



Comparative Study of Multifunctional Irrigation-assisted Vacuum Drainage, Vacuum Sealing Drainage and the Penrose Drain in Treating Severe Multi-space Deep Fascial Infection in the Head and Neck

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Abstract

Background We aimed to compare multifunctional irrigation-assisted vacuum drainage (MIVD), vacuum sealing drainage (VSD) and the Penrose drain in treating severe multi-space deep fascial infection (DFI) in head and neck.

Methods A retrospective study was conducted on 113 patients who had suffered from severe multi-space DFI in head and neck and underwent surgical treatment. Patients were divided into the MIVD group, the VSD group, and the Penrose group according to their treatment. Baseline characteristics and clinical outcome data regarding infection control, clinicians' workload, surgical procedure required, and cost were analyzed.

Results Duration of antibiotic administration was significantly shorter using MIVD and VSD than Penrose drains ($p = 0.002$ with MIVD, $p = 0.008$ with VSD). Hospital stay in the MIVD group was shorter than the Penrose group ($p = 0.034$). Compared to the other two groups, more times of manual irrigation were needed in higher frequency in the Penrose group ($p < 0.001$). Longer Incision and more surgical operation were required in the VSD group than the other two groups ($p < 0.001$). The treatment cost in the VSD group was higher than the MIVD group ($p = 0.045$) and the Penrose group ($p < 0.001$).

Conclusions In the treatment of severe multi-space DFI in head and neck, MIVD and VSD are superior to the Penrose drain in infection control and reduction in clinicians' workload. Meanwhile, MIVD, with fewer surgical procedures required and less cost, seems to be a more promising method than VSD.

Introduction

Deep fascial infection (DFI) in head and neck is a difficult and lethal clinical problem referring to the infection in the potential spaces of maxillofacial and cervical region [1]. Mostly, these infections are secondary to odontogenic

infections, such as carious mandibular molars. As bacteria and their byproduct penetrate through the surrounding tissue, the infection spreads rapidly among the potential spaces due to loose anatomical structure of soft tissues, causing symptoms such as swelling and erythema of involved skin, limited mouth opening and swallowing difficulty [2]. For infections in lower head and neck, the airway could even be obstructed [3–5]. Other life-threatening complications include osteomyelitis, descending mediastinitis, necrotizing fasciitis, sepsis and Lemierre's syndrome [6–10].

Surgical access to the abscess cavity should be established immediately to discharge the purulence, and effective drainage is indispensable afterward to prevent purulence re-accumulation [11]. Although the Penrose

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drain method remains the most acknowledged for DFI, clinicians have been seeking alternatives with higher efficiency [2, 12].

In recent years, negative pressure wound therapy has been proven effective for treating soft tissue damage and abdominal infection [13–15]. Clinicians also increasingly apply vacuum sealing drainage (VSD) to maxillofacial space infection treatment [16–18]. Three years ago, we designed a type of multifunctional irrigation-assisted vacuum drainage (MIVD) which combined vacuum drainage with continuous irrigation and applied it to treat multi-space DFI. It is assumed that MIVD and VSD have potential advantages over Penrose drain in which include but not limited to accelerating healing and reducing clinicians' workload. However, no study has been conducted to prove it. The purpose of this study was therefore to compare the clinical effect of MIVD, VSD and the Penrose drain in treating severe multi-space DFI in head and neck, hoping to provide references for clinical practices.

Subjects and methods

This study was approved by Human Research Ethics Committee of Second Affiliated Hospital, Zhejiang University School of Medicine (No.20210887). We strictly followed the Declaration of Helsinki throughout the study.

Patients

We performed a retrospective study of patients diagnosed with multi-space DFI in head and neck from January 2018 to August 2021, at Department of Oral and Maxillofacial Surgery, Second Affiliated Hospital, Zhejiang University School of Medicine, P. R. China. Inclusion criteria were: (a) at least two infected spaces were found, (b) surgical drainage was performed and (c) the patient's clinical data were complete. Patients were excluded if they met one of the following criteria: (a) they did not undergo surgery due to severe systemic diseases or refused surgical treatment, (b) they suffered from uncontrolled mental disorders or (c) they were diagnosed with infraorbital space infection or mild buccal space infection for which clinicians used simple intraoral incisions.

Before treatment, clinicians fully described MIVD, VSD and the Penrose drain objectively, including potential advantages and disadvantages. Patients made their choices after being fully informed and then were, according to the treatment method, divided into three groups: the MIVD group, the VSD group and the Penrose group. Informed consent was obtained.

Treatment methods

All patients were examined by contrast-enhanced computed tomography preoperatively. Incisions were designed to facilitate full exploration of the abscess and adequate drainage. The most frequently used incision was a sub-mandibular incision, 1.5–2 cm below and parallel to the mandibular body's lower edge. After careful incision through the skin and platysma muscle, clinicians used hemostats to make blunt dissection into the abscess cavity. A small amount of pus was collected for culture and drug sensitivity test before the abscess cavity was alternately irrigated with 1–3% hydrogen peroxide, 0.5% iodophor and saline (Fig. 1). Then, MIVD, VSD or the Penrose drain was applied according to the patient's choice. All patients were prescribed antibiotics and monitored closely after the surgery. Additional surgeries were needed if there was no apparent decline or even an increase in the C-reactive protein (CRP) or white blood cell count (WBC) level for 3 consecutive days and abscess re-accumulation was further confirmed by contrast-enhanced computed tomography. The drainage device was removed when no purulence was observed in the drainage fluid, and CRP and WBC approached normal levels. Antibiotics administration ceased when CRP and WBC decreased to normal levels and previous symptoms of infection vanished, and the patient was discharged 1–2 days afterward if no symptom recurred.

MIVD group

The MIVD device consisted of one silicone catheter (Suzhou McLean medical equipment co., Ltd., Jiangsu, China) and two PVC plastic catheters (Suzhou Jingle polymer medical apparatus co., Ltd., Jiangsu, China). The silicone catheter served as the drainage tube. Side holes were placed on the tube wall near its top, providing additional access for purulence. Two PVC plastic catheters were placed within the drainage tube: one served as the external irrigation with its top extending outwards from either a side hole or the top of the drainage tube, and the other as the internal irrigation tube with its top remained in the drainage tube (Fig. 2). After the MIVD device was put into the abscess cavity, the incision was closely sutured. The surgical area was covered with gauze and sealed with adhesive films (Fig. 3).

Then, the drainage tube was connected to a negative pressure system (150–200 kpa). The external irrigation tube was connected to large amounts of saline (125 ml/h, 3000 ml/a day) to achieve continuous irrigation. Clinicians manually infused 100 ml of saline through the internal irrigation tube to prevent potential tube blockage once

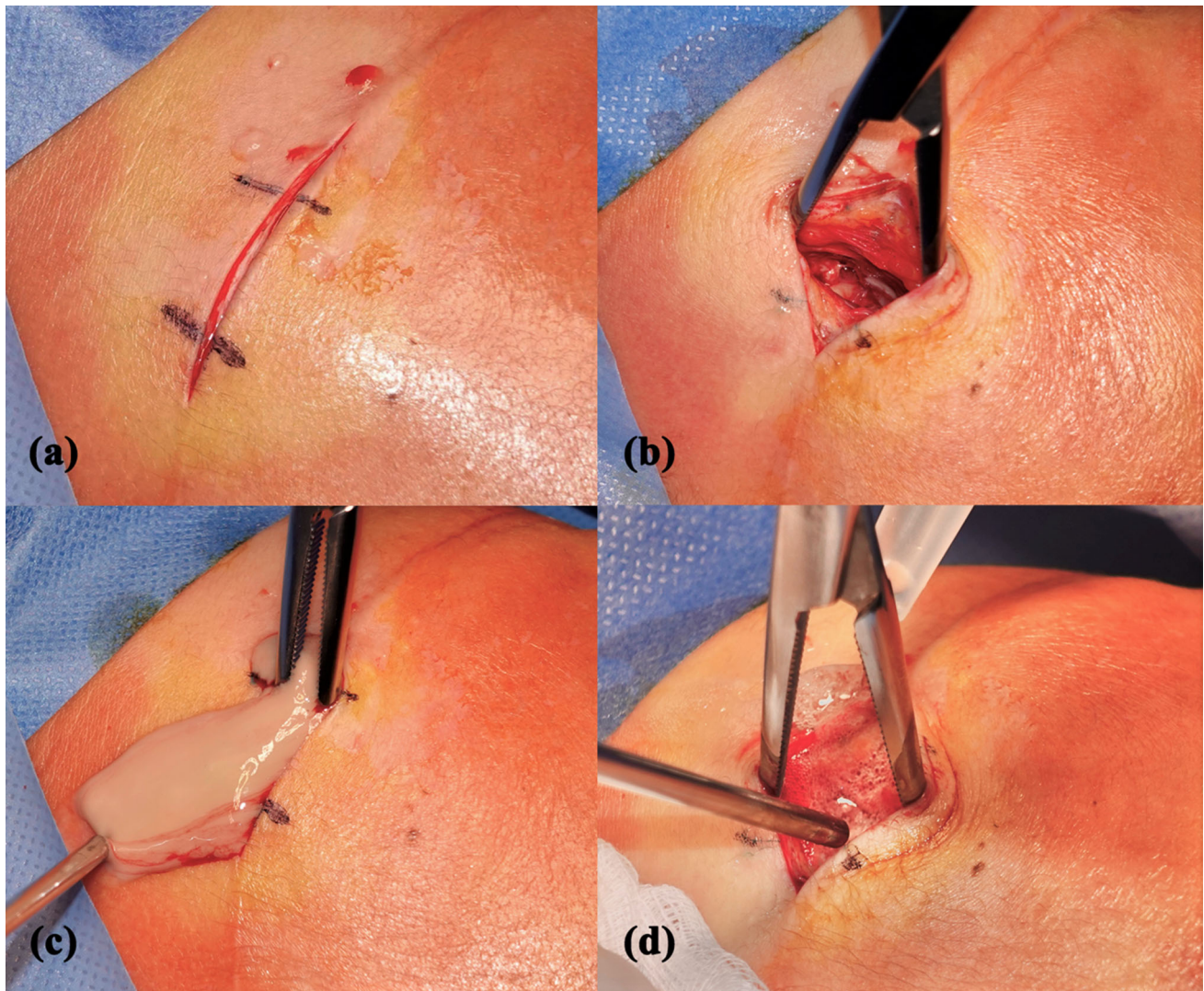


Fig. 1 The surgical procedure of treating deep fascial infection in head and neck. **(a)** A submandibular incision was designed. **(b)** After a careful incision through the skin and the platysma muscle, clinicians

used hemostats to make blunt dissection into the abscess cavity. **(c)** Purulence was observed from the abscess cavity. **(d)** Thorough irrigation was performed

thick purulence or debris was found remaining in the drainage tube. MIVD was directly extracted when no more drainage was needed.

VSD group

The VSD device (Smith & Nephew Medical Ltd., United Kingdom) consisted of foam dressing, a drainage tube and an internal irrigation tube. The drainage tube was embedded within the foam dressing. After the foam dressing was shaped to fit the abscess cavity, it was put into the abscess cavity together with the drainage tube and the irrigation tube. Then, the surgical area was sealed with adhesive films, leaving the drainage tube to be connected to a negative pressure system (150–200 kpa) (Fig. 4). When thick

purulence or debris remained in the drainage tube, manual irrigation by clinicians (MIC) was performed through the irrigation tube to prevent tube blockage. Besides the common criteria for additional surgeries as described above, more surgeries were needed for the regular change of the VSD device every 5–7 days as well as the removal of the device when drainage ceased.

Penrose group

The Penrose drains in this study were manufactured by Well Lead medical co., Ltd., Guangzhou, China. After the drain was placed, the incision was sutured intermittently and covered with sterile gauze to protect the surgical area (Fig. 5). MIC was performed once the gauze was soaked

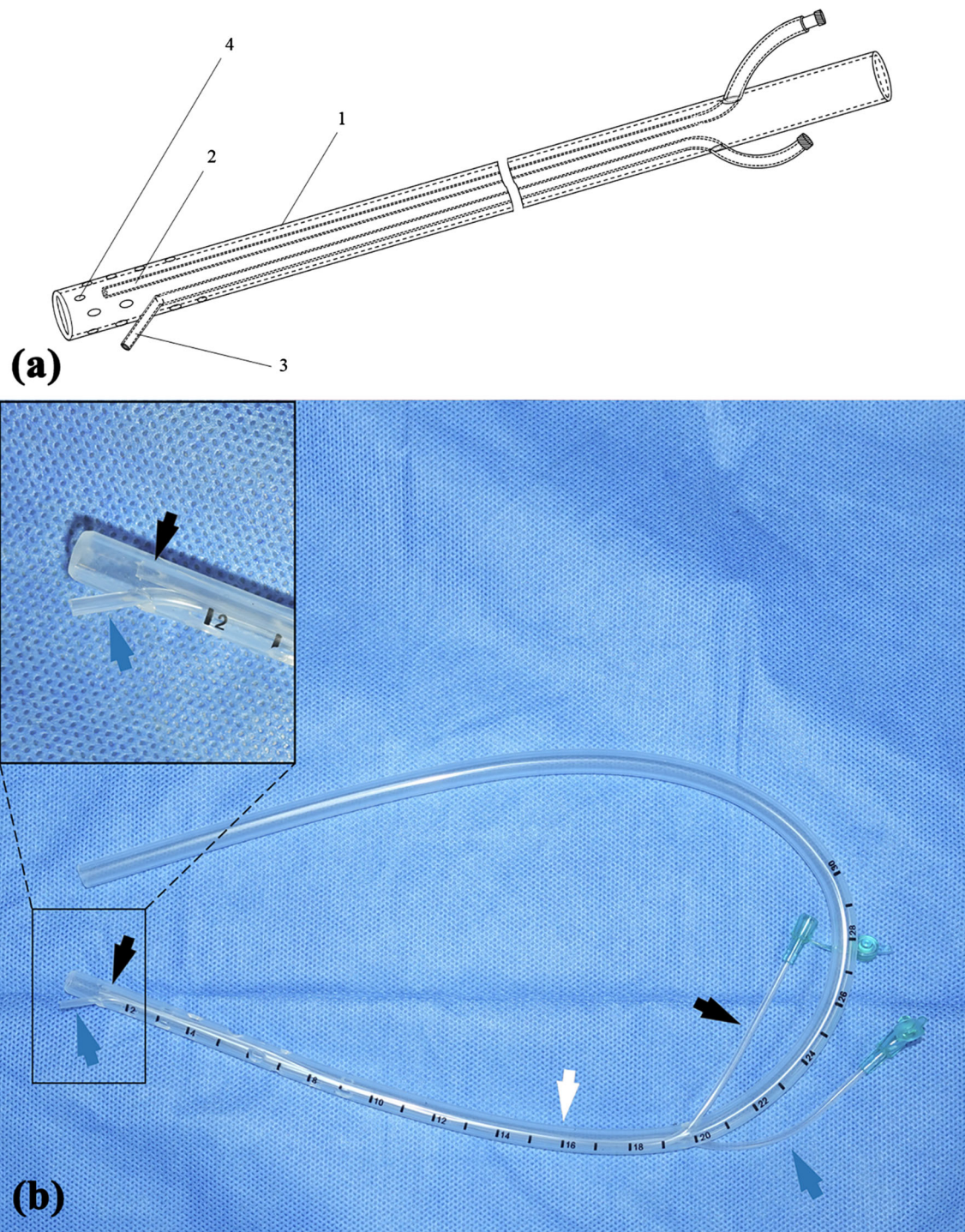


Fig. 2 The structure of multifunctional irrigation-assisted vacuum drainage (MIVD). **(a)** The technical drawing of the MIVD device showed its structure: the drainage tube (**a, 1**), the internal irrigation tube (**a, 2**), the external irrigation tube (**a, 3**), and the side holes (**a, 4**).

(b) The MIVD system was composed of the drainage tube (**b**, the white arrow), the external irrigation tube (**b**, the blue arrow), and the internal irrigation tube (**b**, the black arrow)

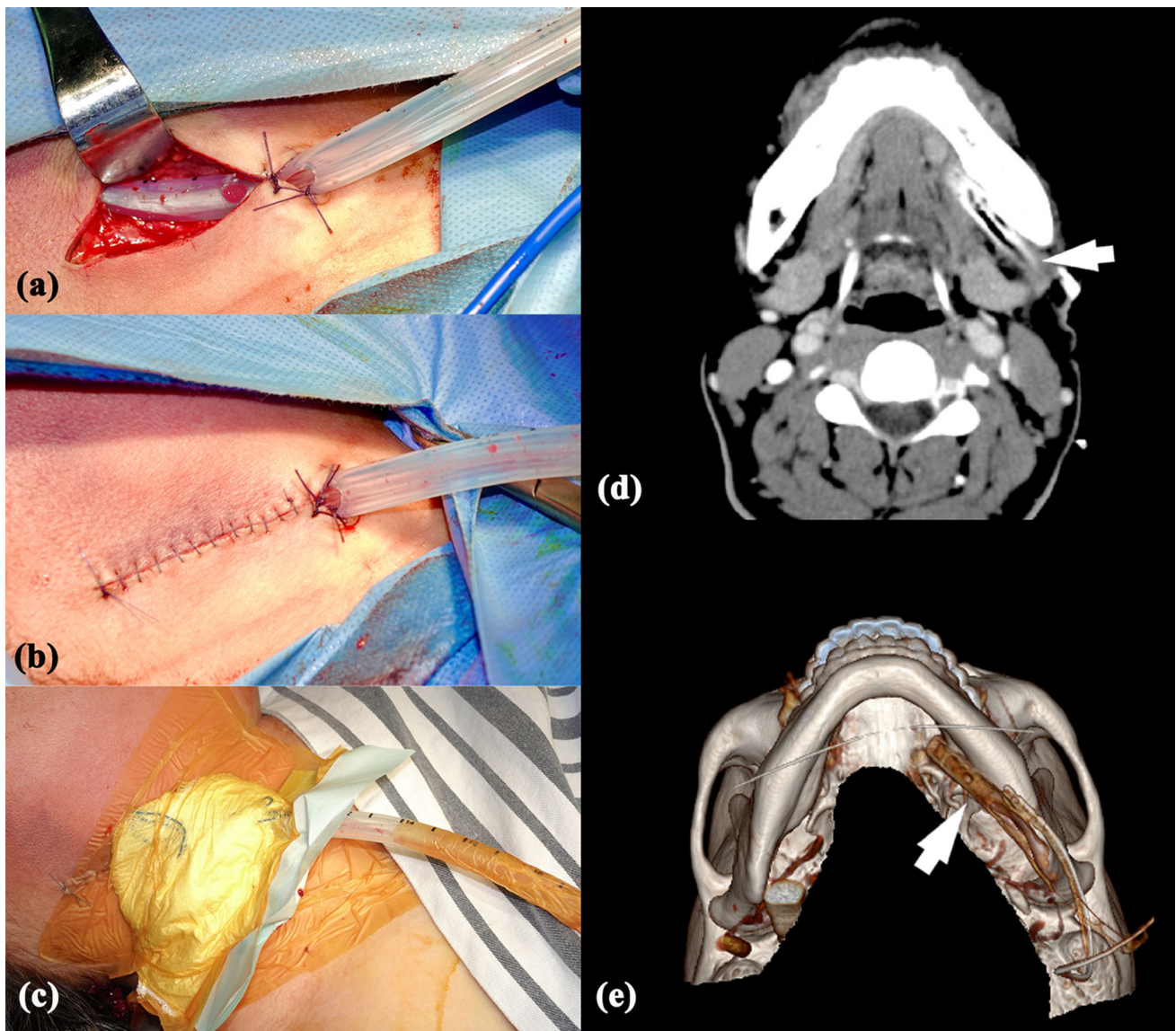


Fig. 3 Surgical pictures and imaging of MIVD. **(a)** MIVD was put into the abscess cavity. **(b)** The incision was closely sutured. **(c)** The surgical area was covered with gauze and sealed with adhesive films.

through by the drainage fluid. The Penrose drain was eventually extracted directly, and the incision was left to heal without additional stitches.

Variables

Baseline characteristics and clinical outcome data were recorded from all patients. Baseline characteristics included age, sex, diabetes, other systemic diseases, tobacco use, etiology, the number of infected spaces and preoperative WBC and CRP. Clinical outcome data included variables related to infection control (duration of antibiotic administration and hospital stay), clinicians' workload (times and

(d–e) Contrast-enhanced computed tomography scan and its three-dimensional reconstructed image displayed the location of the MIVD device (inferior horizontal view) (**d–e**, the white arrow)

frequency of MIC), surgical procedure required (times of operation and incision length) and hospitalization cost.

Statistical analysis

Categorical variables were presented as absolute numbers and numerical variables as mean \pm standard deviation. Pearson Chi-square test was used to analyze categorical variables. For numerical variables, Analysis of Variance was used to compare those with normal distribution, and Kruskal–Wallis test for those with abnormal distribution. The statistical analysis was performed using SPSS 21.0. We considered p values less than 0.05 statistically significant.

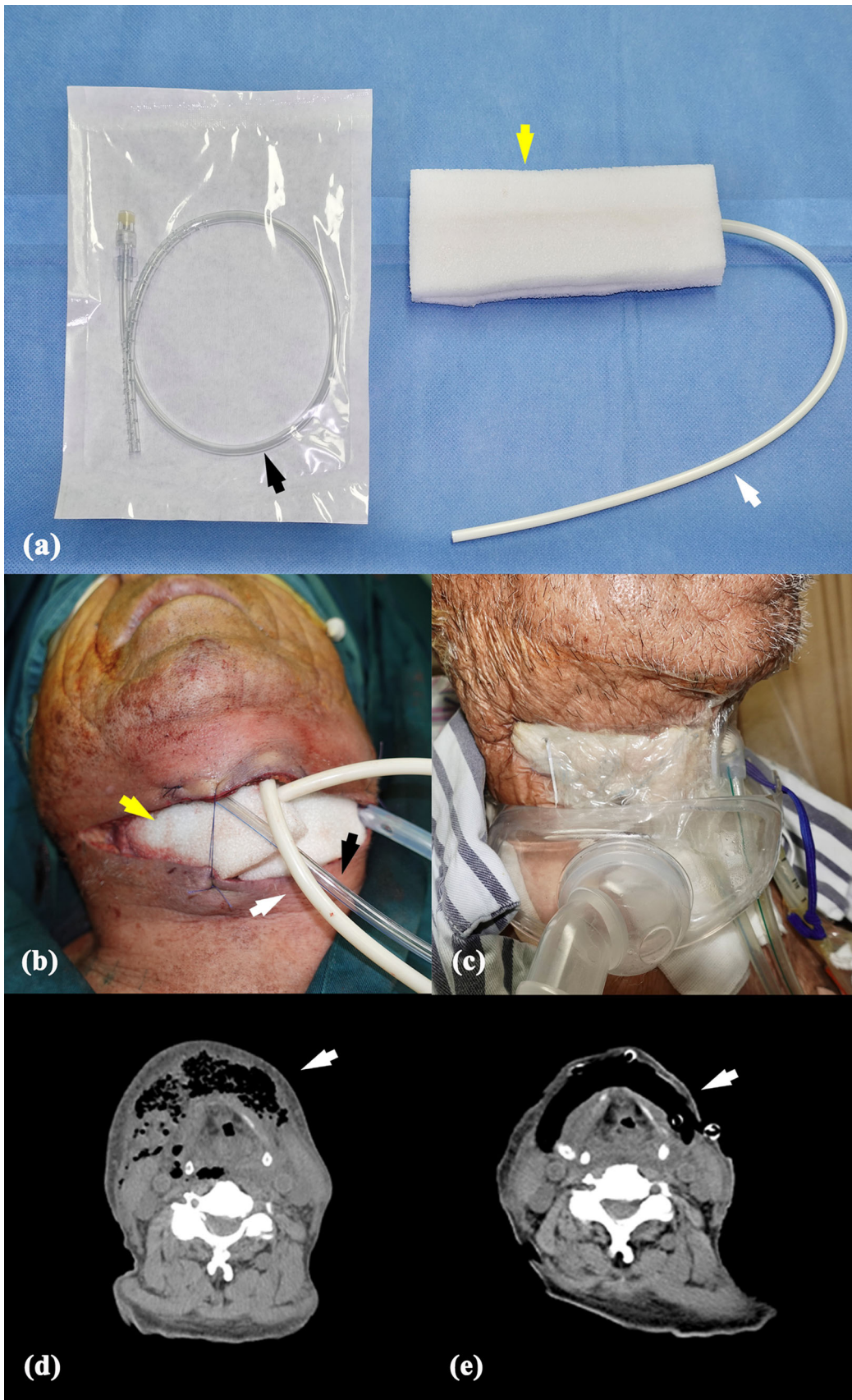


Fig. 4 The structure and clinical pictures of vacuum sealing drainage (VSD). **(a)** The VSD system consisted of the foam dressing (a, the yellow arrow), the drainage tube (a, the white arrow), and the irrigation tube (a, the black arrow). The drainage tube was embedded in the foam dressing. **(b)** Surgical picture of the placement of VSD including the foam dressing (b, the yellow arrow), the drainage tube (b, the white arrow), and the irrigation tube (b, the black arrow). **(c)** The whole surgical area was sealed with adhesive films. **(d–e)** Contrast-enhanced computed tomography scan showing the abscess cavity (d, the white arrow) and VSD after it was put into the abscess cavity (e, the white arrow)

Results

Patient's characteristics

A total of 113 patients (72 males and 41 females) were included in this study, with the MIVD group 30 patients, the VSD group 31 patients and the Penrose group 52 patients. Baseline characteristics are summarized in Table 1. Involved spaces were submandibular space, pterygomandibular space, masseteric space, parapharyngeal space, submental space, buccal space, sublingual space and temporal space (Table 2). No significant difference was found among groups ($p > 0.05$).

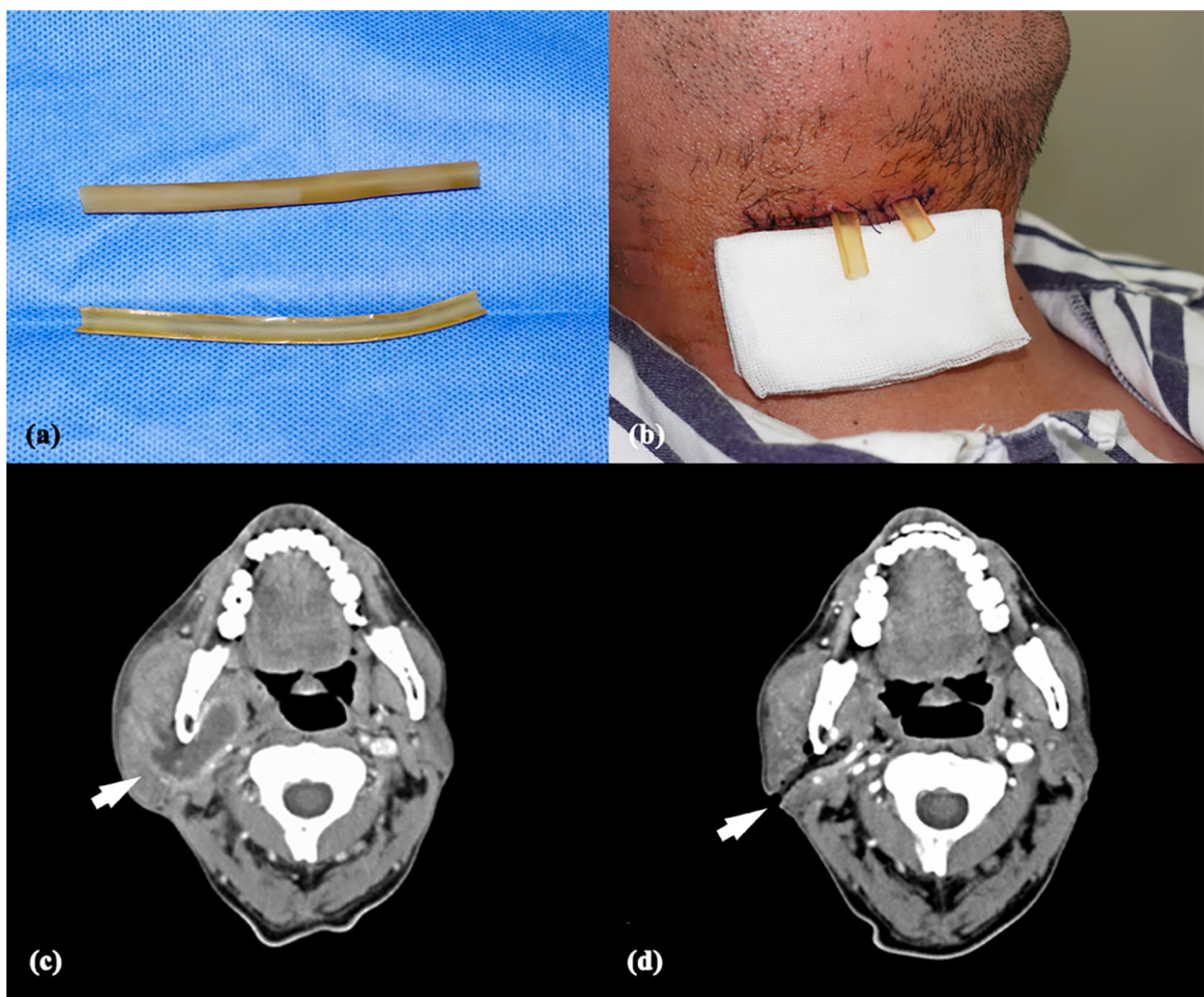


Fig. 5 The picture of the Penrose drain we used in this study and a patient from the Penrose group. **(a)** The Penrose drain. **(b)** The picture of a patient with the Penrose drain. **(c–d)** Contrast-enhanced

computed tomography scan showing the abscess cavity (c, the white arrow) and the path of the Penrose drain into the abscess cavity (d, the white arrow)

Table 1 Baseline Characteristics of the patients involved

Variables	No (%)			<i>p</i> value
	MIVD group (n = 30)	VSD group (n = 31)	Penrose group (n = 52)	
Age (years)	51.10 ± 15.35	53.58 ± 19.62	51.58 ± 16.94	0.831
Sex				
Male	21 (70.0)	19 (61.3)	32 (61.5)	0.705
Female	9 (30.0)	12 (38.7)	20 (38.5)	
Diabetes				
Yes	10 (33.3)	8 (25.8)	8 (15.4)	0.161
No	20 (66.7)	23 (74.2)	44 (84.6)	
Other Systemic diseases				
Yes	18 (60.0)	12 (38.7)	26 (50.0)	0.250
No	12 (40.0)	19 (61.3)	26 (50.0)	
Tobacco use				
Yes	15 (50.0)	11 (35.5)	24 (46.2)	0.486
No	15 (50.0)	20 (64.5)	28 (53.8)	
Etiology				
Odontogenic	16 (53.3)	23 (74.2)	37 (71.2)	0.159
Non-odontogenic	14 (46.7)	8 (25.8)	15 (28.8)	
Infected spaces	3.23 ± 0.77	3.39 ± 0.99	3.02 ± 1.21	0.292
Preoperative WBC (× 10 ⁹ /L)	18.29 ± 5.34	16.78 ± 7.55	15.54 ± 5.19	0.136
Preoperative CRP	123.41 ± 74.24	139.39 ± 83.84	124.11 ± 85.76	0.671

MIVD multifunctional irrigation-assisted vacuum drainage; VSD vacuum sealing drainage; WBC white blood cells; CRP C-reactive protein

Table 2 Infected spaces of the patients in the Penrose group, the VSD group, and the MIVD group

Infected space	Total No. (%) (n = 113)	No. (%)			<i>p</i> value
		MIVD group (n = 30)	VSD group (n = 31)	Penrose group (n = 52)	
Submandibular space	91 (80.5)	22 (73.3)	26 (83.9)	43 (82.7)	0.505
Pterygomandibular space	67 (59.3)	19 (63.3)	20 (64.5)	28 (53.7)	0.551
Masseteric space	62 (54.9)	21 (70.0)	16 (51.6)	25 (48.1)	0.144
Parapharyngeal space	56 (49.6)	20 (66.7)	14 (45.2)	22 (42.3)	0.089
Submental space	30 (25.6)	4 (13.3)	12 (38.7)	14 (26.9)	0.080
Buccal space	22 (19.5)	5 (16.7)	8 (25.8)	9 (17.3)	0.577
Sublingual space	16 (14.2)	4 (13.3)	6 (19.4)	6 (11.5)	0.607
Temporal space	14 (12.4)	2 (6.7)	3 (9.7)	9 (17.3)	0.321

MIVD multifunctional irrigation-assisted vacuum drainage; VSD, vacuum sealing drainage

Infection control

The duration of antibiotic administration in the MIVD group (11.83 ± 3.66 days) and the VSD group (12.58 ± 4.97 days) was shorter than that of the Penrose group (15.54 ± 5.09 days) (MIVD versus Penrose drains, *p* = 0.002; VSD versus Penrose drains, *p* = 0.008) (Table 3). No significant difference was observed between the MIVD group and the VSD group (*p* > 0.05).

Hospital stays of the MIVD group, the VSD group and the Penrose group were 13.60 ± 4.26 days, 15.53 ± 5.82 days and 16.40 ± 5.30 days. There was a significant reduction in the MIVD group compared to the Penrose group (*p* = 0.034). No significant difference was observed between the VSD group and the other groups (*p* > 0.05).

Table 3 Comparison of the clinical outcome among the Penrose group, the VSD group, and the MIVD group

Variables	MIVD group (n = 30)	VSD group (n = 31)	Penrose group (n = 52)	p values		
				MIVD/ VSD	MIVD/ Penrose	VSD/ Penrose
Duration of antibiotic administration (days)	11.83 ± 3.66	12.58 ± 4.97	15.54 ± 5.09	1.000	0.002*	0.008*
Hospital stay (days)	13.60 ± 4.26	15.53 ± 5.82	16.40 ± 5.30	0.912	0.034*	0.487
Times of MIC (times)	4.90 ± 1.63	5.29 ± 3.29	21.88 ± 9.26	0.914	< 0.001*	< 0.001*
Frequency of MIC (times/ a day)	0.37 ± 0.10	0.34 ± 0.13	1.32 ± 0.38	0.468	< 0.001*	< 0.001*
Incision length (cm)	5.00 ± 2.49	8.18 ± 2.66	5.37 ± 3.48	< 0.001*	0.927	< 0.001*
Times of operation (times)	1.13 ± 0.35	2.58 ± 0.72	1.25 ± 0.59	< 0.001*	0.598	< 0.001*
Hospitalization cost (CNY)	35,743.73 ± 20,087.72	56,144.14 ± 36,841.75	33,137.33 ± 41,214.60	0.045*	0.072	< 0.001*

MIVD multifunctional irrigation-assisted vacuum drainage; VSD vacuum sealing drainage; MIC manual irrigation by clinicians; CNY Chinese Currency

*Significant $p < 0.05$

Clinician's workload

In average, 21.88 ± 9.26 times of MIC with 1.32 ± 0.38 times/a day were performed in the Penrose group, significantly more and in higher frequency than those in the MIVD group (4.90 ± 1.63 times, 0.37 ± 0.10 times/a day) ($p < 0.001$) and those in the VSD group (5.29 ± 3.29 times, 0.34 ± 0.13 times/ a day) ($p < 0.001$). There was no significant difference between the MIVD group and the VSD group ($p > 0.05$) (Table 3).

Surgical procedure required

The Incision lengths of the MIVD group (5.00 ± 2.49 cm) and Penrose group (5.37 ± 3.48 cm) were significantly smaller than that of the VSD group (8.18 ± 2.66 cm) ($p < 0.001$). Differences between the MIVD group and the Penrose group were not significant ($p > 0.05$) (Table 3).

The numbers of operation of the MIVD group, the VSD group and the Penrose group were 1.13 ± 0.35 times, 2.58 ± 0.72 times and 1.25 ± 0.59 times, respectively. More operations were performed in the VSD group as compared with the other two groups ($p < 0.001$); however, no significant difference was found between the MIVD group and the Penrose group ($p > 0.05$) (Table 3).

Hospitalization cost

The hospitalization costs of the MIVD group, the VSD group and the Penrose group were $35,743.73 \pm 20,087.72$ CNY (Chinese currency), $56,144.14 \pm 36,841.75$ CNY and $33,137.33 \pm 41,214.60$ CNY (Table 3). The VSD group showed a higher cost as compared with the MIVD group ($p = 0.045$) and the Penrose group ($p < 0.001$). The

difference between the MIVD group and the Penrose group was insignificant ($p > 0.05$).

Discussion

DFI in head and neck is a lethal problem that progresses rapidly unless managed properly. Prompt surgical management is imperative[19]. Penrose drains are the most frequently used form of drainage [2]. Clinicians have also applied negative pressure to drainage recently, which has been proved can not only timely remove purulence and necrotic tissues, but also promote wound healing by increasing microvascular blood flow [13, 20, 21]. In the meantime, continuous abscess irrigation effectively destroys the environment for microbiologic colonization due to ongoing bacterial reduction [22–25]. In this study, we compared the clinical effect of MIVD, VSD and the Penrose drain in treating severe multi-space DFI in head and neck. The results showed that although MIVD, VSD and the Penrose drain are all feasible, there were differences in infection control, clinicians' workload, surgical procedure required and hospitalization cost, which is elaborated as follows.

Duration of antibiotic administration was found shorter in the MIVD group and VSD group than the Penrose group, demonstrating that both MIVD and VSD outperformed the Penrose drain in infection control. The hospital stay of patients with MIVD was significantly shorter than those with the Penrose drain, with no significant difference between VSD and the Penrose drain. In combination, these indicated that MIVD, with its continuous abscess irrigation, seemed to be a more effective method.

Both MIVD and VSD showed advantages over the Penrose drain in reducing clinician's workload. MIC was usually necessary at least 1–2 times a day with the Penrose drain to prevent purulence re-accumulation. With MIVD and VSD, however, thanks to negative pressure continuous irrigation which played a major role in purulence evacuation, MIC was only needed once every other day to avoid device blockage. It should be noted that the reduction in MIC does not suggest a less clinical evaluation by clinicians. All patients were checked at least twice a day for any swelling of the surgical area, dressing status and functioning of the drainage devices.

In terms of surgical procedure, the VSD group had the longest incision in our study. Unlike MIVD and the Penrose drain, VSD depends on the foam dressing to absorb purulence. Incision length should be sufficient for the foam dressing to fully cover the abscess cavity. Additionally, the foam dressing needs to be changed several times to ensure effective drainage, and eventually be surgically removed. The VSD method, therefore, necessitates several times of surgical operations, consequently increasing the cost and trauma. MIVD and the Penrose drain, however, can be directly removed at the end of drainage, causing mild surgical trauma.

Although hospitalization costs varied from patient to patient, it was found the highest with VSD. This was largely due to the costly device and multiple surgical operations. Therefore, VSD may not be the best option for economically disadvantaged patients.

There are other aspects worth discussing. Firstly, incision design was more flexible with MIVD and VSD. The Penrose drain method is gravity-dependent, requiring the incision to be placed at the site lower to the infection. At the same time, potential injury to important nerves and vessels should be avoided. This made the incision design a dilemma in some cases. MIVD and VSD relied on negative pressure drainage systems, which effectively minimized functional damage when placing incisions. Secondly, the skin scars of the patients who underwent MIVD and VSD met the aesthetic requirement better than those with the Penrose drain. The incision with the Penrose drain usually led to pit-shaped scars due to second-intention healing. As for the other two groups, the incision was sutured closely in the first operation with MIVD, or sutured closely after device removal with VSD. Primary-intention healing of incision with these two methods led to minimum scar. But the VSD method usually had relatively long incision scar. Although the VSD method usually had relatively long scar, aesthetic differences were not specifically studied.

The limitations of this study are: (a) This was a non-randomized retrospective study. Though multivariable adjustment was used in statistical analysis, the possibility of residual confounding cannot be eliminated. (b) This

study was conducted in a single center. The sample size might not be large enough, and the results might not be generalizable to all populations. In light of the limitations above, we have planned to conduct a multi-centered randomized controlled trial to further support the results of this study.

In conclusion, although all three methods are feasible for treating DFI, MIVD and VSD outperform the Penrose drain in accelerating infection control and reducing clinicians' workload. Meanwhile, MIVD seems to be a more promising treatment method for DFI for its fewer surgical procedures and less hospitalization cost as compared with VSD.

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Declarations

Conflict of interest All authors reported no conflicts of interest.

Patient consent Informed consent was obtained from all patients.

Ethics approval This study was approved by the Human Research Ethics Committee of the Second Affiliated Hospital, Zhejiang University School of Medicine (No.20210887). We strictly followed the Declaration of Helsinki through all stages of this study. All authors comply with the journal's ethical policies. The final word count: 2500.

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