Review of Negative Pressure Therapy as a Treatment for Diabetic Foot Ulcer

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Abstract
This article focusses on a synopsis review of four articles, which explore negative pressure wound therapy (NPWT) as a treatment option for diabetic foot ulcers. Patients presenting with diabetic foot ulcers are increasing which has a significant financial impact NHS, there is evidence that NPWT is a cost effective treatment. All four articles use a quantitative methodology. This article will critically analyse the methodology, design, sampling, data collection and data analysis that the researchers have chosen to utilise. NPWT has been proven to be an effective treatment option for diabetic foot ulcers however, the evidence is limited in regard to the patient perspective of this treatment.

Keywords
Diabetes, Foot Ulcer, Wound Care, Nurse,

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Introduction

Negative pressure wound therapy (NPWT) has been selected, for this article, as it is a treatment option for diabetic foot ulcers. NPWT occurs when sub-atmospheric pressure is delivered via a dressing of either gauze or foam, which is placed over the wound, sealed and attached to a suction pump, and this provides the negative pressure (Chadwick, 2009). NPWT is an effective treatment, by increasing blood flow and stimulating angiogenesis, granulation of tissue and cell proliferation can occur, while reducing perilesional oedema by the removal of infected fluid and exudate (Meloni et al, 2015). I have decided to research this topic, as I am aware that there are increasing rates of diabetes. Alongside this there are increasing numbers of patients presenting with a diabetic foot ulcer, within a specialist wound unit. I have also chosen this topic, since attending placements as it has increased my knowledge in wound care management, and have used international articles to broaden my knowledge on this topic.

The World Health Organisation (WHO, 2016) estimate in 2014, 422 million adults globally were living with diabetes. WHO (2016) goes on to state the global prevalence of diabetes has doubled since 1980, with as many as 8.5% of the adult population living with diabetes. Diabetes is a condition whereby the body cannot maintain normal blood levels due to either a deficiency of insulin secretion, or a resistance to insulin, and inadequate insulin secretion to make up for the resistance (Masharani, 2015, cited in Papadakis, McPhee and Rabow, 2015).

The most common complication of diabetes is the development of diabetic foot ulcers, specifically, around 10-20% of people with diabetes will have a diabetic foot ulcer at some point in their life (Jan et al., 2016). The financial impact on the NHS in 2012 was estimated to be £650 million due to; increased bed occupancy, prolonged stays in hospital, community care and increased outpatient appointments (National Institute for Health and Care Excellence (NICE, 2016).

There is evidence to suggest NPWT is a more cost effective therapy than others used to treat wounds, for example wet-to-moist therapy (Lavery et al., 2007). They state in their study NPWT cost 42% less than wet-to-moist therapy over a period of 20 weeks.

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Whitehead et al., (2011) agrees, explaining NPWT reduced the cost of care, when compared to advance wound care (€24,881 versus €28,855 respectively) per patient per year. They also found NPWT gave patients a higher quality of life, and also healing rates were greatly improved. This demonstrates the cost benefits of NPWT in terms of resources and patient outcomes, and this is the rationale for this subject choice for this article. This article will compare four research studies that investigate NPWT, in particular reviewing the methodologies used, sampling strategies, data collection and data analysis. The findings will then be discussed in relation to current theories regarding the use of NPWT.

Synopsis

'Discover' was used, to search for the most up to date academic articles on the chosen subject for this article. The rationale is that it contains wide range of resources on clinical subjects. The articles were narrowed down from 16,503 to 40, as the search was further restricted to articles published between 2005 and 2016.

Fife et al., (2008), conducted a study that evaluated the safety of NPWT, specifically by using vacuum assisted closure (V.A.C), in an outpatient setting, with patients that had diabetic foot ulcers. This study was undertaken as there was some evidence suggesting this type of wound therapy can have adverse effects, such as bleeding, pain and infection. A comparison was made between the adverse effects of wound care using V.A.C and non V.A.C. machine, and a quantitative methodology was used in this study. According to Polit and Beck (2012) this methodology is concerned with a positivism paradigm assumption that believes reality exist, and the value of enquiry is based on numbers. Using quantitative methodology is common in research that relates to clinical interventions, as it allows for objective numerical data to be gathered and measured (Addo and Eboh, 2014). A quantitative methodology was also adopted in the Seidel et al., (2014) study, which investigated NPWT, compared to standardised wound care in patients with chronic diabetic foot wounds. This study was undertaken because of the limited evidence of the efficacy of NPWT, which is necessary for robust clinical decision making on which type of wound therapy to use.

Stansby et al., (2010), evaluated diabetic foot ulcers in post amputation wounds and

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Blume et al., (2008) compared NPWT and moist wound therapy for diabetic foot ulcers. Both studies used a quantitative method, thus the independent variable of NPWT could be measured against the outcome (Ellis, 2010). There was a lack of research/ articles that reviewed the subject of NPWT using a qualitative analysis. A qualitative analysis is a method that collects narrative data through the interpretation of a phenomenon derived from feedback or observation (Lindsay, 2007). The reason there may be a lack of qualitative methodologies used in this type of research, to evaluate medical procedures such as NPWT, may be because it can be subjective, where its focus is on personal experiences (Polit and Beck 2012). Thus, when testing out medical interventions such as NPWT, using objective numerical data appears to be the most efficient methodology.

Blume et al., (2008), used a randomised trial in their study, whereby patients with diabetic foot ulcers were randomly assigned to a NPWT group, or to an advanced moist wound therapy group. Using a randomised controlled trial is a common method in clinical research, as highlighted by Coughlan, Cronin and Ryan (2013). They define randomised controlled trials as an experiment that has the intention to test out a particular intervention, and are usually used to trial a new medication or clinical procedure. Seidel et al., (2014), also used this method to gather the data for their study. They randomly allocated patients to different wound care treatment groups, and they ensured there was a balance of participant characteristics in each group. This is a strength of this study as the inclusion and control group will have the same conditions as the treated group, minus the treatment itself. This ensures the treatment, and its effects, could be accurately studied (Bettany-Saltikov, 2012).

Fife et al., (2008), used data from a medical database which was stratified in various ways, including V.A.C versus non V.A.C and wound type/ size. Moule and Goodman (2014) explains this method is used to test a certain characteristic of a population, to address the research question. A limitation of this method is that it can stratify the data in ways that it may not reflect the population. It is important therefore that researchers apply weighting, so the population is more accurately represented (Lindsay, 2007). Conversely Stansby et al., (2010), used an open non-controlled clinical investigation in their study. Sacca (2010) does not consider this method to be effective, as it is mainly used in studies that look at oncology and haematology interventions. It is not possible to randomly assign

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these patients to research study groups, which may lead to a potential weakness of this study.

It is vital that the sampling strategy is planned in any research study in advance, as it will allow the project to be manageable within the required time scale. Sampling is a subset of a population, and not the entire population (Moule and Goodman, 2014). All of the studies, Stansby et al., (2010), Blume et al., (2008), Fife et al., (2008), and Seidel et al., (2014), used purposive sampling. It is also called judgemental sampling, as the researchers purposely select participants using certain criteria, to address the research question (Polit and Beck, 2012). This sampling strategy appears to be the most suitable, as patients with different types of wounds are the ones that could provide data about the wound care they received. It is also important that the sample size selected for the research study reflects the population being studied. The reason is, if there are too many participants, there may be too much of a risk exposed to them, and also if there or too few participants significant findings may be missed (Williamson and Whittaker, 2014).

Fife et al., (2008), used 1331 patients that had undergone V.A.C and non V.A.C treatment, Seidel et al., (2014), used 324 patients with a chronic diabetic foot wound and Blume et al., (2008), used 342 patients that had achieved complete ulcer closer. Finally, Stansby et al., (2010), used 14 patients that had post-amputation wounds. It is difficult to judge whether these sample sizes reflect the population been studied, as none of the articles chosen state their sampling strategies number calculation. This is a weakness as (Kadam and Bhalerao 2010) states that sample size strategies should be indicated, in order to produce ethically and scientifically valid results.

Stansby et al., (2010), collected the research data, by measuring the wound surface area and type at the beginning of the study to get a baseline, then at the end. This is so that the result of the intervention of NPWT can be evaluated. According to Williamson and Whittaker (2014) this data collection method is a type of experimental design, which is successful to test out medical interventions, Seidel et al., (2014), also collected the study data of participant's wounds at primary and secondary endpoints. Blume et al., (2008), also used this data collection method as participant's wounds were evaluated at day one, until all participants wounds had achieved closure.

It is essential that any baseline data is collected in advance, before randomisation, so

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that the researcher can rule out any possibility that participant's group assignment might affect the outcomes before the tested intervention (Polit and Beck, 2012). Data from 16 outpatient wound centres was collected in the study conducted by Fife et al., (2008). Moule and Goodman (2014) described this type of data collection as evaluation research, whereby existing data is used to test out a particular phenomenon. However, there are limitations with this method, as in order to be consistent all 16 outpatient wound centres would have to complete the database in the same way, and this was not verified.

Stansby et al., (2010), and Seidel et al., (2014), studies both used the intention to treat analysis in their data analysis method. This method works on the principle that all data from the randomised groups is analysed, regardless of whether the participant was exposed to the intervention or not (Gupta, 2011). Williamson and Whittaker (2014) debated that this method is also known as double-blinding, and it is used in research to avoid unintentional and intentional bias regarding the findings. Hence, a valid method to use, as the reliability of the findings will be more robust. Blume et al., (2008), also used intention to treat analysis, along with various tests which included Fishers exact test, ANCOVA and Kaplan-Meier survival analysis. When researchers use standardised tests for data analysis it provides them tried and tested tools, without the need for them to develop their own. Furthermore, the type of test to be used should be decided in advance (Polit and Beck, 2014). Fife et al., (2008), used the software Statistical Package for Social Science (SPSS). This statistical software is considered easy to use, as it has a graphical user interface and many statistical functions (Knott and Steube, 2010). However, some argue the licence is time limited, and expensive so may not be fully accessible (Yalta, 2008).

Fife et al., (2008), has suggested there was no difference between participants becoming more at risk to bleeding and infection, or being in more pain using V.A.C than non V.A.C therapy. Fife et al., (2008), have concluded that V.A.C is a safe method to treat diabetic wounds. However, three of the researchers are shareholders within a wound software database system used, which may raise questions about their creditability and transparency, again a potential weakness to this study. The findings of the studies by Stansby et al., (2010), and Blume et al., (2008), state that NPWT is a positive treatment

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for wound healing, and in many cases is more effective than advance moist wound therapy. It was not possible to fully understand the Seidel et al., (2014), findings as the trail was still ongoing. However, initial discussions do point to NPWT being also effective for chronic diabetic foot wounds. The findings are consistent with NICE (2016) which recommends NWPT when a wound has a large amount of exudate. This is also in accordance with other grey literature used to research wound care, NPWT and diabetes.

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