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Efficacy and safety of radiofrequency ablation combined with high ligation vs simple radiofrequency ablation for lower extremity varicose veins: a retrospective comparative study

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KEY WORDS

CEAP classification, clinical efficacy, high ligation of the great saphenous vein, lower extremity varicose veins, radiofrequency ablation

ABSTRACT

INTRODUCTION Simple radiofrequency ablation (RFA) is a standard minimally-invasive treatment for lower extremity varicose veins (LEVV), yet concerns regarding recurrence and efficacy in severe cases persist.

AIM We aimed to evaluate clinical efficacy, safety, and long-term prognosis of RFA combined with high ligation (RFHL) vs simple RFA.

MATERIALS AND METHODS This retrospective study analyzed 108 LEVV patients (from January 2020 to November 2024) divided into 2 groups based on the procedure they underwent: RFHL (n = 54) and RFA (n = 54). The comparisons included perioperative indicators, clinical efficacy, complications, and 1-year recurrence rates. A stratified analysis was performed for severe cases (Clinical-Etiology-Anatomy--Pathophysiology [CEAP] classification, C4–C6).

RESULTS Perioperative metrics (operative time, blood loss, recovery, and pain intensity) showed no differences between the groups. However, RFHL achieved a significantly higher total effective rate than RFA. Notably, in severe cases (C4–C6), RFHL efficacy was superior. The RFHL group demonstrated markedly lower complication and 1-year recurrence rates. Additionally, 6-month venous function was considerably better in the RFHL group.

CONCLUSIONS RFHL is associated with comparable perioperative recovery to RFA but offers significantly higher efficacy, better safety, and lower long-term recurrence, especially in severe LEVV (CEAP, C4–C6). RFHL should be considered the preferred surgical approach for severe cases.

INTRODUCTION Lower extremity varicose veins (LEVV) represent the most common chronic venous disease in vascular surgery, with a global prevalence of 20%–30% in adults. In China, the prevalence among middle-aged and elderly populations exceeds 25%, with an increasing trend observed in the younger demographics.[1] The core pathological mechanism involves primary or secondary valvular incompetence of the great saphenous vein (GSV), leading to venous reflux and elevated intraluminal pressure. Chronic hypertension results in tortuous dilation of the vein wall and fibrosis of the subcutaneous tissue. Clinical manifestations progressively worsen according to the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification: from telangiectasia (C1) and early symptoms of lower limb soreness and superficial venous tortuosity (C2), progressing to edema (C3), skin pigmentation and eczema (C4), lipodermatosclerosis and healed ulcers (C5), to active nonhealing ulcers (C6).[2] Patients with severe disease (CEAP, C4–C6) present a significant clinical challenge due to considerable nutritional impairment of the skin and prolonged ulceration, which gravely compromise quality of life and increase medical burden.[3]

The primary goal of clinical LEVV treatment is the interruption of venous reflux and the elimination of pathological vessels. Simple radiofrequency ablation (RFA), a mainstream

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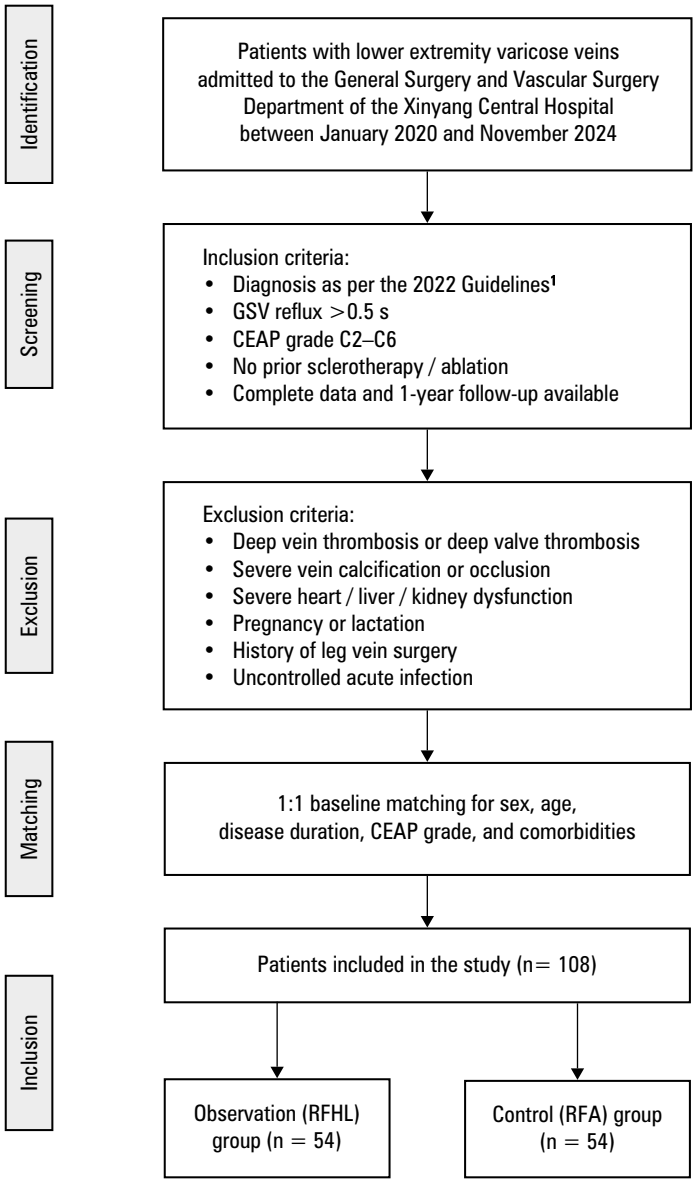

FIGURE 1 Flowchart of the study enrollment process

Abbreviations: CEAP, Clinical-Etiology-Anatomy-Pathophysiology; GSV, great saphenous vein; RFA, radiofrequency ablation; RFHL, radiofrequency ablation combined with high ligation

minimally-invasive procedure, is widely used in mild-to-moderate cases due to its minimal trauma and operative facility. However, this technique only occludes the venous trunk without physically interrupting the reflux source at the saphenofemoral junction (SFJ). Consequently, there is a high risk of residual reflux and venous recanalization postoperatively, leading to a high long-term recurrence rate. Furthermore, the clearance of branch lesions in severe patients is often incomplete, making it difficult to achieve optimal therapeutic outcomes.[4,5]

In recent years, endovascular techniques have been continuously optimized. Radiofrequency ablation combined with high ligation (RFHL) integrates the advantages of reflux interruption via high ligation and lesion closure through radiofrequency ablation. By precisely blocking the reflux source while closing the pathological trunk, RFHL retains minimally-invasive benefits while addressing the "palliative but not curative" limitation of simple RFA.[6-8] Current clinical research has largely focused on comparing this combined approach with traditional stripping. However, direct comparative studies regarding the efficacy, safety, and long-term prognosis of RFHL vs simple RFA remain relatively scarce.[9] Therefore, this study was conducted to clarify the differences in clinical value between these 2 minimally-invasive techniques through a retrospective comparative analysis of LEVV patients treated at the Xinyang Central Hospital, with a specific focus on severe cases, to provide evidence for individualized surgical selection.

AIM We aimed to evaluate the clinical efficacy, safety, and long-term prognosis of RFHL vs simple RFA.

MATERIALS AND METHODS **General data** A total of 108 patients with LEVV admitted to the Department of General Surgery and Vascular Surgery of the Xinyang Central Hospital from January 2020 to November 2024 were selected.

The inclusion criteria were as follows: 1) diagnosis confirmed on color Doppler ultrasound demonstrating GSV valvular incompetence with reflux (reflux time >0.5 s), meeting the diagnostic criteria of the Guidelines for the Diagnosis and Treatment of Chronic Venous Disease of the Lower Extremities (2022 Edition)[1]; 2) clinical classification of CEAP C2–C6 (for C4–C6 patients, the inclusion occurred after control of symptoms related to infected ulcers); 3) first-time surgical treatment without prior minimally-invasive interventions, such as sclerotherapy or laser ablation; and 4) complete clinical data and 1-year regular follow-up for long-term efficacy assessment. The exclusion criteria comprised: 1) comorbid deep vein thrombosis (DVT) or severe deep vein valvular incompetence (reflux time >3 s); 2) severe calcification of the vein wall, vascular occlusion, or congenital venous malformation; 3) severe dysfunction of the heart, liver, or kidneys, coagulation disorders, or systemic infection; 4) pregnancy or lactation; and 5) a history of lower extremity venous surgery or skin ulceration combined with acute infection (uncontrolled inflammation).

The patients were divided into the observation group (RFHL) and the control group (RFA), according to the surgical method used, with 54 cases in each cohort. A 1:1 baseline matching method was employed, matching for sex, age, disease duration, CEAP classification (proportion of severe cases), and comorbidities (hypertension and diabetes). The study enrollment process is presented in FIGURE 1.

Preoperative preparation Color Doppler ultrasound was performed in both groups to define the degree of GSV reflux, lesion extent, and tributary involvement. For the severe patients, reflux source and blood supply to skin ulcers were

assessed. Routine laboratory tests were performed to exclude surgical contraindications. For the patients with comorbid hypertension or diabetes, preoperative optimization was performed as part of routine perioperative management. Antihypertensive or hypoglycemic therapy was adjusted accordingly to ensure that blood pressure was maintained below 140/90 mm Hg and fasting blood glucose below 7 mmol/l for at least 3 consecutive days prior to surgery. Infected ulcers were managed with dressing changes until acute symptoms subsided. All patients were informed of the surgical plan, risks, and prognosis, and signed informed consent forms. Local anesthesia was used for the small incision area, and tumescent anesthesia (lidocaine combined with sodium bicarbonate) was used for the ablation zone.

Surgical methods Radiofrequency ablation combined with high ligation (observation group) In the observation group, the patients underwent RFHL of the GSV at the SFJ. Preoperative ultrasound mapping precisely identified the SFJ, GSV trunk, and major tributaries; in severe cases with ulceration, the distribution of periulcer tributaries was explicitly marked. A 1–1.5 cm transverse incision was made in the groin, the GSV trunk was dissected, and high ligation was performed 0.5 cm distal to its confluence with the femoral vein. All accessible tributaries within the operative field were individually ligated to eliminate all reflux pathways, after which the GSV trunk and major branches were transected. The proximal stump was securely ligated, while the distal GSV stump was preligated with silk sutures to facilitate subsequent catheter insertion.

Under ultrasound guidance, the radiofrequency catheter was introduced via puncture of the distal GSV at the medial ankle, and advanced proximally to 1 cm below the high ligation site. In the cases of failed distal puncture or severe tortuosity, direct puncture of the distal GSV trunk or segmental puncture at the medial knee was performed. RFA was then carried out using identical parameters to the control group (85–120 °C; withdrawal speed, 2–3 mm/s), with continuous ultrasound monitoring to confirm complete vein wall contraction and absence of residual reflux. Following ablation, the distal GSV trunk was definitively ligated with the preplaced silk suture.

Management of tributary varicosities was identical to the control group: stab avulsion phlebectomy for branches larger than 0.5 cm and foam sclerotherapy for those smaller than 0.5 cm. In the patients with severe disease and ulceration, particular attention was paid to thorough clearance of periulcer tributary varices to reduce local venous hypertension. The groin incision was closed intradermally with absorbable suture, sterile dressings were applied, the limb was wrapped with elastic bandages, and class II medical compression stockings were used immediately postsurgery.

Simple radiofrequency ablation (control group) In the control group, the patients underwent standard RFA of the GSV. Preoperative ultrasound mapping was performed to identify the diseased GSV trunk, reflux segment, and to mark the puncture site at the medial ankle. Under ultrasound guidance, the distal GSV was punctured at the medial ankle, and the radiofrequency catheter was advanced proximally to 2 cm below the SFJ, ensuring the catheter tip was centered within the lumen and not adhering to the vein wall. Radiofrequency energy was delivered at 85–120 °C, while the catheter was withdrawn at a constant speed of 2–3 mm/s, with real-time ultrasound monitoring of vein wall contraction and closure until complete occlusion was achieved. Tributary varicosities larger than 0.5 cm in diameter were treated with stab avulsion phlebectomy, whereas those smaller than 0.5 cm were managed with foam sclerotherapy. At the end of the procedure, sterile dressings were applied, the limb was wrapped with elastic bandages, and class II medical compression stockings were used immediately after surgery.

Postoperative management Routine fluid replacement or prophylactic antibiotics were not required unless phlebitis or ulcer infection were present. The patients were encouraged to ambulate immediately postoperatively to reduce DVT risk. Elastic bandages were removed after 48–72 hours, followed by continuous wearing of medical compression stockings (1 month for C2–C3; 3 months for C4–C6). Ulcers in the severe cases were dressed regularly. Follow up was conducted at 1, 3, 6, and 12 months postoperatively.

Outcome measures Perioperative indicators The following indicators were assessed: operative time, intraoperative blood loss, time to first ambulation, length of hospital stay (LOS), and pain intensity at 24 hours postoperatively (assessed using the Visual Analog Scale [VAS], ranging from 0 to 10).

Clinical efficacy The efficacy was evaluated at 6 months postoperatively based on the Guidelines for Diagnosis and Treatment of Chronic Venous Disease.[10,11] The patients were categorized as follows: 1) cured: disappearance of varicose veins and symptoms (eg, swelling, ulcers), with no reflux on ultrasound; 2) markedly effective: 80% or greater improvement in varicosities, significant symptom relief, and 90% or greater reduction in ulcer size; 3) effective: 50%–79% improvement in varicosities or ulcer size; 4) ineffective: failure to meet the above criteria or condition worsening. Total effective rate was defined as: (cured + markedly effective + effective) / total cases × 100%. A stratified analysis was conducted for patients with C2–C3 and C4–C6 CEAP grades.

Postoperative complications The incidence of subcutaneous hematoma, saphenous nerve

TABLE 1 Baseline characteristics of the study population

Parameter		RFHL group (n = 54)	RFA group (n = 54)	*P* value
Sex	Men	29 (53.7)	28 (51.9)	0.85
	Women	25 (46.3)	26 (48.1)	
Age, y		52.8 (8.6)	53.2 (8.3)	0.81
Disease duration, y		7.2 (3.1)	7 (3.3)	0.73
CEAP classification	C2	15 (27.8)	1 (25.9)	0.97
	C3	18 (33.3)	19 (35.2)	
	C4–C6 (severe cases)	21 (38.9)	21 (38.9)	
Comorbidities	Hypertension	11 (20.4)	12 (22.2)	0.77
	Diabetes mellitus	7 (13)	6 (11.1)	0.74

Data are presented as number (percentage) or mean (SD).

Abbreviations: see **FIGURE 1**

TABLE 2 Perioperative indicators of the groups

Indicator	RFHL group (n = 54)	RFA group (n = 54)	*P* value
Operative time, min	38.5 (7.2)	42.3 (6.8)	0.21
Perioperative blood loss, ml	21.3 (5.8)	25.6 (4.9)	0.19
Postoperative time to ambulation, h	1.2 (0.5)	1 (0.2)	0.24
Length of hospital stay, d	1.2 (0.8)	1.5 (0.9)	0.31
Postoperative 24-hour VAS score, points	2.3 (0.7)	2.5 (0.8)	0.23

Data are presented as mean (SD).

Abbreviations: VAS, Visual Analog Scale; others, see **FIGURE 1**

TABLE 3 Clinical efficacy (n = 108)

Group	Healed	Effective	Slightly effective	Ineffective	Total effective rate	*P* value
RFHL	42 (77.78)	8 (14.81)	3 (5.56)	1 (1.85)	53 (98.15)	0.008
RFA	26 (48.15)	12 (22.22)	7 (12.96)	9 (16.67)	45 (83.33)	

Data are presented as number (percentage).

Abbreviations: see **FIGURE 1**

injury, and DVT was recorded within 1 month postoperatively.

Venous function Venous function was assessed at 6 months postoperatively by measuring GSV reflux duration and venous patency score (scale, 0–4).

Long-term prognosis The recurrence rate was evaluated at 1 year postoperatively. Recurrence was defined as ultrasonographic evidence of reflux accompanied by the recurrence of clinical symptoms.

Statistical analysis The data were analyzed using SPSS Statistics software, version 28.0 (IBM Corp., Armonk, New York, United States). Measurement data were expressed as mean (SD) and compared using the independent samples *t* test. Count data were expressed as percentages and compared using the χ^2 test. Non-normally distributed continuous data and ranked data were presented as median (interquartile range [IQR]). Ranked data were analyzed using the Wilcoxon rank sum test. A *P* value below 0.05 was considered significant.

Ethics This study was reviewed and approved by the Medical Ethics Committee of Xinyang Central Hospital (XYZX2020012). Written informed consent was obtained from all participants, and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS Comparison of perioperative indicators Baseline data showed no differences between the RFHL and RFA groups, indicating comparability (**TABLE 1**).

There were no intergroup differences regarding the operative time, intraoperative blood loss, time to ambulation, LOS, or postoperative 24-hour VAS scores. This confirms that the 2 groups were comparable in terms of minimal invasiveness and perioperative recovery (**TABLE 2**).

TABLE 4 Efficacy stratified by the Clinical-Etiology-Anatomy-Pathophysiology classification[2] (n = 108)

CEAP classification	Group	Patients, n	Total effective rate	*P* value
C2–C3	RFHL	33	33 (100)	0.57
	RFA	33	32 (96.97)	
C4–C6 (severe cases)	RFHL	21	20 (96.43)	0.04
	RFA	21	16 (75)	

Data are presented as number (percentage).

Abbreviations: see **FIGURE 1**

TABLE 5 Venous function indicators at 6 months postoperatively

Indicator	RFHL group (n = 54)	RFA group (n = 54)	*P* value
Backflow time, s	0.2 (0.1–0.3)	1 (0.8–1.4)	<0.001
Venous patency score, points	0 (0–0.5)	2 (1–2)	<0.001

Data are presented as median (interquartile range).

Abbreviations: see **FIGURE 1**

TABLE 6 Complications and 1-year recurrence rate (n = 108)

Group	Ecchymoma	Saphenous nerve injury	Deep vein thrombosis	Total incidence of complications[a]	Recurrence rate 1 year postsurgery[b]	*P* value
RFHL	2 (3.7)	1 (1.85)	0	3 (5.56)	1 (1.85)	0.005
RFA	5 (9.26)	4 (7.41)	4 (7.41)	13 (24.07)	8 (14.81)	0.01

Data are presented as number (percentage).

a Total incidence of complications is calculated only for 3 types of complications: subcutaneous hematoma, plexus nerve injury, and deep vein thrombosis.

b Recurrence rate is defined as the recurrence of varicose reflux of the great saphenous vein detected on ultrasound within 1 year after surgery, accompanied by repeated clinical symptoms.

Abbreviations: see **FIGURE 1**

Clinical efficacy The total clinical effective rate in the observation group was 98.15%, markedly higher than in the control group (83.33%; $P = 0.008$). The stratified analysis showed no difference in efficacy for the C2–C3 patients with mild-to-moderate disease. However, among the C4–C6 patients (severe disease), the effective rate in the observation group was considerably superior than in the controls (96.43% vs 75%; $P = 0.04$), highlighting the advantage of RFHL in treating severe cases (**TABLES 3** and **4**).

Quantitative venous function indicators At 6 months postoperatively, median (IQR) GSV reflux time in the observation group was shorter than that in the control group (0.2 [0.1–0.3] vs 1 [0.8–1.4] s; $P < 0.001$), and venous patency score was better (0 [0–0.5] vs 2 [1–2], respectively; $P < 0.001$), suggesting a more pronounced improvement of venous function in the observation group (**TABLE 5**).

Complications and 1-year recurrence rate The total complication rate in the observation group was 5.56%, considerably lower than the 24.07% recorded in the control group ($P = 0.005$). Specifically, the observation group had 2 cases of subcutaneous hematoma (3.7%) and 1 case of saphenous nerve injury (1.85%), with no occurrences of DVT. In contrast, the control cohort reported 5 subcutaneous hematomas (9.26%), 4 saphenous nerve injuries (7.41%), and 4 DVT cases (7.41%). The 1-year recurrence rate was lower in the observation group, as compared with the controls (1.85% vs 14.81%; $P = 0.005$). These results confirm the superior safety and stable long-term efficacy of RFHL (**TABLE 6**).

DISCUSSION The core advantage of RFHL lies in its ability to achieve superior long-term outcomes without compromising the minimal invasiveness and rapid perioperative recovery associated with simple RFA. Minimally-invasive approaches, precision, and rapid recovery are the core developmental directions of modern vascular surgery.[1,12] LEVV patients are often elderly, with comorbidities, and have low tolerance for surgical trauma.[13] The results of this study indicated no significant differences in operative time, blood loss, ambulation time, or LOS between the 2 groups, which is consistent with previous findings. This confirms that RFHL does not increase surgical trauma despite the addition of high ligation,[14] aligning with minimally-invasive principles. Furthermore, postoperative VAS scores in the observation group were not significantly elevated, likely because high ligation rapidly interrupts reflux,

reducing the stimulation of surrounding tissues by venous hypertension.[2]

The core advantage of this combined procedure lies not in the perioperative phase but in superior long-term efficacy and reduced recurrence risk. Simple RFA relies on thermal energy to close the vein trunk but fails to mechanically interrupt the reflux source at the SFJ. Consequently, venous blood may still reflux into the trunk via tributaries, leading to recanalization and symptom recurrence; the recurrence rate in the control group reached 14.81%. In contrast, the observation group achieved a "source interruption + lesion clearance" effect through high ligation and ablation, resulting in a recurrence rate of only 1.85%.

RFHL overcomes the limitations of simple RFA in severe cases (CEAP, C4–C6) through precise interruption of the reflux source and thorough clearance of local lesions. For severe LEVV patients, the disease course is prolonged, and the vein wall undergoes irreversible fibrosis, often accompanied by skin nutritional disorders and ulcers. Treatment requires satisfying 3 core needs: interrupting reflux, clearing lesions, and promoting ulcer healing.[15] Simple RFA focuses only on trunk ablation and often fails to completely clear branch reflux and lesions surrounding ulcers. Persistent local congestion hinders improvement of skin nutritional status and ulcer healing.[3] In this study, the effective rate for patients with severe LEVV in the control group was only 75%.

Conversely, the observation group demonstrated a 96.43% effective rate in the severe cases. The RFHL mechanism involves: 1) high ligation completely blocking reflux and relieving venous hypertension, creating conditions for skin repair; 2) combined trunk ablation and tributary avulsion / sclerotherapy thoroughly clearing lesions around ulcers to reduce congestion; and 3) extended compression therapy (3 months) for severe patients to support functional recovery. This approach resolves the clinical limitation of simple RFA in severe cases.

RFHL exhibits a superior safety profile by allowing for optimized catheter positioning, thereby significantly reducing the risks of thermal injury and DVT. Safety is a prerequisite for clinical promotion. In simple RFA, the catheter must be advanced near the SFJ, and prolonged wall contact can cause thermal injury to surrounding tissues, leading to complications, such as subcutaneous hematoma, saphenous nerve injury, and DVT.[16] The control group had a complication rate of 24.07%, including a 7.41% DVT rate. RFHL optimizes safety through procedural changes: 1) high ligation blocks the reflux channel, allowing for the ablation catheter to be positioned 1 cm below the ligation site rather than near the SFJ, thereby eliminating the risk of heat-induced thrombosis extending into the deep system and reducing deep nerve injury risks[17]; and 2) real-time ultrasound monitoring ensures precise control, minimizing thermal damage to surrounding tissues. The observation group reported a complication rate of only 5.56%, with no DVT cases.

Limitations These findings provide an evidence-based rationale for a stratified surgical strategy, particularly for severe cases, although the results should be interpreted within the context of the study's limitations.

Limitations of this study include its single-center retrospective design, limited sample size, and a follow-up period of only 1 year. Variables such as ulcer surface area were not analyzed in depth. Future multicenter, large-sample, prospective studies with longer follow-up are recommended.

CONCLUSIONS RFHL and RFA demonstrate comparable minimal invasiveness and perioperative recovery, with no significant differences in postoperative pain. However, RFHL offers a superior safety profile and a lower long-term recurrence rate. It shows prominent efficacy in CEAP C4–C6 severe LEVV patients by effectively improving venous function, promoting ulcer healing, and reducing recurrence. This combined technique addresses the limitations of simple RFA in severe cases. RFHL combines minimally-invasive benefits with the radical cure potential of traditional surgery, and is worthy of adoption as a standard surgical modality for LEVV, particularly for patients with severe disease.

ARTICLE INFORMATION

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CONFLICT OF INTEREST None declared.

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