoundExpress is both clinically effective and cost-effective, then this technique and device could produce major benefits for patients with lower limb ulcers and for the nurses and clinicians who treat them.

END

References:

1. Science Direct: Topics: Intermittent Pneumatic Compression: An Overview.
Retrieved on 14 May 2021.
<https://www.sciencedirect.com/topics/nursing-and-health-professions/intermittent-pneumatic-compression-device>
2. Nelson E, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Review: 12 May 2014. Retrieved on 14 May 2021.
<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001899.pub4/full>

3. Naik G, Ivins, NM, Harding KG. A prospective pilot study of thigh-administered intermittent pneumatic compression in the management of hard-to-heal lower limb venous and mixed aetiology ulcers. *International Wound Journal*. 2019 Aug; 16(4): 940-945. Retrieved on 14 May 2021.
<https://onlinelibrary.wiley.com/doi/epdf/10.1111/iwj.13125>
4. Morris RJ, Ridgway BS, Woodcock JP. The use of intermittent pneumatic compression of the thigh to affect arterial and venous blood flow proximal to a chronic wound site. *International Wound Journal*. 2020 Oct;17(5):1483-1489. Retrieved on 14 May 2021.
<https://www.onlinelibrary.wiley.com/doi/epdf/10.1111/iwj.13418>
5. Young T, Chadwick P, Fletcher J, King B, Schofield A, Staines K, Vowden K, Clark M. The benefits of intermittent pneumatic Compression and how to use WoundExpress in practice. *Wounds UK*. 18 February 2021. Retrieved on 14 May 2021.
<https://www.wounds-uk.com/resources/details/the-benefits-of-intermittent-pneumatic-compression-and-how-to-use-woundexpress-in-practice>
6. WoundExpress website.
<https://www.woundexpress.com/static/what-is-wound-express-patient>
7. Gray T A, Rhodes S, Atkinson RA et al (2018) Opportunities for better value wound care: a multiservice, cross- sectional survey of complex wounds and their care in a UK community population. *BMJ Open* (2018); 8: e01440
<https://bmjopen.bmj.com/content/bmjopen/8/3/e019440.full.pdf>
8. Queen's Nursing Institute, Royal College of Nursing. Outstanding Models of District Nursing Report: A joint project by the Queen's Nursing Institute and the Royal College of Nursing. (2019)
<https://www.qni.org.uk/resources/outstanding-models-of-district-nursing-report/>

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