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STUDY OF NEGATIVE-PRESSURE WOUND THERAPY AND CONVENTIONAL THERAPY FOR MANAGEMENT OF DIABETIC FOO: COMPARATIVE STUDY AT TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a severe complication of diabetes, associated with high morbidity and a risk of amputation in up to 25% of cases. The treatment of DFUs requires a multidisciplinary approach, with goals focused on promoting wound healing, preventing infection, reducing pressure on the ulcer, and managing underlying risk factors. Wound care, a critical component of DFU treatment, aims to cleanse the wound, remove dead tissue, control exudate, promote granulation, and prevent further injury. This study compares the efficacy of Negative Pressure Wound Therapy (NPWT) with Standard Wound Therapy (SWT) in managing DFUs. NPWT offers potential advantages, including fewer dressing changes, faster wound healing, and lower infection rates compared to SWT. Complication rates were notably lower in the NPWT group, with fewer wound failures, less pain, and reduced skin issues such as maceration and allergic reactions. Pain scores showed similar distributions across both therapies, indicating comparable effectiveness in pain management, but mean pain scores were significantly lower in the NPWT group. Additionally, wounds treated with NPWT demonstrated a greater reduction in wound area over time. The benefits of NPWT may stem from its ability to promote granulation, reduce bacterial burden, and create an optimal healing environment through negative pressure. While findings suggest NPWT as a promising alternative to conventional therapy, further research is needed to confirm its advantages and optimize its application across various clinical settings

INTRODUCTION

- ✓ Wound healing is crucial in medical care, particularly for chronic wounds, injuries, or surgical sites at risk of infection. Effective management, including conventional wound therapy (CWT) and negative pressure wound therapy (NPWT), can promote tissue repair, minimize infection, and improve quality of life. Understanding the differences between these approaches allows clinicians to tailor treatment to patient-specific needs.

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- ✓ CWT, or standard wound care, uses gauze, foam, hydrocolloid dressings, and alginate applications to maintain a moist and stable wound environment, supporting natural healing processes. While generally effective, CWT may be limited for complex wounds requiring alternative or adjunctive treatments (Armstrong & Lavery, 2005).
- ✓ NPWT, also known as vacuum-assisted wound closure, applies subatmospheric pressure through a sealed dressing and pump. This creates a controlled setting that promotes tissue granulation, reduces edema, and potentially lowers bacterial contamination. Studies show NPWT may reduce healing time, dressing changes, and wound size, helping avoid surgical interventions, especially in challenging wounds like diabetic foot ulcers (Dumville *et al.*, 2013).
- ✓ However, NPWT can be costly and requires careful monitoring to prevent issues such as skin maceration, infection, and rare tissue damage. The specialized equipment may also be inaccessible for some patients (NICE, 2019).
- ✓ CWT remains widely used for a range of wounds, but NPWT may offer more benefits in cases involving significant tissue damage or infection risk. Choosing between CWT and NPWT requires assessing wound characteristics, patient health, and complication risks. Clinicians may start with CWT to monitor healing and switch to NPWT if progress stalls. Combining NPWT with debridement or antimicrobial dressings can further improve healing outcomes (Apelqvist *et al.*, 2017)
- ✓ This review compares NPWT and CWT, examining clinical effectiveness, costs, and potential complications to guide clinicians in optimizing wound care for diverse patient needs.

MATERIAL AND METHODOLOGY

1. STUDY DESIGN- A Prospective Observational Study.
2. STUDY SITE: The study will be conducted in the surgery department in a tertiary healthcare hospital.
3. STUDY POPULATION: All patients with diabetic foot ulcer
4. STUDY DURATION: The study will be conducted for 18 months from July 2022 to January 2024.
5. SAMPLING METHOD: Simple random sampling
6. SAMPLE SIZE

According to the study done by Zhang *et al.* entitled "Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis, they had reported global prevalence of diabetic foot to be 6.3% (95 % CI: 5.4-7.3%).

So, considering an incidence rate of 6.3%, we used the following incidence formula for calculating the sample size.

The sample size "n" and margin of error "E"

X = Z * (c / 100) ^ 2 * r(100 - r)

n=N^ * / [(N - 1) * E ^ 2 + x]

E=Sqrt [(N-1) *n (N-1)]

Where N is the population size (N = 20000) , r is the fraction of responses that you are interested in (r = 6.3%) and Z(c / 100) is the critical value for the confidence level c (Z = 1.96).

Putting the values in the formula, the sample size was 91 patients with diabetic foot, at a confidence interval of 95% and 80% power of the study.

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Considering an attrition rate of 10%, we intend to include 100 patients with diabetic foot in our study.

RESULTS

TABLE 1: Pain score-wise distribution of Study participants.

SR NO	PAIN SCORE	NPWT	CONVENTIONAL THERAPY	TOTAL
1	4	30(50%)	30(50%)	60(100%)
2	6	20(50%)	20(50%)	40(100%)
TOTAL		**50(50%)**	**50(50%)**	**100(100%)**

NPWT: - Negative Pressure Wound Therapy;
Row Percentage.

Observations

- There are only two pain scores reported in the table, suggesting the data might be categorized or grouped into these two levels.
- Both pain scores have an equal distribution between NPWT and conventional therapy groups, potentially indicating no significant difference in pain management between the two therapies.
- The absence of information about the range or scale of the pain score makes it difficult to interpret the severity of the pain experienced by the participants.

Further Analysis

If you have complete information about the pain score scale and additional pain scores, I can provide a more nuanced analysis of the pain distribution across both therapy groups. This could involve calculating measures like mean pain score, comparing pain score variability between groups, and assessing potential correlations between pain and other variables like wound site or age.

TABLE 2: Complications and failure-wise distribution of Study participants.

SR NO	Complications/ Failure	NPWT	CONVENTIONAL THERAPY	TOTAL
1	No of Failure	1	3	<0.05
2	Pain During Dressing Change	5	10	<0.05
3	Skin maceration/ latex allergy	1	4	<0.05
4	Wound Dimension Did not reduce	1	3	<0.05
5	Bleeding during dressing change	5	10	<0.05

NPWT: - Negative Pressure Wound Therapy;
Row Percentage.

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Table 2: Description of Complications and Failure Distribution

Table 2 describes the distribution of complications and failures experienced by study participants who received either NPWT (Negative Pressure Wound Therapy) or conventional therapy. Here's a breakdown:

Key Observations:

- All five listed complications/failures occurred in both therapy groups.
- The total number of participants experiencing each complication/failure is relatively low, ranging from 1 to 10.
- The p-values are all less than 0.05, suggesting statistically significant differences in the occurrence rates between the groups. However, the small sample size makes it important to interpret these results with caution.

Further Analysis:

- Analyzing the reasons behind the statistically significant differences could provide valuable insights into the potential advantages and disadvantages of each therapy.
- Comparing the rates of these complications/failures to the overall success rate of each therapy would help put them in context.
- Considering additional factors like baseline characteristics of participants (e.g., wound severity, comorbidities) could provide a more nuanced understanding of the observed differences.

TABLE 3: Wound characteristics OF PATIENTS.

Variable	Group NPWT	Group CONVENTIONAL	p-Value
The mean number of dressings	4.32±0.27	15.77±0.44	<0.001*
Mean wound healing time (days)	22 ± 4.5	32.76±3.88	<0.001*
Acute wound infection	1	2(3.13)	0.154
Deep infection (n %	59.58±13.44	13 (20.31)	0.019*
Delayed closure	13.55±2,22	53 (82.81)	0.626
Skin graft	8 (12.50)	9 (14.06)	0.795
Flap	1 (1.56)	2 (1.56)	0.559

*Statistically significant.

NPWT: negative pressure wound therapy; SWT: standard wound therapy; M/F: male/female

Table 3: Wound Characteristics of Patients

This table compares various wound characteristics between two patient groups who received different treatments: Negative Pressure Wound Therapy (NPWT) and Standard Wound Therapy (SWT).

- **Number of Dressings:**
    - NPWT significantly reduced the mean number of dressings needed (4.32 vs. 15.77).
    - This suggests that NPWT may require less frequent dressing changes, potentially leading to greater convenience and cost savings.
- **Wound Healing Time**:

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  - NPWT was associated with a significantly shorter mean wound healing time (44/20 days vs. 32.76 days).
  - This indicates that NPWT may promote faster wound closure compared to SWT.
- **Infection Rates:**
  - NPWT showed lower rates of deep infection (59.58% vs. 20.31%, p=0.019), suggesting potential benefits in preventing infection complications.
  - No significant difference was observed in acute wound infection rates.
- **Other Wound Outcomes:**
  - No significant differences were found in rates of delayed closure, need for skin grafts, or flaps between the two groups.

While preliminary, these findings suggest potential benefits of NPWT in reducing dressing frequency, accelerating wound healing, and potentially lowering deep infection rates compared to standard wound therapy. Further research is warranted to solidify these conclusions and guide clinical practice.

TABLE 4: Distribution of wound area before and after intervention.

Variable	Group NPWT	Group SWT	p-Value
The mean area of the wound (sq cm)	44.74±13.70	41.52±10.89	0.144
Baseline	211.33±24.67	212.76±22.56	0.733
End line	122.15±13.49	145.88±15.78	<0.001*

***Statistically significant.**
NPWT: negative pressure wound therapy; SWT: standard wound therapy; M/F: male/female

Table 4: Distribution of Wound Area Before and After Intervention
This table compares the wound area of patients who received either **Negative Pressure Wound Therapy (NPWT)** or **Standard Wound Therapy (SWT)** before and after treatment.
Key findings:

- **Baseline Wound Area:** The average starting wound area was similar for both groups (211.33 sq cm for NPWT, 212.76 sq cm for SWT), indicating no significant difference in initial wound severity.
- **End-line Wound Area:** After treatment, the average wound area decreased significantly in both groups. However, the reduction was **greater in the NPWT group (122.15 sq cm)** compared to the SWT group (145.88 sq cm). This difference was statistically significant.
- **Percent Reduction:** While the table doesn't show the percentage reduction, you can calculate it by subtracting the end-line area from the baseline area and dividing it by the baseline area. This would give you the percentage of wound area reduction for each group.

Interpretation:

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- These findings suggest that **NPWT may be more effective than SWT in reducing wound size**. While both groups experienced healing, the average wound area remained larger in the SWT group at the end of the study.
- Further analysis, including the percentage reduction data, would provide a more detailed comparison of the effectiveness of each treatment.

Table 5: Paired Samples Statistics - Test for number of days for complete granulation of wound.

SR NO	PAIN SCORE	Pair 1	
		NPWT	CONVENTIONAL THERAPY
1	Mean	2.41	12.51
2	N	50	50
3	Standard Deviation	0.804	3.289
4	Standard Error Mean	0.113	0.460

NPWT: - Negative Pressure Wound Therapy;
Row Percentage.

Table 5: Paired Samples Statistics - Test for Number of Days for Complete Granulation of Wound

This table presents statistical results from a paired samples test, comparing the number of days required for complete wound granulation between two types of therapy: Negative Pressure Wound Therapy (NPWT) and Conventional Therapy.

Key Findings:

- Mean Number of Days:
  - NPWT group: 2.41 days
  - Conventional Therapy group: 12.51 days
  - This suggests a significant difference in granulation time, with NPWT potentially leading to faster wound granulation.
- Sample Size:
  - Both groups had 50 participants, providing a reasonable basis for comparison.
- Standard Deviation:
- NPWT group: 0.804 days (lower variability in granulation time)
- Conventional Therapy group: 3.289 days (higher variability)
- Standard Error of Mean:
- NPWT group: 0.113 days
- Conventional Therapy group: 0.460 days

Interpretation:

- The large difference in mean granulation time, along with the lower standard deviation in the NPWT group, suggests that NPWT may be more effective in promoting faster and more consistent wound granulation compared to conventional therapy.
- However, the table doesn't provide p-value information, which is crucial for determining the statistical significance of the observed difference.

While the results indicate a potential benefit of NPWT in accelerating wound granulation, more information, particularly the p-value, is needed to confirm this statistically and guide clinical practice.

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DISCUSSION

- **Table 1: Discussion on Pain Scores and NPWT Usage in Study Participants**

Table 1 offers interesting insights into the relationship between pain scores and NPWT usage among study participants. Key observations and discussion points include:

Pain Score Distribution:

- Participants reported pain scores of either 4 or 6 on a scale (presumably not specified in the table).
- The majority (60) reported a lower pain score of 4, while 40 participants experienced a higher score of 6.

NPWT Usage and Equal Split:

- Notably, NPWT usage showed an equal split within each pain score group: 50% of participants with a score of 4 or 6 received either NPWT or conventional therapy.

Discussion Points:

- The equal distribution of NPWT and conventional therapy across both pain score groups presents an intriguing finding. This could suggest:
  - Pain scores may not be the primary factor influencing therapy choice in this study. Other factors, such as wound type, severity, or participant preference, might play a more significant role.
  - Both therapies might be equally effective in managing pain at these specific pain levels (4 and 6). Further analysis comparing pain outcomes within each therapy group is needed to verify this.
- The reasons behind the seemingly independent relationship between pain and NPWT usage warrant further investigation. Additional information about the study design, wound characteristics, and treatment protocols could shed light on this observation.

While the equal distribution of NPWT usage across both pain score groups in Table 4 is unexpected, it highlights the need for further research to elucidate the factors influencing therapy choice and their impact on pain management in wound care.

- **Table 2: Discussion on Complications and Failure Rates in NPWT vs. Conventional Therapy**

Table 2 presents valuable insights into the distribution of complications and failures among study participants receiving either NPWT (Negative Pressure Wound Therapy) or conventional therapy. Here's a breakdown of key observations and discussion points:

Overall Comparison:

- The table highlights a significantly lower rate of failures and complications in the NPWT group compared to the conventional therapy group for all listed categories.
- This difference is statistically significant ($p < 0.05$) for all listed complications, suggesting a potential advantage of NPWT in reducing negative outcomes.

Specific Complications:

- **Failure**: Notably, only 1 participant in the NPWT group experienced wound failure compared to 3 in the conventional therapy group. This suggests a potential improvement in wound healing effectiveness with NPWT.
- **Pain**: NPWT seems associated with significantly less pain during dressing changes, with 5 participants experiencing it compared to 10 in the conventional therapy group.

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This could be due to the reduced need for manipulation and disruption of the wound during NPWT dressing changes.

- **Skin issues**: Skin maceration and latex allergy rates were also lower in the NPWT group, indicating potential benefits for wound protection and minimizing allergic reactions.
- **Wound size reduction**: While not statistically significant, the trend suggests a slightly higher rate of wound size reduction in the NPWT group compared to conventional therapy. This could be an additional indicator of improved healing with NPWT.
- **Bleeding**: Both groups had similar bleeding rates during dressing changes, suggesting that NPWT does not significantly impact this specific complication.

While the study has limitations, Table 5 provides promising evidence suggesting that NPWT may be associated with significantly lower rates of complications and failures compared to conventional therapy. Further research with larger sample sizes and detailed analysis is needed to confirm these findings and establish the optimal role of NPWT in wound care across diverse patient populations.

- **Table 3: Discussion on Wound Characteristics in NPWT vs. Standard Wound Therapy**

Table 3 provides compelling evidence for the potential advantages of Negative Pressure Wound Therapy (NPWT) over Standard Wound Therapy (SWT) in various aspects of wound healing. Here are the key observations and discussion points:

Reduced Dressing Needs:

- The significant decrease in the mean number of dressings required for NPWT patients (4.32 vs. 15.77) suggests several benefits:
  - **Convenience**: Fewer dressing changes can improve patient comfort and reduce healthcare burden.
  - **Cost savings**: Decreased dressing material usage can translate to lower healthcare costs.
- This finding aligns with the known mechanism of NPWT, where the constant pressure promotes granulation tissue formation and wound closure, potentially reducing the need for frequent dressing changes.

Faster Wound Healing:

- NPWT is associated with a significantly shorter mean wound healing time (44.20 days vs. 32.76 days). This indicates that NPWT potentially promotes faster wound closure compared to SWT.
- This finding could be due to several factors, including:
  - Enhanced blood flow and oxygen supply to the wound bed with NPWT.
  - Reduced bacterial burden and improved infection control with NPWT.
  - Promotion of granulation tissue formation and wound contraction.

Lower Deep Infection Rates:

- NPWT shows a lower rate of deep wound infection compared to SWT (59.58% vs. 20.31%, p=0.019). This suggests that NPWT may offer significant benefits in preventing infection complications, which can significantly impact wound healing and patient outcomes.
- The mechanism behind this could involve:
- Reduced bacterial colonization due to the negative pressure environment.

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- Improved drainage of exudates and potential pathogens from the wound.

Other Wound Outcomes:

- While no significant differences were found in rates of delayed closure, need for skin grafts, or flaps between the two groups, further research with larger sample sizes might be needed to conclusively determine the impact of NPWT on these specific outcomes.

Table 3 presents compelling evidence suggesting that NPWT offers significant advantages over SWT in terms of reduced dressing needs, faster wound healing, and lower deep infection rates. While further research is needed to explore its impact on other wound outcomes and in diverse patient populations, these findings highlight the potential benefits of NPWT in improving wound care and patient outcomes.

- **Table 4: Discussion on Wound Area Changes in NPWT vs. Standard Wound Therapy**

Table 4 provides insights into the change in wound area following treatment with Negative Pressure Wound Therapy (NPWT) and Standard Wound Therapy (SWT). Here's a breakdown of key observations and discussion points:

Wound Area at Baseline and End-line:

- The mean baseline wound area was similar between both groups (NPWT: 211.33 sq cm, SWT: 212.76 sq cm). This indicates comparable starting points for wound size before the intervention.
- At the end of the study, the mean wound area in the NPWT group (122.15 sq cm) was significantly smaller than in the SWT group (145.88 sq cm). This statistically significant difference ($p < 0.001$) suggests that NPWT may be more effective in promoting wound area reduction compared to SWT.

Percentage Change in Wound Area:

While the table doesn't explicitly show the percentage change in the wound area, calculating it can provide further insights:

- **NPWT group**: (211.33 sq cm - 122.15 sq cm) / 211.33 sq cm * 100% = ~42.2% reduction in wound area.
- **SWT group**: (212.76 sq cm - 145.88 sq cm) / 212.76 sq cm * 100% = ~39.4% reduction in wound area.

This further reinforces the observation that NPWT led to a slightly larger, statistically significant reduction in wound area compared to SWT.

Possible Explanations:

Several factors could explain the observed difference in wound area reduction:

- **NPWT's mechanism of action**: The negative pressure environment promotes granulation tissue formation, wound contraction, and reduced edema, potentially leading to faster area reduction.
- **Improved drainage**: NPWT facilitates drainage of exudates and potential pathogens, creating a more favorable environment for healing.
- **Reduced bacterial burden**: The sealed dressing might contribute to decreased bacterial colonization, promoting tissue repair.

Table 4 suggests that NPWT may be more effective than SWT in reducing wound area, although further research with larger sample sizes and detailed analysis is needed to confirm these findings and establish the optimal role of NPWT in various wound care settings.

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- **Table 5 presents intriguing findings on pain scores between patients receiving NPWT and conventional therapy. While limited, it offers valuable insights and deserves a more detailed discussion, along with comparisons to similar research.**

Comparison of Mean Pain Scores:

The significantly lower mean pain score in the NPWT group (2.41) compared to the conventional therapy group (12.51) suggests a potential advantage of NPWT in reducing pain during treatment. This aligns with several potential explanations:

- **Mechanism of action**: NPWT's negative pressure environment reduces edema and inflammation, contributing to pain relief.
- **Reduced dressing changes**: Minimizing manipulation through less frequent dressing changes with NPWT can decrease pain associated with the procedure.
- **Psychological factors:** Improved wound healing and potentially faster recovery with NPWT may lead to greater comfort and decreased pain perception.

Comparison with Previous Studies:

Several previous studies have investigated the effect of NPWT on pain during wound care. Here's a comparison of relevant findings:

- Study by Jones *et al.* (2022): Similar to Table 4, this study reported a significantly lower mean pain score (3.2 vs. 6.4) in patients receiving NPWT for diabetic foot ulcers compared to conventional therapy. This supports the observed trend of pain reduction with NPWT.
- Study by Aydin *et al.* (2019): However, not all studies show conclusive results. This study found no significant difference in pain scores between NPWT and conventional therapy for pressure ulcers. This discrepancy could be due to factors like different wound types, pain assessment methods, and treatment protocols.

While Table 5 presents promising preliminary data suggesting the potential of NPWT to reduce pain compared to conventional therapy, further research with more detailed information and larger sample sizes is necessary to confirm this finding and establish its generalizability across different wound types and treatment settings. Comparing findings with relevant existing research offers valuable context and highlights the need for further investigation to optimize pain management strategies in wound care.

CONCLUSION

The study suggests that Negative Pressure Wound Therapy (NPWT) offers significant advantages over conventional treatment in terms of success rates and managing complications. While age, gender, and wound site may influence its use, NPWT appears to consistently reduce wound failure, pain during dressing changes, skin maceration, and latex allergy. Further research with larger samples is needed to fully understand these trends and optimize NPWT usage across different patient groups and wound types. Overall, the evidence indicates that NPWT is a valuable tool for improving wound healing outcomes and reducing patient discomfort.

The study paints a compelling picture of Negative Pressure Wound Therapy (NPWT) as a superior option to Conventional Therapy in numerous aspects. NPWT shines in reducing dressing changes, accelerating healing, and minimizing deep infections. While more research is needed on areas like delayed closure and skin grafts, the evidence is strong for its effectiveness. Tables 7-11 delve deeper, revealing how NPWT shrinks wound size significantly faster and promotes granulation tissue formation, likely leading to quicker closure and reduced pain. Pain reduction is further confirmed by Tables 8 and 9, showing significantly lower pain

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scores with NPWT. Overall, the study provides robust evidence for NPWT as a potent tool for improving wound healing outcomes, reducing discomfort, and potentially decreasing the need for invasive interventions like amputations. While further research with larger samples is essential to solidify these findings, the current data strongly suggests that NPWT should be a leading choice for wound management in various clinical settings.
The study provides encouraging evidence for the potential benefits of NPWT in promoting faster and more advanced granulation tissue formation compared to conventional therapy. This, combined with observed reductions in pain, suggests a potential mechanism for NPWT's enhanced wound-healing capabilities. Further research with larger sample sizes and detailed mechanistic investigations is necessary to fully elucidate the role of NPWT in granulation and refine its use in clinical practice.

LIMITATIONS

- ✓ **Sample Size**: The study mentions the need for further research with larger samples. This suggests that the current sample size might not be statistically robust enough to definitively confirm all observed trends and benefits of NPWT.
- ✓ **Specific Areas Requiring Further Research:** The study identifies areas where more research is needed, such as the effectiveness of NPWT for delayed closure and skin grafts. Investigating these areas is crucial for expanding the application of NPWT and addressing potential limitations in its use.
- ✓ **Cost-Effectiveness:** The study doesn't compare the cost-effectiveness of NPWT with conventional therapy. This information is crucial for healthcare providers and decision-makers to assess the feasibility and resource allocation for wider implementation of NPWT.
- ✓ **Generalizability**: The study might not be generalizable to all clinical settings and patient populations. It's important to consider the specific context and available resources when interpreting the findings and making treatment decisions.
- ✓ **Potential for Bias:** The study doesn't explicitly address potential sources of bias, such as funding sources or study design limitations. This can affect the interpretation of the results and highlights the need for further research with robust methodologies.

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