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Prophylactic Closed-Incision Negative Pressure Wound Therapy (ciNPWT) in Breast Surgery: A Pilot Study on the Prevention of Surgical Site Complications

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Rezumat

Terapia profilactică cu presiune negativă pe incizia închisă (ciNPWT) în chirurgia mamară: un studiu pilot privind prevenția complicațiilor la locul plagii operatorii

Obiectiv: Complicațiile plăgii operatorii rămân o problemă relevantă în chirurgia mamară, în special la pacientele cu factori de risc precum obezitatea. Terapia cu presiune negativă aplicată pe incizia închisă (ciNPWT) a fost propusă ca strategie de reducere a complicațiilor postoperatorii, inclusiv a formarii seromului. Cu toate acestea, dovezile în cazul mastectomiei fără reconstrucție imediată rămân limitate.
Metode: Acesta este un studiu-pilot observațional prospectiv, unicentric, realizat la Spitalul Universitar Sant'Andrea (Roma). Douăzeci şi două de paciente consecutive la care s-a practicat mastectomie pentru indicații oncologice au fost tratate prin ciNPWT (dispozitiv PICO) şi comparate cu un lot de control de 40 de paciente tratate cu pansamente standard. Fiecare sân a fost considerat o unitate de analiză independentă. Criteriul principal de evaluare a fost seromul postoperator, apreciat clinic şi cuantificat în mililitri. Criteriile secundare au inclus hematomul, necroza cutanată, echimozele, sângerarea postoperatorie, reintervenția şi complianța la dispozitiv. Urmărirea a fost efectuată la 7 şi 14 zile postoperator.
Rezultate: Au fost analizate în total 70 de unități de mastectomie provenite de la 65 de paciente (22 ciNPWT vs 48 în lotul de control). Grupul ciNPWT a avut o vârstă semnificativ mai înaintată (74,09 ± 9,51 vs 65,71 ± 14,12 ani; p = 0,014) şi o proporție mai mare de evidări axilare. La 7 zile, volumul mediu de serom aspirat a fost mai redus în grupul ciNPWT (33,41 ± 59,83 mL vs 44,58 ± 96,49 mL; p = 0,619), fără însă a atinge semnificația statistică. La 14 zile, grupul ciNPWT a prezentat un volum al seromului semnificativ mai mare (59,55 ± 78,95 mL vs 17,02 ± 40,17 mL; p = 0,025). Ratele complicațiilor secundare au fost comparabile între grupuri. Nu s-a observat niciun caz de necroză cutanată. Complianța la dispozitiv a fost de 100%.
Concluzii: Utilizarea ciNPWT prin dispozitivul PICO a demonstrat o siguranță şi o tolerabilitate excelente. Deşi s-a observat o tendință precoce de reducere a seromului, creşterea semnificativă la 14 zile sugerează un posibil efect de rebound

după îndepărtarea dispozitivului. Din cauza limitărilor metodologice, nu se pot formula concluzii definitive privind eficacitatea. Aceste rezultate susțin necesitatea unor studii prospective randomizate multicentrice de amploare mai mare, care să clarifice rolul şi durata optimă a ciNPWT la pacientele supuse mastectomiei.

Cuvinte cheie: chirurgie mamară, ciNPWT prin dispozitivul PICO, mastectomie, serom, complicații la locul intervenției chirurgicale

Abstract

Aim: Surgical wound complications remain a relevant issue in breast surgery, particularly in patients with risk factors such as obesity. Closed-incision negative pressure wound therapy (ciNPWT) has been proposed as a strategy to reduce postoperative complications, including seroma formation. However, evidence in mastectomy without immediate reconstruction remains limited.

Methods: A prospective observational single-center pilot study was conducted at Sant'Andrea University Hospital (Rome). Twenty-two consecutive patients undergoing mastectomy for oncologic indications were treated with ciNPWT (PICO device) and compared with a historical cohort of 40 patients managed with standard dressings. Each breast was considered an independent unit of analysis. The primary endpoint was postoperative seroma, assessed clinically and quantified in milliliters. Secondary endpoints included hematoma, skin necrosis, ecchymosis, postoperative bleeding, reintervention, and device compliance. Follow-up was performed at 7 and 14 days postoperatively.

Results: A total of 70 mastectomy units from 65 patients were analyzed (22 ciNPWT vs 48 controls). The ciNPWT group was significantly older (74.09 ± 9.51 vs 65.71 ± 14.12 years; p = 0.014) and had a higher proportion of axillary dissections. At 7 days, mean aspirated seroma volume was lower in the ciNPWT group (33.41 ± 59.83 mL vs 44.58 ± 96.49 mL; p = 0.619), although not statistically significant. At 14 days, the ciNPWT group showed a significantly higher seroma volume (59.55 ± 78.95 mL vs 17.02 ± 40.17 mL; p = 0.025). Secondary complication rates were comparable between groups. No skin necrosis was observed. Device compliance was 100%.

Conclusions: ciNPWT using the PICO device demonstrated excellent safety and tolerability. While an early trend toward reduced seroma was observed, a significant increase at 14 days suggests a possible rebound effect after device removal. Due to methodological limitations, definitive conclusions on efficacy cannot be drawn. These findings support the need for larger prospective randomized multicenter studies to clarify the role and optimal duration of ciNPWT in mastectomy patients.

Keywords: breast surgery, ciNPWT, PICO, mastectomy, seroma, surgical site complications

Introduction

Surgical wound complications represent a significant clinical concern across multiple surgical specialties, including breast surgery, with a substantial impact on postoperative outcomes, patient quality of life, and healthcare costs. Surgical site infections (SSIs) are defined as infections occurring within 30 days after surgery and may involve the skin, subcutaneous tissue, deep soft tissues, or organs/spaces related to the surgical procedure (1,2). These complications may result in wound dehiscence, seroma and hematoma formation, skin necrosis, and delayed wound healing, leading to prolonged hospitalization and potential delays in the initiation of adjuvant oncologic therapies (1,3,4).

Among the main risk factors for postoperative complications, obesity plays a particularly relevant role. Excess adipose tissue represents a multifactorial risk factor for surgical site infections, seroma formation, hematomas, and wound dehiscence. Obesity is associated with chronic low-grade inflammation, reduced tissue perfusion, and impaired wound healing (5-9). Reduced tissue oxygenation and altered immune response further create a favorable environment for bacterial proliferation and delayed reparative processes (5,10-12). Multiple large-scale studies have demonstrated that increasing body mass index (BMI) is an independent predictor of wound complications in breast cancer surgery, with SSI rates rising progressively from 4.66% in patients with BMI 20 -25 to 10.58% in those with BMI >40 (2,13-19). Considering the increasing global prevalence of obesity, the management of this risk factor represents a growing challenge for modern surgery (5,6,20).

Surgical wounds are traditionally classified into four categories-clean, clean-contaminated, contaminated, and dirty-based on intraoperative contamina-

tion and infection risk (21). Although breast surgery is generally classified as clean surgery, wound complications remain relatively frequent, particularly in patients with specific risk factors (2,13-19,22). Even in elective breast surgery, complications such as seroma formation, hematomas, and skin flap necrosis are relatively common and may lead to prolonged hospital stay, increased outpatient visits, and delayed initiation of adjuvant oncologic therapies (3,4,23-25).

In recent years, Negative Pressure Wound Therapy (NPWT) has shown promising results in preventing surgical wound complications. Initially developed for the management of complex wounds, this technique has progressively been applied to closed surgical incisions for prophylactic purposes, known as closed-incision Negative Pressure Wound Therapy (ciNPWT) (26,27). The mechanism of action includes reduction of edema, improvement of local perfusion, decreased tension across wound edges, and removal of subcutaneous fluid, thereby promoting wound healing (26-31). At the molecular level, NPWT appears to shift the cytokine profile toward an anti-inflammatory phenotype, promote angiogenesis through increased vascular endothelial growth factor expression, and enhance extracellular matrix remodeling (27,28,31).

Several studies and meta-analyses have demonstrated the effectiveness of NPWT in reducing postoperative complications. Recent meta-analyses showed a significant reduction in surgical site infections across different surgical specialties, with high level of evidence (1,32-37). A comprehensive meta-analysis including 28 randomized controlled trials (n=4398) demonstrated that incisional ciNPWT reduced SSI with a relative risk of 0.61 (95% CI: 0.49-0.76, p<0.0001) and a number needed to treat of 19 (32). The World Health Organization issued a conditional recommendation for the use of prophylactic ciNPWT on primarily closed surgical incisions in high-risk wounds for the purpose of preventing SSI (38). Other studies reported reduced complications in abdominal surgery and abdominal wall reconstruction, suggesting a prophylactic role of ciNPWT in high-risk patients (39-42).

In breast surgery, the use of negative pressure therapy has been associated with a significant reduction in seroma formation, aspirated volume, and number of percutaneous aspirations. A systematic review and meta-analysis specific to breast surgery, including seven studies with 1500 breast incisions, demonstrated that ciNPWT was associated with significantly lower rates of total wound complications (OR 0.36; 95% CI 0.19-0.69; P=0.002), SSI (OR 0.45; 95% CI 0.24-0.86; p=0.015), seroma (OR 0.28; 95% CI 0.13-0.59; p=0.001), wound dehiscence (OR 0.49; 95% CI 0.32-0.72; p<0.001), and wound necrosis (OR 0.38; 95% CI 0.19-0.78; p=0.008) (43). Moreover, prospective studies and systematic reviews have demonstrated a reduction in overall complications, skin necrosis, and wound dehiscence in patients undergoing breast surgery (3,4,23-25,44-46). More recently, observational studies in oncoplastic breast-conserving surgery and immediate prepectoral breast reconstruction have also reported reduced complications and hospital admissions with the use of portable negative pressure dressings (47,48).

Despite the available evidence, the routine use of prophylactic negative pressure therapy in breast surgery is not yet standardized. Available data remain heterogeneous and often based on limited sample sizes, highlighting the need for further studies to better define the role of this technology in clinical practice, particularly in patients with risk factors such as obesity and comorbidities (49).

This pilot study aimed to evaluate the effectiveness of prophylactic closed-incision negative pressure wound therapy in patients undergoing mastectomy without immediate reconstruction, compared with a historical control cohort. The primary endpoint was postoperative seroma, quantified in milliliters (mL), while secondary endpoints included skin necrosis, hematoma formation, and ecchymosis. The objective was to provide further evidence on the effectiveness of negative pressure therapy in preventing postoperative complications in breast surgery, with particular attention to patient-related risk factors, including obesity.

Materials and Method

Study Design

A prospective, observational, single-center pilot study was conducted at the Breast Unit of Sant'Andrea University Hospital, Rome, between July 2025 and April 2026, to evaluate the effectiveness of prophylactic ciNPWT using the PICO™ 7 system (Smith & Nephew Medical Ltd., Hull, UK) in preventing seroma formation in patients undergoing mastectomy for oncologic indications.

A total of 22 consecutive patients undergoing mastectomy for oncologic disease were included, regardless of sex (men and women) and type of associated axillary surgery, including sentinel lymph node biopsy, axillary dissection, or no axillary surgery.

Patients were not randomized; treatment allocation was based on routine clinical practice. Patients were assigned either to the ciNPWT group (PICO) or to the standard dressing group according to postoperative wound management. The prospective cohort

included 22 patients treated with ciNPWT, while the control group consisted of 40 consecutive patients treated at the same center with standard dressings prior to the study period.

In cases of bilateral mastectomy, each breast was considered an independent unit of analysis.

At the end of the surgical procedure, a closed suction drain was placed in all patients according to routine clinical practice and in accordance with the ciNPWT device protocol. The drain was removed on postoperative day 1 or 2 when drainage output was <50 mL over the preceding 24 hours, provided no clinical complications were observed.

In the prospective group, closed-incision negative pressure wound therapy (ciNPWT) was applied immediately after completion of skin closure and routine surgical skin disinfection using the PICO™ 7 system (Smith & Nephew Medical Ltd., Hull, UK), according to the manufacturer's instructions, replacing the conventional postoperative dressing. PICO™ 7 is a portable, single-use negative pressure wound therapy system that delivers continuous nominal negative pressure of –80 mmHg through an adhesive absorbent dressing designed for closed surgical incisions. After activation, correct device function and seal integrity were verified before completion of the surgical procedure. The dressing remained in place for 7 days and was removed during the first scheduled outpatient follow-up visit, when it was replaced with a conventional dressing.

In the control group (historical cohort), patients received standard dressing at discharge with outpatient reassessment at 5–7 days.

All patients underwent scheduled outpatient follow-up visits at 5–7 days and again at 12–14 days postoperatively.

The primary endpoint of the study was the presence of postoperative seroma, with volumetric quantification expressed in milliliters (mL). Seroma was assessed clinically and, when detected, quantified by means of percutaneous aspiration.

Secondary endpoints included the occurrence of skin necrosis, hematoma, and ecchymosis, as well as postoperative bleeding, the need for surgical reintervention, and patient compliance with the device.

All patients undergoing oncologic mastectomy at the Breast Unit of Sant'Andrea University Hospital during the study period were consecutively included. Clinical data were collected in anonymized form from electronic medical records and entered into a secure digital database. For each patient, the following variables were recorded: sex, age, type of surgical procedure, type of axillary surgery, presence of seroma and its volume (mL), presence of hematoma, skin necrosis, and ecchymosis, as well as postoperative bleeding, need for reintervention, and compliance with the device.

Eligible patients included both male and female individuals undergoing mastectomy for oncologic disease, regardless of the type of axillary surgery performed, and treated at the Breast Unit of Sant'Andrea University Hospital, provided that written informed consent had been obtained.

Patients were excluded if they were receiving home therapy with anticoagulants or antiplatelet agents other than low-dose aspirin, had a known allergy to adhesive device materials, or had been previously enrolled in other investigational drug studies within the previous year. Additional exclusion criteria included prior chemotherapy for other malignancies within the past five years or ongoing treatment, the presence of severe comorbidities potentially interfering with wound healing, participation in other potentially interfering clinical trials, and inability to ensure adequate postoperative follow-up.

Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Between-group comparisons were performed using the Student's t-test for independent samples for continuous variables and Categorical variables were compared using the chi-square test or Fisher's exact test when appropriate.

The study was conducted in accordance with the Declaration of Helsinki and applicable regulations. Data were collected in anonymized form and managed in compliance with European GDPR regulations.

Given the observational nature of the study and the use of a device already approved and routinely used in clinical practice, the study protocol was submitted to the Department of Sant'Andrea University Hospital, which approved its execution.

Results

During the study period, a total of 70 mastectomy units from 65 patients undergoing mastectomy without immediate reconstruction for oncologic indications were analyzed. The prospective ciNPWT group (PICO) included 22 mastectomy units from 22 patients, whereas the historical control group treated with standard dressings comprised 48 units from 43 patients. One case in the PICO group was lost to follow-up at 14 days and was excluded from the 14-day analysis.

The mean age of the entire sample was 68.34 ± 13.37 years, ranging from 39 to 94 years. The PICO-treated group had a significantly higher mean age compared with the control group (74.09 ± 9.51 vs 65.71

Table 1. Baseline patient characteristics

Variable	PICO Group (n=22)	Control Group (n=48)	p-value
Age, years (mean ± SD)	74.09 ± 9.51	65.71 ± 14.12	0.014
Male sex, n (%)	4 (18.2%)	2 (4.2%)	0.083*
Bilateral mastectomy, n (%)	0 (0%)	5 (10.4%)	0.154*
Axillary surgery, n (%)			0.095
Axillary dissection	11 (50.0%)	14 (29.2%)	
Sentinel lymph node biopsy	4 (18.2%)	21 (43.8%)	
None	7 (31.8%)	13 (27.1%)	

Data are presented as mean ± standard deviation or number (%).
Comparisons between groups were performed using the independent samples t-test for continuous variables and Fisher's exact test for categorical variables.

± 14.12 years; p = 0.014).

In the overall cohort, 6 male patients were included, 4 in the PICO group (18.2%) and 2 in the control group (4.2%). Five bilateral mastectomies were recorded, all belonging to the control group.

The distribution of axillary surgery did not show statistically significant differences between the two groups (p = 0.095). In the PICO group, 11 cases (50.0%) underwent axillary dissection, 4 (18.2%) sentinel lymph node biopsy, and 7 (31.8%) no axillary surgery. In the control group, 14 cases (29.2%) underwent axillary dissection, 21 (43.8%) sentinel lymph node biopsy, and 13 (27.1%) no axillary surgery.

Patient demographics and baseline characteristics are summarized in *Table 1*.

Primary Endpoint: Seroma

At the first outpatient evaluation (7 days), the mean aspirated seroma volume was lower in the PICO group compared with the control group, although the difference did not reach statistical significance (33.41 ± 59.83 mL vs 44.58 ± 96.49 mL; p = 0.619).

At the second evaluation (14 days), the PICO group showed a significantly higher mean aspirated seroma volume compared with the control group (59.55 ± 78.95 mL vs 17.02 ± 40.17 mL; p = 0.025).

Secondary Endpoints

Secondary endpoints showed comparable complications rates between the two groups. In the PICO group, the following events occurred: 1 case of ecchymosis (4.5%), 1 surgical reintervention for bleeding (4.5%), and 1 wound dehiscence (4.5%). In the control group, 2 surgical reinterventions for bleeding (4.2%) and 2 wound dehiscences (4.2%) were observed. No cases of skin necrosis were recorded in either group. One hematoma in the PICO group was managed conservatively with dressing.

Compliance

All patients in the PICO group (22/22, 100%) completed the 7-day treatment with the ciNPWT device, demonstrating excellent tolerability and acceptance of the dressing.

Study outcomes are summarized in *Table 2*.

Table 2. Primary and secondary outcomes

Outcome	PICO Group	Control Group	p-value
Primary endpoint	(n=22)	(n=48)	
Seroma volume at 7 days, mL (mean ± SD)	33.41 ± 59.83	44.58 ± 96.49	0.619
Seroma volume at 14 days, mL (mean ± SD)*	59.55 ± 78.95	17.02 ± 40.17	0.025
Secondary endpoints	(n=22)	(n=48)	
Wound dehiscence, n (%)	1 (4.5%)	2 (4.2%)	1.000
Reoperation for bleeding, n (%)	1 (4.5%)	2 (4.2%)	1.000
Hematoma (conservative management), n (%)	1 (4.5%)	0 (0%)	0.314*
Ecchymosis, n (%)	1 (4.5%)	0 (0%)	0.314*
Skin necrosis, n (%)	0 (0%)	0 (0%)	Not applicable
Device compliance (7 days), %	100%	N/A	Not applicable

SD = standard deviation; N/A = not applicable. Data are presented as mean ± standard deviation or number (%).
Comparisons between groups were performed using the independent samples t-test for continuous variables and Fisher's exact test for categorical variables.
Analysis at 14 days was performed on 21 patients in the PICO group (1 patient lost to follow-up) and 47 patients in the control group.
P-values <0.05 were considered statistically significant.

Discussion

This pilot study evaluated the effectiveness of prophylactic ciNPWT using the PICO device in patients undergoing mastectomy without immediate reconstruction for oncologic indications. The results demonstrated a different temporal pattern in seroma formation between the two groups, with potential clinical implications and directions for future research.

At 7 days postoperatively, with the PICO device still in place, a favorable trend was observed in the treated group, with a lower mean aspirated seroma volume compared with the control group (33.41 vs 44.58 mL), although the difference did not reach statistical significance. This finding is consistent with the mechanism of action of ciNPWT, which, through the application of controlled negative pressure, promotes wound edge approximation, reduces tissue edema, and facilitates removal of fluids from the surgical cavity.

However, the most relevant finding emerged at 14 days postoperatively, when the PICO-treated group showed a significantly higher seroma volume compared with the control group (59.55 vs 17.02 mL; $p = 0.025$). This apparently counterintuitive result should be interpreted considering the baseline differences between the two groups and potential confounding factors.

In particular, the PICO group consisted of significantly older patients compared with the control group (74 vs 66 years; $p = 0.014$) and showed a higher proportion of axillary dissections (50% vs 29%), both recognized in the literature as risk factors for increased seroma formation (18). Moreover, the observational nature of the study and the absence of randomization may have introduced selection bias, with preferential use of the device in patients considered at higher risk of complications.

Another possible explanation is the presence of a "rebound" effect after device removal at 7 days, with subsequent accumulation of fluid in the surgical cavity once negative pressure was discontinued. This phenomenon, previously described in other applications of negative pressure therapy (31), suggests that the optimal duration of treatment may exceed 7 days, particularly in high-risk patients.

The high variability observed in the data, reflected by the large standard deviations, further highlights the multifactorial nature of post-mastectomy seroma formation. Factors such as extent of surgical dissection, operative technique, use of dissection devices, and patient-specific characteristics may significantly influence outcomes, making it challenging to isolate the effect of ciNPWT in a relatively small sample.

The findings of the present study contribute to a still heterogeneous body of evidence regarding ciNPWT in breast surgery. Prior studies have reported a significant reduction in seroma formation with NPWT in breast surgery(23), while other investigations have demonstrated benefits mainly in prosthetic reconstructive surgery(24). Further evidence has suggested reduced complication rates in oncoplastic breast-conserving surgery using portable negative pressure devices. Nevertheless, specific data addressing mastectomy without immediate reconstruction remain limited, positioning the present study as a preliminary yet meaningful contribution to a field that remains substantially underinvestigated .

Regarding secondary endpoints, complication rates were comparable between the two groups. Wound dehiscence occurred in 4.5% of patients in the PICO group and 4.2% in the control group, while surgical reintervention for bleeding occurred in 4.5% and 4.2% of cases, respectively. No cases of skin necrosis were observed in either group, and the single hematoma in the PICO group was managed conservatively. These findings suggest a favorable safety profile of the device, without an increased risk of postoperative complications.

An additional relevant finding was the high degree of patient compliance observed, with all subjects in the PICO group completing the 7-day treatment protocol without early removal or interruption. This outcome supports the favorable tolerability profile of the device and underscores its potential applicability in routine clinical practice.

This study has several methodological limitations. As previously mentioned, the non-randomized design and comparison with a historical cohort introduce potential selection bias and confounding. The limited sample size (22 vs 48) reduces statistical power and does not allow multivariate analysis to control for confounding variables. Furthermore, the absence of complete data on BMI, comorbidities, and neoadjuvant therapies limited more accurate risk stratification. Finally, the 14-day follow-up did not allow evaluation of late seroma formation or long-term complications.

Despite these limitations, the study provides useful preliminary data for the design of future prospective multicenter studies. The hypothesis of a potential rebound effect following device removal suggests the need to evaluate protocols with longer treatment duration, while the favorable safety profile and high compliance support the feasibility of randomized controlled trials with larger samples.

It is also important to emphasize that, regardless of technological devices, surgical technique and surgeon experience remain fundamental in preventing post-

operative complications. Standardization of procedures, meticulous hemostasis, and careful management of skin flaps are key elements for optimizing surgical outcomes.

Conclusion

This pilot study confirmed the safety and good tolerability of prophylactic ciNPWT using the PICO device in patients undergoing mastectomy without immediate reconstruction. The observation of a favorable trend in seroma reduction at 7 days, followed by an increase at 14 days, suggests a possible "rebound" effect after device removal, which warrants further investigation and may have implications for optimal treatment duration.

The methodological limitations of the study, including lack of randomization, observational design, and baseline differences between groups, do not allow definitive conclusions regarding the effectiveness of ciNPWT in preventing post-mastectomy seroma. However, the collected data represent a relevant preliminary contribution, providing useful information for future study design and confirming the feasibility and safety of device use in this clinical setting.

Regardless of adjunctive technologies, surgical technique and operator experience remain essential for preventing postoperative complications, with ciNPWT serving as a complementary - not substitutive - tool.

Overall, although this is a pilot study with limited sample size, the findings are encouraging and support further research in this field. Prospective randomized multicenter studies with adequate statistical power will be necessary to better define the role of ciNPWT in oncologic breast surgery, identify patient subgroups most likely to benefit from treatment, and determine the optimal duration of device application.

Author's Contributions

M.Y. conceived the study and drafted the manuscript. L.I. contributed to data analysis and manuscript revision. A.L. supervised the study and contributed to study design. V.V., G.S., F.M.C., V.D.D., and G.S. contributed to data collection and clinical management. All authors critically revised the manuscript and approved the final version.

Conflicts of Interest

The authors declare no conflict of interest.

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Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki and applicable regulations. Given the observational, non-interventional nature of the study, involving a medical device already approved and routinely used in clinical practice, and the use of anonymized data, formal approval by an independent Ethics Committee was not required according to local institutional policies. The study protocol was reviewed and authorized by the Department of Sant'Andrea University Hospital. All patients had previously provided written informed consent for the use of their clinical data for scientific purposes.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

AI Disclosure

AI tools (ChatGPT) were used to support language editing and manuscript drafting. All scientific content, data analysis, and interpretation were independently performed and validated by the authors.

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