Published in final edited form as:

J Surg Res. 2020 October ; 254: 197–205. doi:10.1016/j.jss.2020.04.025.

Inpatient Versus Outpatient Management of Negative Pressure Wound Therapy in Pediatric Patients

Katherine B. Santosa, MD, MS^a, Alexandra M. Keane, MD^b, Matt Keller, MS^c, Margaret A. Olsen, PhD, MPH^d, Erika D. Sears, MD, MS^e, Alison K. Snyder-Warwick, MD, FACS^f

^aResearch Fellow, Division of Plastic and Reconstructive Surgery, Department of Surgery, House Officer, Section of Plastic Surgery, Department of Surgery, University of Michigan, 1500 E. Medical Center Drive, Ann Arbor, MI 48109

^bResident, Division of Plastic and Reconstructive Surgery, Department of Surgery, Washington University, 660 S. Euclid Avenue Campus Box 8238, St. Louis, MO 63110

^cSenior Statistical Data Analyst, Division of Infectious Diseases, Department of Medicine, Washington University, 660 S. Euclid Avenue Campus Box 8238 St. Louis, MO 63110

^dProfessor, Division of Infectious Diseases, Department of Medicine, and Division of Public Health Sciences, Department of Surgery, Washington University, 660 S. Euclid Avenue Campus Box 8238 St. Louis, MO 63110

^eAssistant Professor, Section of Plastic Surgery, Department of Surgery, University of Michigan, 1500 E. Medical Center Drive Ann Arbor, MI 48109 and VA Ann Arbor Healthcare System Center for Clinical Management Research

^fAssistant Professor, Division of Plastic and Reconstructive Surgery, Department of Surgery, Washington University, 660 S. Euclid Avenue Campus Box 8238 St. Louis, MO 63110 St. Louis, MO

Abstract

Background: Negative pressure wound therapy (NPWT) is commonly used to manage complex wounds in the pediatric population. With recently developed portable NPWT devices, providers have the opportunity to transition NPWT to the outpatient setting. However, there are no studies describing outpatient NPWT in pediatric patients. Therefore, the purpose of our study was to

Corresponding Author: Alison K. Snyder-Warwick, MD, FACS, Washington University School of Medicine, 660 S. Euclid Avenue Campus Box 8238, Saint Louis, MO 63110, snydera@wustl.edu; Phone: 314-454-4892, Fax: 314-367-0225.

Author Contributions: Dr. Santosa assisted with study design and data interpretation, and wrote the first draft of the manuscript. Mr. Keller assisted with study design, performed all data analysis, and assisted with data interpretation. Dr. Olsen assisted in study design, statistical analyses, and data interpretation. Dr. Keane helped with data interpretation and writing of the first draft of the manuscript. Dr. Sears assisted with study design, statistical analysis and data interpretation. Dr. Snyder-Warwick assisted with study design and data interpretation. All authors contributed critical revisions of the manuscript. The corresponding author, Dr. Snyder-Warwick, takes responsibility for the integrity of the data and the accuracy of the data analysis. She had final responsibility for the decision to submit for publication.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Declarations of Interest: none

leverage a population-level analysis to advance our current knowledge about outpatient NPWT use in pediatric patients.

Materials and Methods: We analyzed the Truven Health Analytics MarketScan® Commercial Claims Database from 2006 to 2014 to identify children treated with NPWT. We compared patient characteristics, indications, complications before and after NPWT, healthcare utilization within 30 days of NPWT initiation, and healthcare cost profile of patients treated with NPWT primarily as outpatients versus inpatients. Outpatient NPWT was defined as patients with 50% of NPWT coded during an inpatient hospitalization; inpatient was defined as >50%.

Results: We identified 3184 patients (1621 inpatients, 1563 outpatients) ages 0–17 years who were treated with NPWT from 2006–2014. Outpatient NPWT was implemented across multiple ages, comorbidities, and indications with a low complication rate (2.4%). After controlling for hematologic comorbidity and indications, outpatient NPWT was associated with lower risk of complications (OR = 0.57, 95% CI 0.38–0.86), and lower median total costs (\$5,602.03) compared to inpatient (\$15,233.21) therapy.

Conclusions: Outpatient NPWT management in pediatric patients was associated with low complication rates. Additional studies are necessary to determine the most overall cost-effective treatment setting for NPWT in the pediatric population.

Keywords

Negative-pressure wound therapy; vacuum-assisted closure; infants; children; inpatient; outpatient

Introduction

Since its introduction in 1997, negative pressure wound therapy (NPWT) has revolutionized the management of complex wounds.(1, 2) NPWT delivers sub-atmospheric pressure to an open-cell foam dressing in a wound cavity. Its success in treating chronic and difficult-to-manage wounds can be attributed to mechanical deformation and its ability to decrease edema, increase localized blood flow, speed granulation tissue formation, and improve bacterial clearance.(1–5) Owing to its demonstrated safety, ease of use, and ability to heal wounds more quickly than conventional dressings, NPWT is widely used in the pediatric population for the treatment of complex wounds across all ages, specialties, and indications. (6, 7)

Traditionally, NPWT was solely utilized in the inpatient setting; however, with the recent development of portable NPWT devices, providers now have the option to administer this treatment modality in the outpatient setting. However, there is a paucity of literature comparing inpatient and outpatient NPWT use in pediatric patients. Although limited, studies in the adult population demonstrate that outpatient NPWT for treatment of a variety of surgical and non-surgical conditions is feasible, safe, efficacious, and cost-effective.(8–14) Furthermore, outpatient NPWT in adults has been associated with less pain and increased tolerability compared to inpatient use.(10) Qualitative studies to assess experiences of adults with home NPWT devices suggest that, although patients may initially feel anxious, embarrassed, or dependent as a result of their NPWT device, they progressively become more confident with wound management, feel more actively involved in their care,

and are relieved to be managing their condition at home.(15–17) Outpatient treatment in the pediatric population has the additional theoretical benefits of decreased cost by reducing inpatient hospital costs, enhanced patient and parent satisfaction, and reduced risk of nosocomial infections, disruption to family life, and development of adverse psychiatric or behavioral changes.(18–23)

Given the lack of literature describing outpatient NPWT use in children and its demonstrated benefits in adult patients, the purpose of this study was to leverage a population-level approach to compare the indications for NPWT, adverse conditions prior to and incident complications after NPWT initiation, healthcare utilization after NPWT, and cost profile of NPWT use in pediatric patients treated primarily as inpatients versus outpatients.

Methods

Data Set and Study Sample

A retrospective analysis was performed between 2006 and 2014 using the Truven Health Analytics MarketScan® Commercial Claims Database. This database is comprised of beneficiaries from large employers and health plans, and includes inpatient, outpatient, and pharmacy claims for approximately 18 million patients each year.(24) The database is a limited dataset without patient identifiers; however, encrypted patient identifiers are included, allowing for longitudinal study of a patient's healthcare utilization.(24) Individual chart reviews are not possible in the database. This study was deemed exempt by the Human Research Protection Office at Washington University in St. Louis.

The Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT) codes were used to identify patients under 18 years of age coded for NPWT (Table A.1). Inpatient and outpatient claims for first-coded NPWT were identified between July 1, 2006 and December 1, 2014. We defined patients primarily treated with NPWT as inpatients as those who had >50% of NPWT codes in the inpatient setting. If patients had ≤50% of NPWT coded during an inpatient hospitalization, then they were classified as being treated primarily as outpatients. To meet eligibility criteria, patients had to: (1) have a minimum of 180 days of insurance enrollment prior to the first-coded NPWT date (unless they were 0-years-old) and (2) have a minimum of 30 days of continuous healthcare enrollment after the first-coded NPWT date. The eligibility criterion was utilized: (1) to identify previous healthcare encounters; (2) to determine the indication for NPWT; (3) and to identify medical comorbidities using a previously described comprehensive algorithm of 18 underlying conditions for pediatric patients (represented in Table 1).(25)

Indications, Adverse Conditions, and Healthcare Utilization

For outpatient claims, comorbidity was defined as having at least two codes from the same diagnosis category spaced at least 30 days apart; for inpatient claims, only one code was necessary to meet the definition for comorbidity.(26) These specific definitions were established given that in the outpatient setting, a single International Classification of

Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code could indicate a diagnostic workup rather than an established diagnosis.

Indications for NPWT were identified using ICD-9-CM procedure codes and CPT codes for surgical categories, and additional relevant medical conditions that are common indications for NPWT in children based on clinical knowledge and experience with NPWT use in the pediatric population (Tables A.2A and A.2B). Surgical categories were based on the Center for Disease Control and Prevention National Healthcare Safety Network procedure list for surgical site infection surveillance.⁽²⁷⁾ Claims filed from 180 days prior through 7 days after the first-coded NPWT date were used to identify indications for NPWT. This timeframe was used to capture all possible claims that may have provided information regarding preexisting conditions (Table A.3) within 6 months prior to treatment and the indications for treatment with NPWT.

Follow-up was conducted to identify incident adverse conditions present within 30 days of NPWT initiation (Table A.3), and to determine healthcare utilization outcome measures (Table A.4). The adverse conditions investigated included bleeding, cellulitis or abscess, fistula, sepsis, septicemia, and surgical site infection. Healthcare utilization outcome measures included visits coded for anesthesia or sedation, emergency department (ED) visits classified as treat-and-release, home health visits, inpatient hospitalizations, and total reimbursed amounts divided into NPWT-specific and non-NPWT specific payments. For total costs, the MarketScan variable PAY was used which represents gross covered payments. The MarketScan variable NETPAY which is PAY minus deductible (DEDUCT), coinsurance (COINS) and coordination of benefits (COB) was used to determine insurance reimbursement. Patient out of pocket expenses are the sum of the patient's copayments (COPAY), coinsurance (COINS) and deductibles (DEDUCT). Both definitions for insurance reimbursement and out-of-pocket expenses follow the MarketScan documentation. All costs were adjusted for inflation to 2014 using the medical care component of the Consumer Price Index (www.bls.gov). For patients treated in the outpatient setting, these outcomes were identified during the 30-day follow-up period from the date of NPWT initiation. In the inpatient setting, if NPWT was not initiated on the first day of an admission, follow-up for all outcome measures, including total charges, was started on the date of NPWT placement and was continued for 30 days thereafter. The MarketScan variable SVCSCAT ending in 20 was used to identify ED visits, as recommended by Truven. The SVCSCAT variable includes information on the facility type (first three digits, e.g., inpatient hospital) and the service type (last two digits) in one field. The last 2 digits of "20" indicate emergency department services (which correlates well with emergency department revenue center codes). If ED visits were not associated with an inpatient admission, they were classified as treat-and-release. Inpatient hospitalizations were identified from the inpatient_services file. To identify home health visits, CPT and HCPCS codes were used, or revenue codes for skilled nursing with the MarketScan database's standard place (STDPLAC) variable indicating place of service was the patient's home (Table A.4).

Statistical Analysis

Patient characteristics were summarized for each group using counts and percentages. Indications, pre-existing and incident complications, and healthcare utilization based on number of children were compared by setting of NPWT treatment using Chi-square and Fisher's exact tests, as appropriate. Measures of healthcare utilization and charges were compared between patients treated primarily as inpatients compared to outpatients using Wilcoxon rank sum tests. To further compare the odds of any complication between the two groups, a step-wise logistic regression model was performed with setting of NPWT placement as the primary predictor variable. Predictor variables were entered into the initial model if they had a p-value of 0.2 or less, and retained in the model with p-values of 0.1 or less. Data management and statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC), and statistical significance for all tests was set at $p < 0.05$.

Results

Patient and clinical characteristics

The patient demographics of our pediatric NPWT cohort including age, sex, region, and comorbidities are summarized in Table 1. In total, we identified 3,184 infants and children treated with NPWT, 1621 (50.9%) of whom were primarily treated as inpatients and 1563 (49.1%) who were primarily treated as outpatients. Across both cohorts, the majority of patients were 12–17 years old and male.

Among inpatients, the most common underlying comorbidity was related to the musculoskeletal system, affecting 14% of patients. The two next most common comorbidities among inpatients were neurological (13%) and mental health-related (11%). Among outpatients, the top three comorbidities were similar in proportion (neurological 10%, musculoskeletal 9%, and mental health 8%), although the overall proportion of outpatients with comorbidities was less than those in the inpatient group.

Indications for NPWT placement

The indications and setting for initial NPWT placement are summarized in Table 2. Among inpatients, 79% had a surgical indication while 21% had a non-surgical indication. These frequencies differed significantly among outpatients, with 33% of outpatients with a surgical indication and 67% with a non-surgical indication. Across both cohorts, surgery of the musculoskeletal system was the most common surgical indication (inpatients 58%, outpatients 24%). Among patients undergoing major abdominal (19% vs 7%, $p < 0.001$), cardiothoracic (6% vs 1%, $p < 0.001$), or neurological surgery (8% vs 4%, $p < 0.001$), significantly more patients were treated with NPWT in the inpatient compared to the outpatient setting.

Outpatient NPWT was more commonly utilized in patients with common clinical diagnoses such as ulcer (10% versus 6%, $p < 0.001$) and pilonidal cysts (37% versus 5%, $p < 0.001$). In contrast, among patients with osteomyelitis or burns, inpatient NPWT was more commonly utilized (12% vs 6%, $p < 0.001$ and 5% vs 3%, $p = 0.031$, respectively).

Pre-existing adverse conditions before and incident complications after NPWT placement

Pre-existing adverse conditions before the first coded NPWT therapy are summarized in Table 3A. Infection-related conditions were relatively common during the 6 months before NPWT placement in both groups. Prior surgical site infection was significantly more common among children treated with NPWT as inpatients than outpatients (30% versus 16%, $p < 0.001$). In addition, prior bleeding, septicemia, sepsis, and fistula were significantly more common among children treated with NPWT as inpatients than outpatients. Cellulitis or abscess, in contrast, was more common among children treated with outpatient than inpatient NPWT (26% versus 20%, $p < 0.001$).

Incident complications after NPWT placement are summarized in Table 3B. Across both groups, incident complications were relatively uncommon, but occurred more frequently among inpatients than outpatients (6% versus 2%, $p < 0.001$). With the exception of cellulitis or abscess and fistula, all other complications, such as bleeding ($p = 0.001$), surgical site infection ($p = 0.016$), septicemia ($p = 0.007$), and sepsis ($p = 0.001$), occurred more frequently among patients treated with NPWT as inpatients compared to those treated as outpatients.

Results from the multivariable analysis with the outcome of any complication (bleeding, surgical site infection, cellulitis/abscess, septicemia, sepsis, or fistula) are summarized in Table 4. After controlling for hematologic comorbidity and indications for NPWT placement, outpatient NPWT use was associated with reduced risk of complications (OR 0.57, 95% CI 0.38–0.86). Additionally, having a hematological comorbidity (OR 2.10, 95% CI 1.08–4.09), undergoing major abdominal surgery (OR 1.95, 95% CI 1.29–2.95), and undergoing surgery in the “other” category, which included procedures such as breast or neck surgery, peripheral vascular bypass, or dialysis shunt placement (OR 3.91, 95% CI 1.54–9.94), were all associated with increased risk of any complication after NPWT placement. Pilonidal cyst as the indication for NPWT was associated with significantly lower complication risk (OR 0.29, 95% CI 0.12–0.67).

Healthcare utilization within 30 days of NPWT placement

Healthcare utilization within 30 days of initial NPWT placement is summarized in Table 5. Significantly more children treated with NPWT as inpatients had a subsequent visit coded for anesthesia (65% vs 25%, $p < 0.001$) or sedation (4% vs 1%, $p < 0.001$) compared to outpatients. Additionally, the number of children admitted to the hospital via the ED (19% vs 2%, $p < 0.001$) and number of admissions on or after the index NPWT date (37% vs 9%, $p < 0.001$) were greater among patients treated as inpatients than outpatients. Home health visits, however, were more common among children treated with NPWT as outpatients than inpatients (37% vs 31%, $p = 0.001$), and there was no difference in the number of children who visited the ED and were subsequently treated and released between inpatient and outpatients (11% vs 9%, $p = 0.215$).

Charges 30 days after NPWT placement

Medical payments within 30 days of NPWT initiation are summarized in Tables 6A and 6B. Costs specific to NPWT were broken out by payments for durable medical equipment

(DME) (HCPCS codes: A6550, E2402, G0456, G0457) and professional claims (CPT codes: 97605–97608) for NPWT-specific costs. The care of children treated primarily as outpatients involved significantly higher total NPWT-related costs, insurance reimbursement, and patient out-of-pocket expenses compared to children treated primarily as inpatients, with the majority of the expenses in both groups related to DME.

For non-NPWT related costs within 30 days of NPWT placement, children treated primarily as inpatients incurred significantly higher median total costs (\$12,657.14 inpatient vs \$2,354.45 outpatient), professional payments (\$5,354.38 inpatient vs \$1,013.09 outpatient), out-of-pocket payments (\$170.98 inpatient vs \$103.55 outpatient), facility payments (\$4,565.32 inpatient vs \$1,039.68 outpatient), and insurance reimbursement (\$11,765.75 inpatient vs \$2,088.21 outpatient), than children treated primarily as outpatients.

Discussion

Given the recent development of portable NPWT systems, providers have the opportunity to transition complex wound management from the inpatient to outpatient setting. Only a handful of studies, however, have investigated outpatient NPWT use, none of which have focused on the pediatric population. The purpose of our study, therefore, was to leverage the MarketScan Database to perform a population-level analysis of outpatient versus inpatient NPWT use in infants and children over an 8-year period in the United States. To our knowledge, this is the first study in the pediatric population describing the patient characteristics, indications, complications, healthcare utilization, and cost profile associated with outpatient versus inpatient NPWT.

Our population-level analysis revealed that of the 3184 patients treated with NPWT, half were treated primarily in the outpatient setting. Compared to inpatient treatment, outpatient NPWT was more common in the treatment of medical diseases that are typically managed in the outpatient setting – ulcers and pilonidal cysts. Although significantly fewer patients who underwent musculoskeletal surgery were treated as outpatients compared to inpatients (24% vs 58%, $p < 0.001$), the second most common indication for outpatient NPWT was musculoskeletal surgery (24% of all outpatient NPWT indications), second only to pilonidal cysts (37%).

The most common indication for inpatient NPWT was musculoskeletal surgery (58% of all inpatient NPWT indications), followed by major abdominal surgery (19%). Relative to outpatient NPWT use, inpatient use was significantly more common in the treatment of all post-surgical conditions, except for surgeries deemed “other” – which included arteriovenostomy and breast, neck, thyroid, and peripheral bypass surgery. Additionally, burns and osteomyelitis were more commonly reported as indications for inpatient NPWT management. Post-surgical patients who have undergone major abdominal, cardiothoracic, or neurological surgery require close inpatient monitoring, thus precluding them from outpatient NPWT. Patients with osteomyelitis typically require 6 weeks of intravenous antibiotics, which may require inpatient care. Finally, burn patients requiring NPWT may have suffered severe burns, placing them at high risk for disrupted thermoregulation, severe dehydration, life-threatening electrolyte imbalances, and infection, thus necessitating

hospitalization. Overall, the children treated as inpatients were likely more ill than those treated in the outpatient setting.

In 2011, the United States Food and Drug Administration issued an official communication regarding NPWT complications.(28) From 2007–2011, 12 deaths and 174 injuries associated with NPWT were reported.(28) Nine of the deaths and 27 of the injuries were attributed to bleeding.(28) Over half of the patients suffered new-onset or worsening infections related to retained dressing pieces. Further studies have demonstrated that bleeding(29–34), infection or sepsis related to retained sponges(35–41), and fistula formation(37, 41–43) are potential complications of NPWT. We sought, therefore, to determine the new-onset complications within 30 days of NPWT initiation in the outpatient versus inpatient settings. Incident complication rates after NPWT initiation were low; only 2.4% of children treated primarily as outpatients and 6% of those treated as inpatients suffered a complication. Although low in both groups, there were significantly lower rates of serious complications with outpatient NPWT relative to inpatient, including bleeding, surgical site infection, sepsis, or septicemia. This difference is logical and likely attributable to selection bias; the children treated primarily as inpatients were generally more ill than outpatients and, thus, more prone to complications related and unrelated to NPWT. After controlling for hematological comorbidity and indication for NPWT use, children treated with NPWT as outpatients were about half as likely to suffer any complication than inpatients. This could suggest that outpatient NPWT should be prioritized if there are no additional indications for hospitalization; however, strong conclusions cannot be drawn as the claims data did not allow for direct comparison of outpatients treated with NPWT to inpatients who were solely admitted to the hospital for NPWT. Expectedly, hematologic comorbidities or “other” surgeries were associated with almost 2-fold and 4-fold increased risks of developing a complication, respectively. These complications were likely related to bleeding, given that surgeries within the “other” category included peripheral vascular bypass surgery and arteriovenostomy. Given the data available in the MarketScan database, we cannot definitively conclude that the incident adverse conditions we identified within the first 30 days after NPWT were related to NPWT itself; therefore, we may be overestimating the complications attributable to NPWT.

Depending on the indication for NPWT management, prolonged NPWT use may be necessary. When able, and particularly if possible for prolonged use, NPWT administration in the outpatient setting has several advantages. First, outpatient therapies reduce the risk of nosocomial infections. Second, outpatient management reduces the risk of psychiatric disturbances in the child. One month after hospitalization or surgery, 52–78% of children ages 3–12 years old have emotional or behavioral changes, including sleep or eating disorders, developmental regression, or death anxieties.(18) Additional studies suggest that hospitalization can have a permanent effect on a child’s developing personality.(20) Third, outpatient therapies have been shown to cause less disruption to family life, reduce the risk of separation anxiety, and improve patient and parent satisfaction.(21, 22, 44)

Another important aspect of NPWT in infants and children is pain sensitivity. Prior studies have shown that pain associated with NPWT initiation and with subsequent dressing changes is one of the foremost patient complaints.(45, 46) Expert opinion panels suggest

that the use of sedation or anesthesia prior to performing dressing changes in pediatric patients may decrease pain, discomfort, and psychological trauma.(47, 48) We were unable to assess quality-of-life metrics or pain scores. Therefore, we utilized visits requiring anesthesia or sedation within 30 days after NPWT initiation as a proxy for severe pain with dressing changes. We found that children treated as inpatients were significantly more likely to be given anesthesia (65% vs 25%) or sedation (4% vs 1%) than children treated as outpatients. Across both groups, however, most patients did not require anesthesia or sedation within 30 days after NPWT initiation, suggesting that NPWT management can be successfully executed without sedation or anesthesia in both the inpatient and outpatient settings.

Costs are a major concern when considering healthcare delivery. In 2017, healthcare spending accounted for 17.9% (\$3.5 trillion) of the United States Gross Domestic Product, with 33% related to hospital care, 20% to physician and clinical services, and 2% to DME. (49) A recent study revealed that the total annual Medicare spending estimate for wound management is \$28–97 billion.(50) Given this cost burden, we sought to determine the costs attributable to NPWT and costs not directly attributable to NPWT (non-NPWT-specific costs). Although total NPWT-specific costs were significantly higher with outpatient NPWT, total costs (including NPWT- and non-NPWT-specific costs) within 30 days after NPWT initiation were significantly higher with inpatient NPWT use. The total increased costs of the inpatient group are logical and likely reflect selection bias with the inpatient patient group being more ill than the outpatient patient group, thus necessitating inpatient care. NPWT-specific costs were significantly higher in the outpatient group, and this is logical given the nature of inpatient care reimbursement and the limitations related to the reliability of the claims data. Many of the inpatient claims specific to NPWT may not have been reimbursed given that inpatient stays are a global reimbursement tied to a diagnosis-related group; therefore, it is difficult to disentangle NPWT and non-NPWT specific costs in the inpatient setting. For inpatients, for example, providers may be less likely to bill for vacuum changes related to a procedure as they are unlikely to be reimbursed based on the global reimbursement system. Additionally, supplies used for vacuum changes from hospital floors may go unbilled. Given these limitations, inpatient NPWT-specific costs are likely underestimated. It is logical that total charges were higher in the inpatient group as they incur costs not only related to NPWT, but to their additional comorbidities and illnesses requiring hospital admission. Since we were unable to control for these confounding variables in our cost analysis, future studies that compare costs for outpatients treated with NPWT to inpatients solely admitted for NPWT management are needed to investigate whether outpatient NPWT is more cost-effective than inpatient NPWT.

Despite the strengths of our study, there are several limitations, many of which are inherent to utilizing a claims database. The claims data may not be completely accurate, as the assigned ICD-9-CM diagnosis codes may be incorrect. A major limitation to using claims data is the lack of granular details about the wound. As such, we are unable to comment on the size or severity of wounds, which could conceivably have been different between the two groups and have led to the difference in complications that were observed. To determine the indication for NPWT, we examined diagnosis and procedure codes within 6 months prior to NPWT placement; therefore, indications for NPWT that were coded more than 6 months

prior to NPWT initiation may have been missed. We were unable to control for the severity of injury, and had no replicate surrogate measures for severity. Minor complications that lack ICD-9-CM diagnosis codes or are less commonly coded and the precise details of NPWT management (dressing change frequency, pressure settings, type of foam dressing, etc) could not be evaluated. Apart from the limitations associated with using a claims database, NPWT utilization patterns may have shifted since the end of our study period in 2014. The use of NPWT over infected wounds and closed incisions has become increasingly common, and closed surgical incisions were not included in our indications as they could not be identified. To that end, it is important to note that this analysis was limited to the experiences of patients treated with NPWT between 2006 and 2014, and may not reflect the current practice patterns or outcomes. It is important to note that these findings in healthcare utilization could represent selection bias as inpatients treated with NPWT may have been more ill than patients treated as outpatients. Diagnoses and medical severity could be confounders as patients treated as outpatients likely do not have additional medical or surgical conditions necessitating inpatient management. Additionally, our results may not be generalizable to uninsured patients as the MarketScan Database only includes data from commercially insured patients. Patients from the Southern United States are overrepresented in the MarketScan database because of the states that Truven includes in that region. Claims databases cannot be used to evaluate patient-reported outcomes, which are arguably the most important outcomes for this study question. Therefore, future prospective studies that collect clinical data regarding the size and severity of wounds and utilize patient-reported outcome measures to assess and compare pain, quality of life, and overall experience with NPWT in pediatric outpatients versus inpatients are necessary contributions to the literature. Importantly, our findings summarize the claims data available in MarketScan between 2006 and 2014, and may not be an entirely accurate reflection of the current management and/or experiences of NPWT use among pediatric patients treated in the inpatient versus outpatient setting. Our findings are preliminary; prospective, clinical trials are imperative to better compare the experiences and outcomes of pediatric patients treated with NPWT to determine the necessity of inpatient versus outpatient management.

Conclusions

Our population-level analysis reveals that NPWT is utilized in the outpatient setting with a low complication rate in the pediatric population. Differences in illnesses and indications for use of NPWT in the inpatient versus outpatient setting were observed. NPWT-specific costs were higher in the outpatient setting, but total 30-day expenditures were highest among patients in the inpatient setting. Further studies are necessary to determine the most overall cost-effective treatment setting for NPWT in the pediatric population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Disclosures: Research reported in this publication was supported by the Washington University Institute of Clinical and Translational Sciences grant UL1TR000448 from the National Center for Advancing Translational Sciences

(NCATS) of the National Institutes of Health (NIH), and by the National Institute of Neurological Disorders and Stroke (NINDS) under Award Numbers F32NS098561 (to K.B.S.) and K08NS096232 (to A.K.S.W.).

Additionally, the work was supported by the Center for Administrative Data Research, which is supported in part by the Washington University Institute of Clinical and Translational Sciences grant UL1TR002345 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), Grant Number R24 HS19455 through the Agency for Healthcare Research and Quality (AHRQ), and Grant Number KM1CA156708 through the National Cancer Institute (NCI) at the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health (NIH). All authors have nothing to disclose. The funding sources had no involvement in study design; in the collection, analysis and interpretation of data; in writing of the report; or the decision to submit the article for publication. The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article. All authors have approved the final article.

References

1. Argenta LC, Morykwas MJ Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg* 1997;00338:563–576; discussion 577.
2. Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Ann Plast Surg* 1997;38:553–562. [PubMed: 9188970]
3. Chen SZ, Li J, Li XY, Xu LS Effects of vacuum-assisted closure on wound microcirculation: an experimental study. *Asian journal of surgery* 2005;28:211–217. [PubMed: 16024319]
4. Morykwas MJ, Simpson J, Pungner K, Argenta A, Kremers L, et al. Vacuum-assisted closure: state of basic research and physiologic foundation. *Plast Reconstr Surg* 2006;117:121s–126s. [PubMed: 16799379]
5. Wackenfors A, Sjogren J, Gustafsson R, Algotsson L, Ingemansson R, et al. Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. *Wound repair and regeneration* : official publication of the Wound Healing Society [and] the European Tissue Repair Society 2004;12:600–606.
6. Argenta LC, Morykwas MJ, Marks MW, DeFranzo AJ, Molnar JA, et al. Vacuum-assisted closure: state of clinic art. *Plast Reconstr Surg* 2006;117:127s–142s. [PubMed: 16799380]
7. Santosa KB, Keller M, Olsen MA, Keane AM, Sears ED, et al. Negative-Pressure Wound Therapy in Infants and Children: A Population-Based Study. *Journal of Surgical Research* 2019;235:560–568. [PubMed: 30691843]
8. Fife CE, Walker D, Thomson B, Otto G The safety of negative pressure wound therapy using vacuum-assisted closure in diabetic foot ulcers treated in the outpatient setting. *International wound journal* 2008;5 Suppl 2:17–22. [PubMed: 18577134]
9. Trueman P, Flack S, Loonstra A, Hauser T The feasibility of using V.A.C. Therapy in home care patients with surgical and traumatic wounds in the Netherlands. *International wound journal* 2008;5:225–231. [PubMed: 18494628]
10. Stryja J, Staffa R, Riha D, Stryjova K, Nicielnikova K [Cost-effectiveness of negative pressure wound therapy in outpatient setting]. *Rozhledy v chirurgii : mesicnik Ceskoslovenske chirurgicke spolecnosti* 2015;94:322–328. [PubMed: 26395955]
11. Driver VR, Eckert KA, Carter MJ, French MA Cost-effectiveness of negative pressure wound therapy in patients with many comorbidities and severe wounds of various etiology. *Wound repair and regeneration* : official publication of the Wound Healing Society [and] the European Tissue Repair Society 2016;24:1041–1058.
12. Mushin OP, Bogue JT, Esquenazi MD, Toscano N, Bell DE Use of a home vacuum-assisted closure device in the burn population is both cost-effective and efficacious. *Burns : journal of the International Society for Burn Injuries* 2017;43:490–494. [PubMed: 28256293]
13. Dowsett C, Davis L, Henderson V, Searle R The economic benefits of negative pressure wound therapy in community-based wound care in the NHS. *International wound journal* 2012;9:544–552. [PubMed: 22321132]

14. Ker H, Al-Murrani A, Rolfe G, Martin R WOUND Study: A Cost-Utility Analysis of Negative Pressure Wound Therapy After Split-Skin Grafting for Lower Limb Skin Cancer. *J Surg Res* 2019;235:308–314. [PubMed: 30691811]
15. Moffatt CJ, Mapplebeck L, Murray S, Morgan PA The experience of patients with complex wounds and the use of NPWT in a home-care setting. *Journal of wound care* 2011;20:512, 514, 516, passim.
16. Ottosen B, Pedersen BD Patients' experiences of NPWT in an outpatient setting in Denmark. *Journal of wound care* 2013;22:197–198, 200–192, 204–196. [PubMed: 23702673]
17. Monsen C, Acosta S, Kumlien Patients experiences of negative pressure wound therapy at home for the treatment of deep perivascular groin infection after vascular surgery. *J Clin Nurs* 2017;26:1405–1413. [PubMed: 28001332]
18. Bar-Mor G Preparation of children for surgery and invasive procedures: milestones on the way to success. *Journal of pediatric nursing* 1997;12:252–255. [PubMed: 9271886]
19. Brain DJ, Maclay I Controlled study of mothers and children in hospital. *Br Med J* 1968;1:278–280. [PubMed: 20791444]
20. Briggs RF The emotional needs of children in hospital. *Canadian Medical Association journal* 1966;94:485–487. [PubMed: 5907321]
21. Orme LM, Babl FE, Barnes C, Barnett P, Donath S, et al. Outpatient versus inpatient IV antibiotic management for pediatric oncology patients with low risk febrile neutropenia: a randomised trial. *Pediatric blood & cancer* 2014;61:1427–1433. [PubMed: 24604835]
22. Stanwick RS, Horne JM, Peabody DM, Postuma R Day-care versus inpatient pediatric surgery: a comparison of costs incurred by parents. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* 1987;137:21–26.
23. Wright MC Behavioural effects of hospitalization in children. *Journal of paediatrics and child health* 1995;31:165–167. [PubMed: 7669371]
24. Hansen L The Truven Health MarketScan Databases for life sciences researchers. Truven Health Analytics, 2017.
25. Simon TD, Cawthon ML, Stanford S, Popalisky J, Lyons D, et al. Pediatric medical complexity algorithm: a new method to stratify children by medical complexity. *Pediatrics* 2014;133:e1647–1654. [PubMed: 24819580]
26. Klabunde CN, Potosky AL, Legler JM, Warren JL Development of a comorbidity index using physician claims data. *Journal of clinical epidemiology* 2000;53:1258–1267. [PubMed: 11146273]
27. CDC Surgial Site Infection (SSI) Event. 1 2013;9–1 - 9–21.
28. U.S. Food and Drug Administration UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems: FDA Safety Communication. 2011.
29. Kiessling AH, Lehmann A, Isgro F, Moritz A Tremendous bleeding complication after vacuum-assisted sternal closure. *Journal of cardiothoracic surgery* 2011;6:16. [PubMed: 21306630]
30. Li Z, Yu A Complications of negative pressure wound therapy: a mini review. *Wound repair and regeneration : official publication of the Wound Healing Society [and] the European Tissue Repair Society* 2014;22:457–461.
31. Petzina R, Malmsjo M, Stamm C, Hetzer R Major complications during negative pressure wound therapy in poststernotomy mediastinitis after cardiac surgery. *The Journal of thoracic and cardiovascular surgery* 2010;140:1133–1136. [PubMed: 20832086]
32. Sjogren J, Gustafsson R, Nilsson J, Lindstedt S, Nozohoor S, et al. Negative-pressure wound therapy following cardiac surgery: bleeding complications and 30-day mortality in 176 patients with deep sternal wound infection. *Interactive cardiovascular and thoracic surgery* 2011;12:117–120. [PubMed: 21106567]
33. Vos RJ, Yilmaz A, Sonker U, Kloppenburg GT Acute mediastinal bleeding during vacuum-assisted closure. *International wound journal* 2013;10:348–350. [PubMed: 22630562]
34. White RA, Miki RA, Kazmier P, Anglen JO Vacuum-assisted closure complicated by erosion and hemorrhage of the anterior tibial artery. *Journal of orthopaedic trauma* 2005;19:56–59. [PubMed: 15668586]
35. Beral D, Adair R, Peckham-Cooper A, Tolan D, Botterill I Chronic wound sepsis due to retained vacuum assisted closure foam. *BMJ (Clinical research ed.)* 2009;338:b2269.

36. Caniano DA, Ruth B, Teich S Wound management with vacuum-assisted closure: experience in 51 pediatric patients. *J Pediatr Surg* 2005;40:128–132. [PubMed: 15868572]
37. de Jesus LE, Martins AB, Oliveira PB, Gomes F, Leve T, et al. Negative pressure wound therapy in pediatric surgery: How and when to use. *J Pediatr Surg* 2018;53:585–591. [PubMed: 29241963]
38. Dessy LA, Serratore F, Corrias F, Parisi P, Mazzocchi M, et al. Retention of polyurethane foam fragments during VAC therapy: a complication to be considered. *International wound journal* 2015;12:132–136. [PubMed: 23590296]
39. Leijnen M, Steenvoorde P A retained sponge is a complication of vacuum-assisted closure therapy. *The international journal of lower extremity wounds* 2008;7:51. [PubMed: 18372273]
40. Mazoch M, Montgomery C Retained wound vacuum foam in non-healing wounds: a real possibility. *Journal of wound care* 2015;24:S18–20. [PubMed: 26075511]
41. Rentea RM, Somers KK, Cassidy L, Enters J, Arca MJ Negative pressure wound therapy in infants and children: a single-institution experience. *J Surg Res* 2013;184:658–664. [PubMed: 23768766]
42. Baharestani MM Use of negative pressure wound therapy in the treatment of neonatal and pediatric wounds: a retrospective examination of clinical outcomes. *Ostomy/wound management* 2007;53:75–85. [PubMed: 17586874]
43. Shaikh IA, Ballard-Wilson A, Yalamarathi S, Amin AI Use of topical negative pressure in assisted abdominal closure does not lead to high incidence of enteric fistulae. *Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland* 2010;12:931–934. [PubMed: 19438884]
44. Othersen BH Jr., Clatworthy HW Jr. Outpatient herniorrhaphy for infants. *American journal of diseases of children (1960)* 1968;116:78–80. [PubMed: 5690520]
45. Upton D, Andrews A Negative pressure wound therapy: improving the patient experience. Part 1 of 3. *Journal of wound care* 2013;22:552–557. [PubMed: 24142077]
46. Waldie K Pain associated with negative pressure wound therapy. *British journal of nursing (Mark Allen Publishing)* 2013;22:S15–16, s18–21.
47. Baharestani M, Amjad I, Bookout K, Fleck T, Gabriel A, et al. V.A.C. Therapy in the management of paediatric wounds: clinical review and experience. *International wound journal* 2009;6 Suppl 1:1–26.
48. Horn PL, Ruth B, Kean JR Use of wound V.A.C. therapy in pediatric patients with infected spinal wounds: a retrospective review. *Orthopedic nursing* 2007;26:317–322; quiz 323–314. [PubMed: 17921893]
49. National Health Expenditures 2017 Highlights. *Centers for Medicare & Medicaid Services*:1–3.
50. Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, et al. An economic evaluation of the impact, cost, and medicare policy implications of chronic nonhealing wounds. *Value in Health* 2018;21:27–32. [PubMed: 29304937]

Table 1.

Demographics of pediatric patients treated with NPWT

Characteristic	Inpatient	Outpatient
Total (%)	1621	1563
Age		
0–1	107 (7)	31 (2)
2–11	433(27)	239 (15)
12–17	1081 (67)	1293 (83)
Female	593 (37)	587 (38)
Region		
Northeast	193(12)	163 (10)
North Central	429 (26)	403 (26)
South	723 (45)	724 (46)
West	230 (14)	234 (15)
Unknown	46 (3)	39 (3)
Surgical Indication	1283 (79)	522 (33)
Comorbidities		
Neurological	205 (13)	163 (10)
Musculoskeletal	228 (14)	137 (9)
Mental Health	174 (11)	129 (8)
Respiratory	163 (10)	73 (5)
Dermatological	86 (5)	102 (7)
Cardiac	129(8)	46 (3)
Gastrointestinal	89 (5)	30 (2)
Renal	56 (3)	50 (3)
Endocrine	50 (3)	31 (2)
Immunological	29 (2)	19 (1)
Malignant	57 (4)	35 (2)
Metabolic	51 (3)	15 (1)
Hematological	76 (5)	21 (1)
Ophthalmological	15 (1)	5 (0)
Otological	0 (0)	1 (0)
Genitourinary	10 (1)	5 (0)
Craniofacial	5 (0)	1 (0)
Genetic	38 (2)	14 (1)

Table 2.

Indications for NPWT placement

Indication for NPWT Placement*	Inpatient (n=1621)	Outpatient (n=1563)	<i>p</i>
Post-surgical NHSN categories, n (%)			
Major Abdominal	307 (19)	110 (7)	<0.001
Cardiothoracic	93 (6)	15 (1)	<0.001
Musculoskeletal	940 (58)	369 (24)	<0.001
Neurological	127 (8)	64 (4)	<0.001
Other	23 (1)	13 (1)	0.117
Other common clinical diagnoses			
Burn	81 (5)	54 (3)	0.031
Osteomyelitis	189 (12)	87 (6)	<0.001
Pilonidal cyst	86 (5)	571 (37)	<0.001
Ulcer	91 (6)	156 (10)	<0.001
Setting of initial NPWT placement			
Inpatient	1604 (99)	199 (13)	<0.001
Outpatient	17 (1)	1364 (87)	<0.001

NHSN-National Healthcare Safety Network

* Identified in the six months prior to NPWT initiation

Table 3A.

Pre-existing adverse conditions in the six months before NPWT placement

Condition	Inpatient (n=1621) N (%)	Outpatient (n=1563) N (%)	<i>P</i>
Bleeding	221 (14)	83 (5)	<0.001
Cellulitis or abscess	318 (20)	402 (26)	<0.001
Fistula	8 (0)	1 (0)	0.020
Sepsis	140 (9)	31 (2)	<0.001
Septicemia	78 (5)	12 (1)	<0.001
Surgical site infection	480 (30)	243(16)	<0.001

Table 3B.

Incident complications in the 30 days after NPWT placement

Condition*	Inpatient (n=1621) N (%)	Outpatient (n=1563) N (%)	P
Any complication	97 (6)	37 (2)	<0.001
Bleeding	17 (1)	2 (0)	0.001
Cellulitis or abscess	22 (1)	14 (1)	0.218
Fistula	2 (0)	0 (0)	0.500
Sepsis	15 (1)	1 (0)	0.001
Septicemia	13 (1)	2 (0)	0.007
Surgical site infection	38 (2)	19 (1)	0.016

* If the patient suffered a complication prior to NPWT, a new complication with the same classification could not be differentiated from the pre-NPWT complication based on the claims data available. i.e. a patient with bleeding before NPWT could not have a bleeding complication after NPWT.

Table 4.

Multivariable analysis of risk for any complication after NPWT

	OR of any complication (95% CI)	<i>P</i>
Setting of NPWT treatment		
Inpatient	Reference	
Outpatient	0.57 (0.38 – 0.86)	0.007
Comorbidities		
Hematological	2.10 (1.08 – 4.09)	0.029
Surgical indications		
Major Abdominal	1.95 (1.29 – 2.95)	0.002
Neurological	1.64 (0.92 – 2.94)	0.096
Other *	3.91 (1.54 – 9.94)	0.004
Clinical Indications		
Pilonidal cyst	0.29 (0.12 – 0.67)	0.004

OR-odds ratio

* e.g. breast, neck, or thyroid surgery; peripheral vascular bypass surgery; arteriovenostomy

Table 5.

Healthcare utilization during the 30 days after NPWT initiation

	Inpatient (n=1621)	Outpatient (n=1563)	p
Patients with at least one	N (%)	N (%)	
Visit utilizing anesthesia *	1051 (65)	394 (25)	<0.001
Visit utilizing sedation *	61 (4)	15 (1)	<0.001
ED visit (treat and release) *	175 (11)	148 (9)	0.215
ED visit resulting in inpatient admission *	300 (19)	38 (2)	<0.001
Home health visit *	510(31)	577 (37)	0.001
Inpatient hospitalization †	597 (37)	140 (9)	<0.001
Total hospitalization length of stay with inpatient admission, median days (range)	7 (1–378)	3 (1–84)	<0.001

ED-emergency department

* These visits do not include the NPWT index date.

† Inpatient hospitalization is any admission on or after the index date of NPWT. Therefore, if index date of NPWT occurred during an inpatient hospitalization, then that hospitalization was not included.

Table 6A.

NPWT specific costs 30 days after NPWT initiation, broken out by durable medical equipment and CPT professional claims.

	Variable	Inpatient ^{*§}	Outpatient ^{*§}	<i>p</i>
Total^{†‡}		Median (range)	Median (range)	
Professional (CPT Codes)	PAY	64.01 (0 – 11460.24)	142.32 (0 – 23062.32)	<0.001
DME (HCPCS Codes)	PAY	2512.06 (0 – 11251.61)	3105.26 (0 – 13558.95)	<0.001
Insurance reimbursement^{†‡}				
Professional (CPT Codes)	NETPAY	60.38(0 – 11460.24)	106.82 (0 – 23062.32)	<0.001
DME (HCPCS Codes)	NETPAY	2372.51 (0 – 10396.35)	2855.13(0 – 10288.02)	<0.001
Patient out-of-pocket expenses^{†‡}				
Professional (CPT Codes)	Sum(COPAY, DEDUCT, COINS)	0 (0 – 1316.48)	0 (0 – 2449.39)	<0.001
DME (HCPCS Codes)	Sum(COPAY, DEDUCT, COINS)	0 (0 – 2398.48)	0 (0 – 6667.73)	<0.001

CPT- Current Procedural Terminology, DME-durable medical equipment, HCPCS-Healthcare Common Procedure Coding System

^{*} 6 children were excluded from cost analysis because they had no charges in the follow up period.

[†] Same variables are used, except professional charges only used lines coded for NPWT with CPT codes (97605–97608), and DME charges only used lines with HCPCS codes (A6550, E2402, G0456, G0457).

[‡] All values from lines coded for NPWT (CPT or HCPCS).

[§] Costs adjusted for inflation to 2014 dollars.

Table 6B.

Non-NPWT specific costs 30 days after NPWT initiation

	Variable	Inpatient ^{*,†}	Outpatient ^{*,†}	<i>p</i>
Total, median (range) [‡]	PAY	12657.14 (0–1293745.06)	2354.45 (0 – 830908.25)	<0.001
Professional payments [‡]	PAY (facprof=P)	5354.38 (0 – 197377.73)	1013.09 (0 – 139329.91)	<0.001
Facility payments [‡]	PAY (facprof=F)	4565.32 (0 – 1253476.92)	1039.68 (0– 691578.34)	<0.001
Insurance reimbursement [‡]	NETPAY	11765.75 (0 – 1292821.86)	2088.21 (0 – 830242.18)	<0.001
Patient out-of-pocket expenses [‡]	Sum(COPAY, DEDUCT, COINS)	170.98 (0 – 26086.11)	103.55 (0 – 13981.82)	<0.001

* 6 children were excluded from cost analysis because they had no charges in the follow up period.

[†]Excluding NPWT-specific costs as in Table 6A.

[‡]Costs adjusted for inflation to 2014 dollars.