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Review Article

A Review on Cost Effectiveness of Negative Pressure Wound Therapy Vs Traditional Dressing In Diabetic Wounds.

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Abstract

A wound is a break or disruption in normal skin tissue. Several factors can hinder proper wound healing including hyperglycemia, a manifestation of diabetes mellitus. The hyperglycemic state brings about delayed repair thus creating chronic wounds. This may lead to amputation, in cases of poor healing, with significant physical, psychosocial and economic burden. Timely and proper treatment is needed to alleviate these complications, with wound care being the prime technique to drive optimal and fast healing. NPWT is a relatively new technique that is useful in diabetic wounds. Benefits of NPWT in diabetic ulcers include reduction in ulcer size, reduction in length of hospital stay, reduction in total costs for diabetic patients and less costs for diabetic wound dressings [1]. The aim of this review is to analyze the cost effectiveness of NPWT when compared to traditional dressings in diabetic wounds.

Keywords: Cost effectiveness; Negative pressure wound therapy; Vacuum assisted closure; Diabetic wounds

Abbreviations: VAC: Vacuum Assisted Closure; NPWT: Negative Pressure Wound Therapy; DFU: Diabetic Foot Ulcer; AMWT: Advanced Moist Wound Therapy; RCT: Randomised Controlled Trial; SNPWT: Single-use Negative Pressure Wound Therapy; TNPWT: Traditional Negative Pressure Wound Therapy; TWC: Traditional wound care; QALY: Quality-Adjusted Life Years

Introduction

A wound is a break or disruption in normal skin tissue. Wounds can range from superficial disruption to deeper structures such as nerves, vessels, muscles and tendon [2]. Proper healing involves a physiological response to tissue injury mediated by a multitude of factors including cytokines, numerous cell types and vascular events [3]. A few factors can impair adequate wound healing including hyperglycemia, a manifestation of diabetes mellitus. The hyperglycemic state encourages biofilm formation with subsequent delayed repair and development of chronic wounds [3]. It is roughly calculated that 25% of all diabetic patients have impaired wound healing and develop a foot ulcer at some point in time [4]. A devastating consequence to this is lower limb amputation, a complication with significant physical, psychosocial and economic costs [5].

Diabetic foot wounds account for almost 50% of all diabetes-related hospital stays and it is estimated that 10-15% of diabetic patients develop foot ulcers during their lifetime [6]. Timely and proper treatment is needed to alleviate these complications. This includes elevation, appropriate wound care and dressings, antibiotics in case of infection and assessment and correction of the patient's vascular status. All this is done through the involvement of a multidisciplinary team but primarily depends on patient education and wound care to prevent more critical issues [7,8].

Over the years there has been increasing research into developing new therapies to limit the serious complications and high costs incurred. In 1997, Morykwas et al. [9] put forward a new principle in wound management. They explored VAC following previous experiments with negative pressure dressing where it was found that negative pressure through a suction mechanism drains fluid exudate and increases blood flow to wounds, thus promotes healing [9]. An increased Doppler flow was observed with higher vacuum settings, creating a better wound bed, decreased oedema and increased perfusion of granulation tissue [10].

NPWT has been observed as particularly useful in diabetic wounds as a salvage technique after other treatment options have failed. Benefits of NPWT in diabetic ulcers include reduction in ulcer size, reduction in length of hospital stay, reduction in total costs for diabetic patients and less costs for diabetic wound dressings [1]. In the light of the improvements in healing through NPWT, hospitals around the world have increased their use over the years.

The aim of this review is to analyze the cost effectiveness of NPWT when compared to traditional dressings in diabetic wounds. This review evaluates recent literature relating to cost benefit analysis and assesses the length of hospital stay and quality of life in patients treated with VAC as a secondary outcome.

Table 1 summarizes aim as per PICO framework.

Table 1: Aim as per PICO Framework.

Patient	Patients with diabetic wounds
Intervention	NPWT
Comparison	Traditional dressing
Outcome	Assess cost effectiveness of NPWT in diabetic wounds

Search Strategy

An online search was conducted on Ovid Medline to address the objective of this literature review. English language literature from 2012 to 2022 was considered. A ten-year period was selected to obtain the most recent results about the topic and cover ongoing studies.

Table 2: Search Results.

Keywords	Cost effectiveness, negative pressure wound therapy, diabetic wounds
Search Terms	*Word* / *MeSH terms* Cost effectiveness / Cost benefit, cost analysis, economics Negative pressure wound therapy / Vacuum-assisted closure Diabetes Mellitus / Diabetic Wounds
Inclusion Criteria	Wounds in lower extremities, namely diabetic wounds Treated with NPWT Single or multi-centre observational studies or randomized controlled trials Human studies Studies from 2012 onwards
Exclusion Criteria	Wounds that are not in lower extremities and not diabetic ulcers Treated with other dressings not NPWT Animal studies Studies before 2012

Database results

	Keyword/s	Database	Number of hits
1	Cost effectiveness	Ovid MEDLINE	56098
2	Cost benefit	Ovid MEDLINE	80525
3	Cost analysis	Ovid MEDLINE	30687
4	Economics	Ovid MEDLINE	7041
5	1 OR 2 OR 3 OR 4	Ovid MEDLINE	134550
6	Vacuum-assisted closure	Ovid MEDLINE	1292
7	Negative pressure wound therapy	Ovid MEDLINE	4190
8	6 OR 7	Ovid MEDLINE	4715
9	Diabetes mellitus	Ovid MEDLINE	367235
10	Diabetic wounds	Ovid MEDLINE	992
11	9 OR 10	Ovid MEDLINE	367153
12	5 AND 8 AND 11	Ovid MEDLINE	9
13	Articles in English language only	Ovid MEDLINE	8
14	Articles from 2012 - 2022	Ovid MEDLINE	8

Screening Evidence	Titles and abstracts were screened to choose the relevant papers. Inclusion and exclusion criteria were applied. Articles that do not fall in such categories were not included.
Final Number	3

Studies retrieved include cost effectiveness and cost utility analysis of NPWT when compared to alternative dressings. One of the cost-effectiveness analyses by Kirsner et al. [11] analyses venous and DFUs but only data relating to diabetic ulcers will be considered for this review.

The Critical Appraisal Skill Programme checklist [12] will be used to evaluate the literature.

Literature Review

The studies considered include:

1. Evaluation of Wound Care and Health-Care Use Costs in Patients with Diabetic Foot Ulcers Treated with Negative Pressure Wound Therapy versus Advanced Moist Wound Therapy by Driver and Blume [1].

2. A Cost-Effectiveness Analysis Comparing Single-use and Traditional Negative Pressure Wound Therapy to Treat Chronic Venous and Diabetic Foot Ulcers by Kirsner et al. [11].

3. Cost-Utility Analysis of Negative Pressure Wound Therapy Compared with Traditional Wound Care in the Treatment of Diabetic Foot Ulcers in Iran by Alipour et al. [13].

The retrospective analysis by Driver and Blume [1] deals with evaluation of wound care and healthcare use costs in patients with DFUs treated with NPWT vs AMWT. Data for this study was acquired from a RCT by Blume et al. [10] whereby three hundred and forty-two patients were engaged in a multi-centre trial involving two study arms, NPWT or AMWT, for treatment of DFUs until closure or for a maximum of one hundred and twelve days. This initial study evaluated wound care while Driver and Blume et al. [1] study analysed wound management and cost analysis. For this review, only cost analysis will be considered.

The principal finding from this study was that NWPT is more cost effective when compared to AMWT in diabetic wounds mainly due to lower costs on procedures and reduced use of hospital resources.

Table 3 summarizes the aim, methods, results and limitations for this study.

Table 3: Aims, method, results and limitations for Driver and Blume [1].

Aim	To evaluate overall costs of NPWT vs AMWT in treating diabetic foot wounds over a period of twelve weeks. Secondary endpoints include assessment of clinical conditions of wounds, namely complete or incomplete closure.
Methodology	Three hundred and forty-two patients previously enrolled in a multi-centre RCT in Texas were included in an original study by Blume et al. [10]. This study compared clinical efficacy of NPWT vs AMWT until ulcer closure or at one hundred and twelve days from initiating treatment. Inclusion criteria included diabetic patients over eighteen years of age with calcaneal, dorsal or plantar foot ulcers greater than $2cm^2$ in area after debridement. Patients were randomized to each different arm of the study. Data from this study was included in the study by Driver and Blume [1] and used as basis for cost analysis. One hundred and sixty-nine patients from NPWT arm and one hundred and sixty-six patients from AMWT group were included. Patients with missing data for hospitalizations or those requiring graft or flap reconstruction were excluded. Costs were split into wound therapy and non-wound therapy treatment costs. Costs were calculated retrospectively based on the frequency that participants used health care resources. Mean doctor expenses for amputation, debridement and other wound related surgical procedures were considered. Average cost per inpatient day at hospital was estimated. Statistical analysis was performed using Fisher's exact test for wound closure rates and rates of amputation and log-rank test for time to closure in wounds that failed to close completely. Descriptive statistics were compiled for continuous parameters such as total cost per patient. All statistical tests were two sided.
Results	The total healthcare resource cost for all patients was $11,984.40 in NPWT vs $13,557.51 in AMWT per patient. The total wound cost was higher for the NPWT group ($4718.47) compared to the AMWT group ($2312.34) on a per patient basis. The total non-wound cost per patient was lower for NPWT ($7265.93) as opposed to AMWT ($11,245.17). When comparing the costs for health-related costs in complete vs incomplete wound closure, NPWT was cheaper in patients who achieved wound closure ($10,716.67 in NPWT vs $13,525.26 in AMWT patient). In patients who failed to achieve wound closure the average cost for those treated with NPWT was $13.262.34 per patient as opposed to $15,068.52 in the patient treated with AMWT. Median cost per cm2 reduction was also calculated. Clinically, NPWT wounds were reduced by 85% while AMWT decreased in size by 61.8%. In patients who achieved complete wound closure, the median cost to close 1cm2 by NPWT was $1226,53 compared to $1695.45 by AMWT closure. This price difference was also reflected in non-wound closure patients ($1633.47 in NPWT vs $2926.51 in AMWT). The overall median cost to close 1cm2 irrespective of degree of wound closure was found to be $1460.42 in NPWT compared to $2566.17 in AMWT.
Limitations	Data from one RCT only, no sensitivity analysis, short follow up time (12 weeks).

The aim of the study is detailed and well defined with a primary endpoint of cost analysis and secondary endpoint of clinical analysis. A lot of information is given about the previous study with an explanation of numbers until the end of study. However, the authors fail to mention how the patients were selected from the initial study. This creates a risk for selection bias and reduces reliability.

The study was a multi-centered study. However, power calculation is lacking, thus an increased risk for Type II error is created and it has decreased external validity. A good summary of how cost per patient is calculated is given and this makes the study reproducible in case similar studies are carried out.

The study tackles cost analysis from a different perspective when compared to Kirsner et al. [11] and Alipour et al. [13]. These two studies use the Markov model to compare wound management techniques in diabetic foot and carry out cost-benefit analysis through different strategies (case base and sensitivity analysis) whereas Driver and Blume [1] analyze results by Fisher's exact test and log-rank test. While Fisher exact test studies the relationship between two categorical variables and the log-rank test evaluates the risk adjusted event rates, a cost benefit analysis would have been more appropriate to analyze expected benefits from each wound dressing in relation to its cost. A sensitivity analysis for instance would have been good enough to analyze how independent variables affect dependent variables and provide a better cost-benefit analysis with respect to any additional costs. Besides this, any assumptions regarding cost estimates were not accounted for in data analysis.

Cost for NPWT is consistently lower than AMWT in all scenarios as indicated in Table 3. The fact that wound-related and non-wound related costs are divided provides a distinction where main costs are incurred. A comparison of this study to other studies is carried out namely to the study by Apelqvist et al. [14] and Flack et al. [15]. These studies had similar conclusions to this study increasing reliability of findings and validity.

In conclusion, overall NPWT is more cost-effective when compared to AMWT as it incurs lower cost and decreases hospital resource use. However, there are several potential sources of bias in the study, namely lack of power calculation and limited cost-benefit analysis representations. Hence, the study may be graded as 1- according to the Harbour &Miller classification [16].

The retrospective study by Kirsner et al. [11] analyses the cost-effectiveness of SNPWT vs TNPWT to treat chronic venous ulcers and DFUs. The study extrapolated data from a multi-centre perspective RCT of one hundred and sixty-one patients by Kirsner et al. [17] which compared SNPWT and TNPWT for treatment of venous ulcers and diabetic wounds in the United States. This study is a follow up to analyze the cost-effectiveness of SNPWT over TNWPT using a decision analytic model. For this review, only data related to DFUs will be considered. The key finding from this review is that SNPWT is more cost effective than TNWPT. The preferred therapy was found to provide a less economic burden to healthcare policy makers regarding DFUs.

The aim, methods, results and limitations of cost-benefit analysis are summarized in Table 4.

Table 4: Aims, method, results and limitations for Kirsner et al. [11].

Aim	To determine the cost effectiveness of SNPWT compared to TNPWT for treatment of venous leg ulcers and diabetic foot wounds in the United States.
Methodology	One hundred and sixty-one patients previously included in a randomized controlled, multi-centre study were included in this study. The Markov model was used to estimate costs as it is appropriate for chronic conditions that change over time. The study had time checks at twelve and twenty-six weeks and a cycle length of one week. A hypothetical cohort of patients began their weekly cycle in the open ulcer health state and moved to the closed wound cohort by end of the one-week cycle. The closed ulcer state refers to an absorbing state in wound healing. Two arms of the model, TNPWT and SNPWT were calculated separately for venous and diabetic ulcers in the proportion previously reported by Kirsner et al. [17] with 37.3% representing DFUs. The cost for each arm of treatment was summed up for each arm of the model and the difference was calculated as SNPWT–TNPWT. Cost effectiveness was analysed as: 1) Incidence of healing at 12 and 26 weeks 2) Total number of open ulcer weeks Cost benefit analysis was done using base case analysis, one-way sensitivity analysis, scenario analyses, probabilistic sensitivity analysis and threshold analysis. One-way sensitivity analysis tests the parameters one by one while probabilistic analysis changes the input values simultaneously. Threshold analysis estimates the daily cost of treating a wound using TNPWT was cost-neutral with respect to TNPWT.
Results	Base case analysis revealed that SNPWT was found to be more effective from clinical and cost aspects. This analysis also evaluated the possibility of switching from TNPWT to SNPWT with cost saving of $7756 per patient, reduction of 1.67 open ulcer weeks per patient at 12 weeks and reduction of $15749 and 5.31 open ulcer weeks at 26 weeks. This renders SNPWT, the alternative treatment, as dominant. One-way sensitivity analysis indicated that TNPWT had an incremental daily cost over SNPWT of $11358 - $20140. SNPWT remained dominant across the analysis. Scenario analysis also highlights cost saving on switching from TNPWT to SNPWT with an expected cost saving of $7976 and reduction of 4.42 open ulcer weeks per patient at 26 weeks. Probabilistic sensitivity analysis shows that at 12 weeks the expected value of incremental cost showed a savings of $7834 with 1.83 ulcer weeks less. At 26 weeks, cost was reduced by $15819 and 5.44 ulcer weeks less. Threshold analysis showed a slightly contradicting result with a break even on costs.
Limitations	Data limited to one RCT, one cost-minimization analysis, payer perspective only.

The objective of the study is defined as a similar statement similar to the title however no primary or secondary outcomes are indicated. Reference is made to the initial RCT however no details are available with regards to characteristics for patient recruitment and power calculation, increasing risk for bias and decreasing validity and reliability of the study. A strong point of the study is that data was obtained from a multi-centre study, however data analysed is only obtained from one RCT of one hundred sixty-one patients. Although the sample size is large, lack of power calculation increases the risk of Type II error and reduces external validity. Data from only one trial, thus one cost-minimization analysis, may create room for bias mostly in design, recruitment, sample population and data analysis. Despite data from only one RCT, this provides substantial evidence when assessing the cost effectiveness of SNPWT as it is based on updated trial analyzing the clinical effectiveness of this wound therapy. Although it requires several assumptions that might affect the average cost-effectiveness, the authors carried out a probability sensitivity analysis, based on the uncertainty in the parameters of the technique. This confirmed that the results of SNPWT were sensitive to alternative model assumptions.

The results described in the study showed that SNPWT was economically dominant in four analysis - base case analysis, one-way sensitivity analysis, scenario analysis, probabilistic sensitivity analysis. The consistent dominance is namely due to difference incidence of healing and reduced mean duration of SNPWT and TNPWT. SNPWT was also cost-effective when switching treatment. The use of multiple analyses sets makes the results more significant as they remain constant with all analyses. Within sensitivity analysis, the effect of a shorter duration of TNPWT was also studied. In this case SNPWT also remained economically better than the other therapy. This indicates that SNPWT is valid over a multitude of different treatment pathways.

Kirsner et al. [11] make a comparison of SNWPT with other studies that tackle the subject from other points of views other than cost analysis. Hurd et al. [18] suggest that change of dressing time is often shorter in SNPWT when compared to other dressings while Kirsner et al. [17] state that patient satisfaction was higher with SNPWT. These factors indicate that in addition to cost effectiveness, SNPWT also offers overall better patient satisfaction.

The study concludes that SNPWT for lower extremity DFUs is more cost effective than TNPWT. Results showed increased cost savings and a reduction in the total number of open ulcer weeks between 12 and 26 weeks. SNPWT was found to be economically dominant in multiple scenarios and analyses. The study would be graded as 1- according to the Harbour & Miller classification [16] due to significant risk of bias and only one RCT involvement. Further studies with more RCTs and dated economic evaluations are required to improve external validity.

Alipour et al. [13] analyze the cost-utility analysis of NPWT compared with TWC in DFU treatment in Iran. Two hundred patients treated for DFUs in Iran in 2016 over the course of one year were considered with half being treated with TWC and the rest treated by NPWT. A cost utility analysis was performed to assess mortality and morbidity of each type of wound dressing. The main inference was that NPWT is more cost effective than TWC with NPWT at $4668 lower cost per patient per year as opposed to TWC. NPWT also showed a higher QALY index over TWC.

Table 5 summarizes the aim, method, results and limitations of cost-benefit analysis for this study.

Table 5: Aims, method, results and limitations for Alipour et al. [13].

Aim	To establish the cost utility of NPWT when compared to TWC for DFUs treated in Iran over one year from the health care providers' perspective.
Methodology	One hundred Iranian patients with DFUs treated in 2016 over the period of one year were considered. The Markov model was utilized in this study. This was initially built on models used in older studies by Flack et al. [15] and Whitehead et al. [19]. The wound state categories considered included uninfected, infected, infected postamputation, healed, healed post-amputation, amputation and death. Transition between one health condition to another was determined based on ulcer development. Transition rates were assessed monthly, showing the probability of moving between two possible health conditions for one month. Probabilities were derived from Flack et al. [15] and Whitehead et al. [19]. Resources used for each health diagnosis monthly were estimated for every inpatient and outpatient. Costs were calculated for NPWT and TWC treatment strategies per month for inpatient days, nursing visits, doctor visits, amputation costs if any and DFU dressing. Additional costs for antibiotics, prostheses and investigations were obtained directly from patients' medical records. The cost of mortality was not considered in this study. Model effects were expressed as QALY. Economic evaluations were reported in terms of Incremental Cost Effectiveness Ratio. Base case and sensitivity analysis were carried out.
Results	Base case analysis showed that cost per patient per year for NPWT was $5164 +/- $3258 while TWC costs per patient per year was $9833 +/- $5861. The corresponding QALY was 0.1052 higher than NPWT. Sensitivity analysis revealed equal cost variations between NPWT and TWC. However, when comparing QALY, NPWT was still in the first region for cost effectiveness meaning a higher cost but greater cost effectiveness.
Limitations	Limited timeframe (1 year), country-specific context, no data on utility weights and quality of life index in Iran, provider's perspective only.

The study comprises data from Iran with no mention of a single-centre or multi-centre data collection. Although one may assume that data from a whole country is a population base study, the study has no power calculation. The authors do not mention how the sample size was selected, and this increases the risk of Type II error and decreases the study's external validity. Additionally, no inclusion or exclusion criteria are identified, and selection methods are not declared thus increasing the risk of inconclusive results and decreasing reliability.

Cost benefit analysis is done through base case and sensitivity analysis. The base case analysis collects data regarding one model while the sensitivity analysis accounts for any deviations that results may show due to variable figures. Probabilities relating to transition rates were obtained from Flack et al. [15] and Whitehead et al. [19]. This is useful as using common principles from other studies may increase transferability of information and add external validity.

Results indicate that NPWT is more cost effective when compared to TWC with a v4668 cost difference between the two dressing types over one year per patient. NPWT also had a higher QALY index over TWC. Varying parameters did not change the dominant strategy. Results also showed that NPWT reduces the number of amputations. The results of this study are like Flack et al. (2008) and Whitehead et al. (2011) studies increasing validity of this study. The former identified 0.53 QALY in NPWT patients when compared to 0.52 in TWC patients and a reduction in cost per patient with NPWT of $22004 per year. Whitehead et al. (2011) had similar results with a cost reduction of $4.68 million and 3

more QALY in NPWT patients. Thus, NPWT has a lower cost and greater QALY out of the two dressing types with a reduced effect on morbidity and mortality in diabetic patients.

The authors are aware of the limitations of this study and indicate that the one-year timeframe of this study does not assess long-term effectiveness and lifelong rates of disability and amputation. The analysis lacks data on utility weights, transition probabilities and quality of life indices in Iran. Furthermore, it only presented the provider's perspective for the cost benefit analysis. A social perspective may be considered in future studies for a better economic evaluation. Given these limitations for this economic evaluation, the study may be classified as 2- according to Harbour & Miller grading system [16] due to the high risk of bias. More multi-centered studies with longer timeframes and a social perspective with regards to cost benefit analysis are required to improve external validity.

Conclusion

The studies relating to cost-effectiveness of NPWT vs alternative dressing in diabetic wounds show that NPWT is cost-effective when compared to the other management strategies [1,11,13]. This is due to a shorter length of stay and lower cost for patients being treated with NPWT, mostly in relation to diabetic wound dressings.

The studies have some common limitations, namely lack of power calculation and high risk of bias giving them a score of 1- or 2- on Harbour & Miller classification [16]. This creates a need for more rigorously conducted studies with greater sample sizes and improved cost benefit analysis. Additionally, study data should be obtained from more than one potential source to improve research validity as much as possible. In summary, the existent data shows good evidence that NPWT is cost effective in management of diabetic patients, but research is limited.

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None.

Conflict of Interest

No conflict of interest.

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