Negative Pressure Wound Therapy: Comparison of Outpatient and Inpatient Approaches

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ABSTRACT

Background: The results of recent studies regarding the efficacy of Negative Pressure Wound Therapy (NPWT) for the prevention of sternal wound infection (SWI) after adult cardiac surgery are not conclusive.

Methods: Data were collected from patients who were operated upon at the GVM Care & Research group in Italy from 2013 to 2021; all patients who required treatment for sternotomy wound infection with Negative Pressure Wound Therapy (NPWT) through WaterLily™ system (Eurosets, Medolla, MO, Italy) were selected. We compared the preoperative risk characteristics, and particularly those that were most strongly associated with possible dehiscence of the wound. A statistical analysis was performed for comparison of the groups.

Results: Out of the total 40,267 patients who underwent cardiac surgery with extracorporeal circulation within this time frame, 1,483 (3.68%) required NPWT, including 690 (46.52%) in the HOME group and 793 (53.47%) in the HOSPITAL group (p =0.76). Thirty-nine (5.65%) patients in the HOME group and 37 (4.66%) in the HOSPITAL group required re-treatment for re-dehiscence after secondary closure (p =0.79).

Conclusions: The use of a WaterLily™ system (Eurosets, Medolla, MO, Italy) was safe and effective for the treatment of sternotomy wounds with superficial and deep infections and was associated with a low rate of dehiscence, even when used with discharged and managed outpatient patients.

BACKGROUND

Post-surgical wound care, especially in cardiac surgery, remains an important problem that is burdened by the risk of mediastinitis and mortality.[1,2] Patients who require a cardiac surgeon have characteristics that are associated with a higher risk of wound infection (for example, they are often diabetic, elderly, or frail).[3,4] The use of wound care systems that include the suction of secretions and vacuum has significantly improved the outcome of these patients. However, there is often still a need for long-term care, especially in cases that require antibiotic therapy against resistant germs.[4]

Vacuum-generation equipment has been significantly miniaturized (Fig. 1). One of the objectives of this miniaturization is to minimize care in an in-hospital environment and favor home management.[5,6]

The potential advantages and risks of wound care with a Negative Pressure Wound Therapy (NPWT) system in a home or inpatient setting are not yet known. Furthermore, little is known of the feasibility of this home approach in cases where the sponge is positioned under vacuum in a pre- or infra-sternally.[7,8] The purpose of this study was to compare home and inpatient care strategies in a large population of patients undergoing therapy for sternal wound infection with a vacuum system.[9,10]

MATERIALS AND METHODS

Data were collected from patients who were operated upon at the GVM Care & Research group in Italy from 2013 to 2021, and particularly all patients who required treatment of a sternotomy wound infection with the WaterLily™ system (Eurosets, Medolla, MO, Italy) (Fig. 1). Of the total 40,267 patients who were operated upon in this time frame for cardiac surgery with extracorporeal circulation, 1,483 (3.68%) required this therapy.

The indication for implantation of the system was determined clinically and assessed on a case-by-case basis by the surgeon. The depth of the wound was staged according to international guidelines.[11] Implantation of the NPWT therapy system was always performed under local anesthesia even when the sponge was positioned infra-sternally. In the case of sternal diastasis, the previously positioned steel points were removed and bone curettage was performed.[12]

At the first placement of the sponge, wound swab was always performed even if the patient had already started empiric antibiotic therapy before placement of the vacuum system; the mean negative pressure used in the NPWT pump was -125 (mmHg) (Fig. 2).[13]

Based on the patient's preferences, as

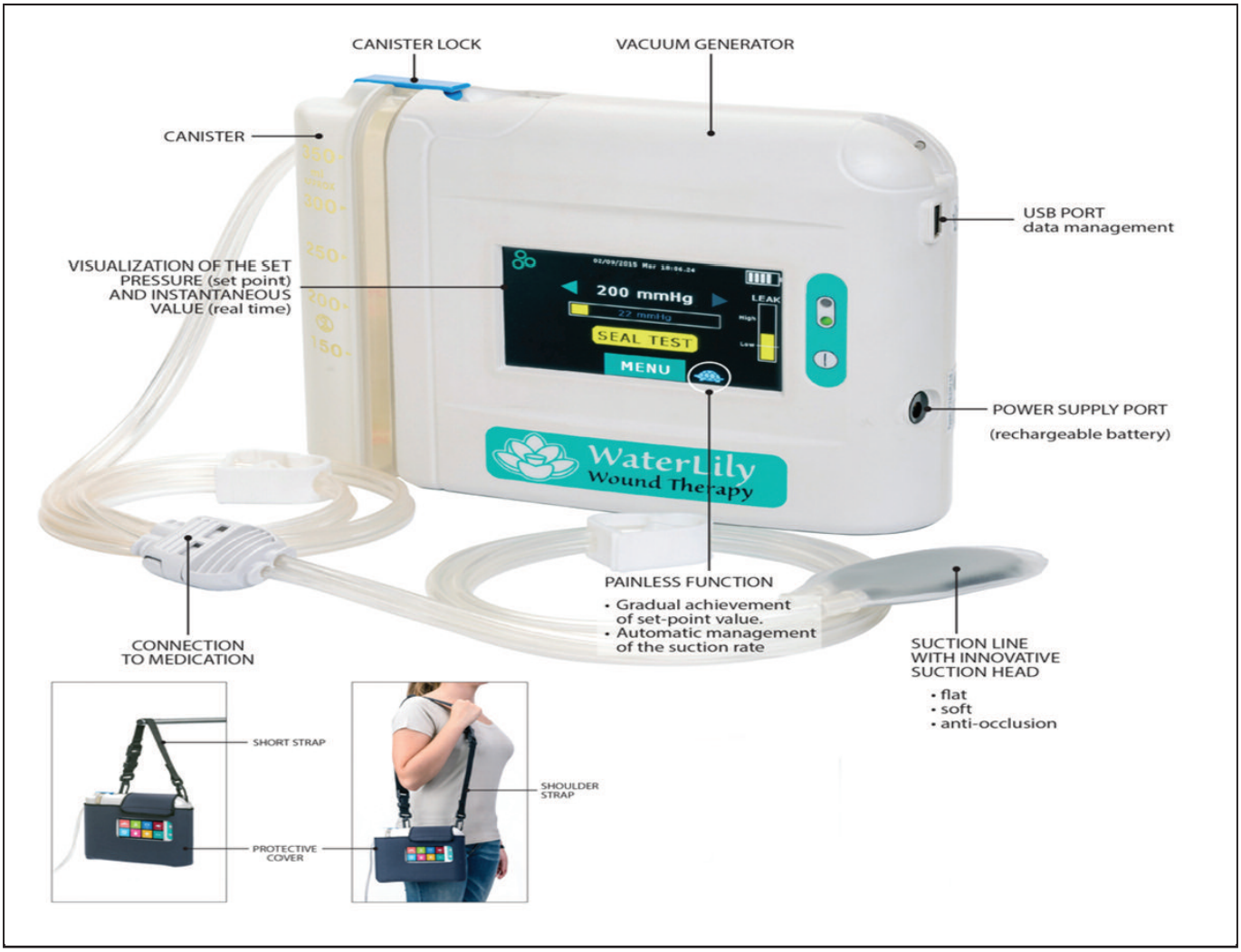

Figure 1. Features of the WaterLily™ system. (Eurosets, Medolla, MO, Italy)

well as the logistical and clinical possibility of discharging the patient at the discretion of the treating physician, some of the patients were discharged with an active system and returned to the clinic only for periodic changes, system malfunctions and secondary wound closure.[14,15]

We compared preoperative risk factors, and particularly those that were most strongly associated with possible dehiscence of the wound, the infectious disease characteristics and the primary outcome (the duration of therapy) in patients who received inpatient therapy to those in patients who underwent therapy as an outpatient. Cases with minimally invasive sternotomy access were excluded.

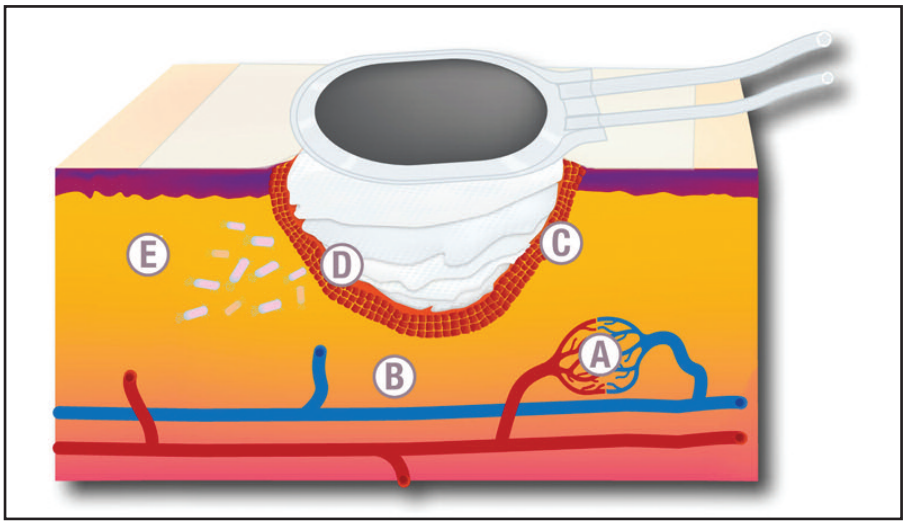

Figure 2. Effects of the suction line, sponge and suction head. (A) Increase the local circulation. (B) Reduce edema. (C) Stimulate the formation of granulation tissue. (D) Stimulate cell proliferation. (E) Reduce the bacterial load.

STATISTICAL ANALYSIS

Continuous data are expressed as the mean ± standard deviation or as the median with the interquartile range and categorical data are shown as percentages. Cumulative survival was evaluated by the Kaplan-Meier method. All reported *p*-values were two-sided, and *p*-values of <0.05 were considered to indicate statistical significance. All statistical analyses were performed with SPSS 22.0 (SPSS, Inc., Chicago, IL, USA).

RESULTS

The characteristics of the patients treated at home (Group HOME) and those treated at the hospital (Group HOSPITAL) are shown in Table I. The HOME and HOSPITAL groups consisted of 690 (46.52%) and 793 (53.47%) patients, respectively (p =0.76). The number of sponge changes needed in the HOME group before achieving secondary closure was 3±1, while that in the HOS-

Table I
Characteristics of the study population

Cardiac Surgery Population (n=40,267)	All n = 1,483	HOME group n = 690 (46.52%)	HOSPITAL group n = 793 (53.47%)	P-value
Age (years)	76 (71–80)	75 (69–78)	76 (67–80)	0.81
Male sex	54.5%	30.15%	24.35%	0.61
Body mass index (kg/m^2)	23.8 (22.2–28.8)	25.8 (23.4–29.0)	26.3 (21.7–28.4)	0.191
Arterial hypertension	32.2%	33.3%	36.1%	0.789
Diabetes mellitus	52%	24%	28%	0.67
Oral antidiabetic drugs	28%	15%	13%	0.73
Diet	13%	6%	7%	0.87
Insulin	11%	5%	6%	0.82
Hypercholesterolemia	77.4%	38.1%	39.3%	0.899
Renal dysfunction*	1.4%	2.3%	2.1%	0.254
Respiratory or lung disease	2.1%	2.3%	1.9%	0.187
Previous disabling stroke	1.5%	1.5%	1.3%	0.687
History of cancer	1.4%	1.9%	2.5%	0.030
Atrial fibrillation	9.4%	8.3%	11.2%	<0.001
Peripheral vascular disease	1.8%	1.6%	1.9%	0.556
CABG surgery	75%	36%	39%	0.81
Bilateral internal thoracic artery use	30%	17%	13%	0.97
LVEF				0.347
>50%	93.0%	92.0%	91.2%	
30–50%	6.3%	7.5%	7.5%	
<30%	0.7%	0.5%	1.3%	
Previous surgery	2.3%	1.7%	1.9%	0.211
EuroSCORE II (%)	1.2 (1.1–2.8)	1.2 (1.1–2.7)	1.2 (1.1–2.8)	0.87

Values are given as median (interquartile range) or percentage. LVEF, left ventricular ejection fraction.
*Dialysis or creatinine >2 mg/dL.

PITAL group was 2±1 (p = 0.78). The number of patients with a sub-sternal wound swab was 190 (27.53%) in the HOME group and 210 (26.48%) in the HOSPITAL group (p =0.83).

The most common microbiological agents causing sternal infection in NPWT patients were staphylococcus and epidermidis in both groups. Antibiotics were chosen based on the results of the wound swab, and the susceptibility of a microorganism was expressed in terms of the minimal inhibitory concentration using an antibiogram. Furthermore, 39 (5.65%) patients in the HOME group required re-treatment for re-dehiscence after secondary closure, while this value was 37 (4.66%) in the HOSPITAL group (p=0.79). The hospital length of stay for patients in the HOSPITAL group was significantly longer than that for the HOME patients, even when every hospital access by the latter group was considered to be a full day of hospitalization with an overnight stay (even for possible dysfunction of the system): HOSPITAL 25 ±2 days versus HOME 8 ±4 days (p = 0.005). None of the patients in the HOME group were converted to the HOSPITAL group and all of the HOME patients were converted to the HOME status after a first sponge exchange in the HOSPITAL approach.

These results show that there were no problems of discomfort or complications related to the use of HOME NPWT management (Table II).

DISCUSSION

Until recently, the morbidity rate for sternal wound dehiscence was close to 50%; however, this has improved with recent advances including sternal fixation techniques and various reconstructive surgical options.[16] Our study demonstrates that home management (HOME patients) of NPWT of superficial and deep sternotomy wounds can represent an organizational / curative strategy that is capable of significantly reducing the hospital stay without compromising the safety or efficacy of the procedure.[17] To help prevent problems and unforeseen events in the group with home-based NPWT , all of the patients were traceable, either directly or indirectly through a family member or the hospital secretariat. A team for inpatient home care, consisting of a doctor and a nurse specialized in the management of NPWT , was made available in case they were needed. This organization has allowed good home management, while building trust in the patient being assisted.

There is currently an emphasis on pharmaco-economy, reduction of healthcare costs, and the need for post-bed treatment for serious pathologies. The approach proposed here can allow us to achieve all of these objectives together.[18] Obviously, our retrospective analysis has several limitations, including the fact that the two groups were not randomized and there was a possible selection bias, since the patients in the HOSPITAL group were probably more "at risk" and therefore kept in the hospital. Despite these limitations, the important result remains that home therapy was shown to be safe and effective. There are doubts related to the patient's ability to manage the device and the possible risk of dislocation of the sponge, especially if it is positioned in the infra-sternal position, but our data showed that this approach is very safe. This is a very interesting and important result in view of the shift from hospital-based to home-based medicine. The efficacy and safety of the "NPWT" treatment system have also been recognized in certain patients at risk [19] and in the setting of cardiac surgery,[18] but our study is the first to compare the effectiveness and safety of the system managed by healthcare professionals in a hospital to those managed by a healthcare staff but in an outpatient setting.

The next potential step is that healthcare professionals would go to the patient for treatment, rather than the patient going to healthcare professionals. In other applications of NPWT, this approach has already been described,[20] but our proposal is absolutely innovative in the field of cardiac surgery. For example, the first NPWT change could occur in the HOME setting, rather than starting with the second change.

Due to its retrospective nature, our study also does not include questionnaires on patient quality of life and satisfaction which, especially in the patients analyzed here, i.e., those with a serious postoperative complication who therefore may have a negative attitude toward healthcare professionals and are psychologically usually anxious / depressed, are very important for making patients feel reassured and potentially also reducing risks of a medico-legal nature. Anecdotally, patients in the HOME group were more satisfied, or rather less dissatisfied, than HOSPITAL patients, but we do not have the data to prove this. Furthermore, we do not have data to demonstrate that the HOME approach is more economically advantageous than the HOSPITAL approach. HOME patients received the same drugs (antibiotics) as the HOSPITAL patients, but were hospitalized for many fewer days. While this should represent a significant reduction in healthcare costs, any numerical confirmation will require additional studies.

Table II
Results and Outcomes

	HOME group n = 690	HOSPITAL group n = 793	p-value
Number of sponge changes (per patient)	3±1	2±1	0.78
Sub-sternal "deep" wound swab	190 (27.53%)	210 (26.48%)	0.83
Secondary closure needed re-treatment	39 (5.65%)	37(4.66%)	0.79
Days of hospitalization	25 ±9	8 ±4	0.005
Days of therapy	23±2	12±4	0.023
Wound closure time (days)	27±4	25±4	0.85
Deaths (n)	8 (1.0%)	6 (0.8%)	0.82

Values represent the mean, median (interquartile range) or percentage.

CONCLUSION

Potential wound complications following median sternotomy include superficial or deep wound infections, desiccation of wound margins, wound breakdown, wound dehiscence, osteomyelitis, mediastinitis, and exposure of vital structures and major vessels. In our experience, the use of a WaterLily™ system (Eurosets, Medolla, MO, Italy) for the management of sternotomic wounds with superficial and deep infections and the low rate of dehiscence was safe and effective even in discharged and managed outpatients. This approach may significantly reduce the hospital length of stay of patients suffering from these complications and is proposed as an intermediate step for the potential management of these wounds entirely at the patient's home. STI

AUTHORS' DISCLOSURES

G Santarpino and I Condello are consultants for Eurosets SPA, Medolla, Italy. The other authors declare that there are no conflicts of interest.

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