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ORIGINAL RESEARCH

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Investigating the effects of Qingre Lifei decoction combined with terbutaline in treating male patients with acute exacerbation of chronic obstructive pulmonary disease

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Abstract

This study aimed to evaluate the therapeutic efficacy of Qingre Lifei decoction combined with terbutaline in men suffering from acute exacerbation of chronic obstructive pulmonary disease (COPD). 100 male patients with COPD acute exacerbation admitted to our hospital between May 2020 and May 2023, were enrolled and randomly assigned to an experimental group and a control group (n = 50 each) based on a computer-generated randomization table. As a control treatment, a terbutaline nebulizer solution was inhaled alongside with conventional Western medicine. The experimental group additionally received Qingre Lifei Decoction. A comparison was made between the therapeutic effects of the two treatment methods. The experimental group exhibited a significantly higher overall effective rate than the control group ($p < 0.05$). One month after treatment, the experimental group showed significantly higher forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), and FEV1/FVC ratios than the control group ($p < 0.05$). C-reactive protein (CRP), white blood cells (WBC), and neutrophils (N) in the experimental group were significantly lower than the control group one month after treatment ($p < 0.05$). Compared to controls, the arterial oxygen partial pressure (PaO_2) and oxygen saturation (SaO_2) levels in the experimental group were significantly higher, and the carbon dioxide partial pressure ($PaCO_2$) levels were significantly lower ($p < 0.05$). Adverse drug reactions incidence did not differ between both groups ($p > 0.05$). In men with acute exacerbations of COPD, Qingre Lifei decoction combined with terbutaline nebulization can be effective in improving breathing symptoms and functional ventilation. It is safe and worthy of wider clinical promotion.

Keywords

Qingre Lifei decoction; Chronic obstructive pulmonary disease; Terbutaline nebulization

1. Introduction

Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory condition characterized by persistent inflammation triggered by noxious gases or particulates that results in irreversible airflow obstruction and progressive illness. Symptoms of COPD consists of chronic coughing, expectoration, dyspnea, and shortness of breath, with complications including cor pulmonale, heart failure, and respiratory failure [1, 2]. Acute COPD exacerbations are characterized by a rapid worsening of symptoms, such as increased coughing, sputum production, dyspnea, wheezing, and possible fever, which may culminate in respiratory failure without prompt treatment [3]. China has the highest prevalence of COPD globally, affecting primarily individuals aged over 40 [4]. Even as Western medicine's target symptom management, its long-term effectiveness is suboptimal, with limited control over disease progression. As defined by Traditional Chinese Medicine (TCM), COPD is characterized by "lung distension" and "asthma syndrome". According to TCM, the etiology is due to impairment of the lung, spleen, and kidney systems, which are exacerbated by internal phlegm dampness and qi obstruction resulting from physical exertion [5, 6]. Consequently, TCM emphasizes enhancing lung qi, alleviating asthma symptoms, addressing exterior pathogenic factors, dispelling cold, and transforming phlegm to reduce stagnation [7]. As a phlegm-clearing, bronchodilating, and immunomodulating decoction, Qingre Lifei decoction has been used in the prevention and treatment of acute and chronic pulmonary disorders. Men are more likely to suffer from COPD, which is caused by unhealthy lifestyle choices like tobacco use, alcohol consumption, inadequate rest, and stress. To prevent chronic

obstructive pulmonary disease, men need to become aware of early treatment and pay attention to relevant information. Therefore, this study examines the clinical efficacy of Qingre Lifei decoction combined with conventional Western therapy in treating acute exacerbations of COPD in male patients, and contributes to the adoption of more evidence-based practices in clinical settings.

2. Materials and methods

2.1 General information

100 male patients with acute exacerbation of COPD at our hospital from May 2020 to May 2023 were enrolled in this study. Based on the patient selection flow chart (Fig. 1), participants were randomly allocated to an experimental group (50 participants) or a control group (50 participants). Both groups have comparable general information ($p > 0.05$) (Table 1).

Western Medicine Diagnostic Criteria: (1) Rapid deterioration of respiratory symptoms, increased coughing, wheezing, expectoration, difficulty breathing, mucopurulent or purulent sputum production, and significant inflammation. (2) Progressive worsening of respiratory symptoms that exceed the normal range of daily variation, requiring a change in treatment. (3) The presence of persistent airflow limitation, FEV1/FVC $<$70% after bronchodilators inhalation.

Traditional Chinese Medicine Diagnostic Criteria: Pertaining to "Phlegm-Heat Obstructing the Lungs Syndrome". Main symptoms: coughing, panting, shortness of breath, asthma, chest tightness, abundant sputum and yellowish or white sticky dry sputum. Secondary symptoms: fever, thirst for cold drinks and constipation. Tongue and pulse: red tongue body, yellow, thick and greasy tongue coating, slippery and rapid pulse.

Inclusion Criteria: (1) Meet both the Western and Traditional Chinese Medicine diagnostic criteria. (2) Aged 40–85 years. (3) Complete clinical data. (4) Informed consent form signed and willing to cooperate. Exclusion Criteria: (1) Accompanied by malignant tumors, or endocrine system diseases. (2) Infectious diseases. (3) Accompanied by severe extrapulmonary organ dysfunction. (4) Mental disorder or uncertainty. (5) Chronic obstructive pulmonary disease in a

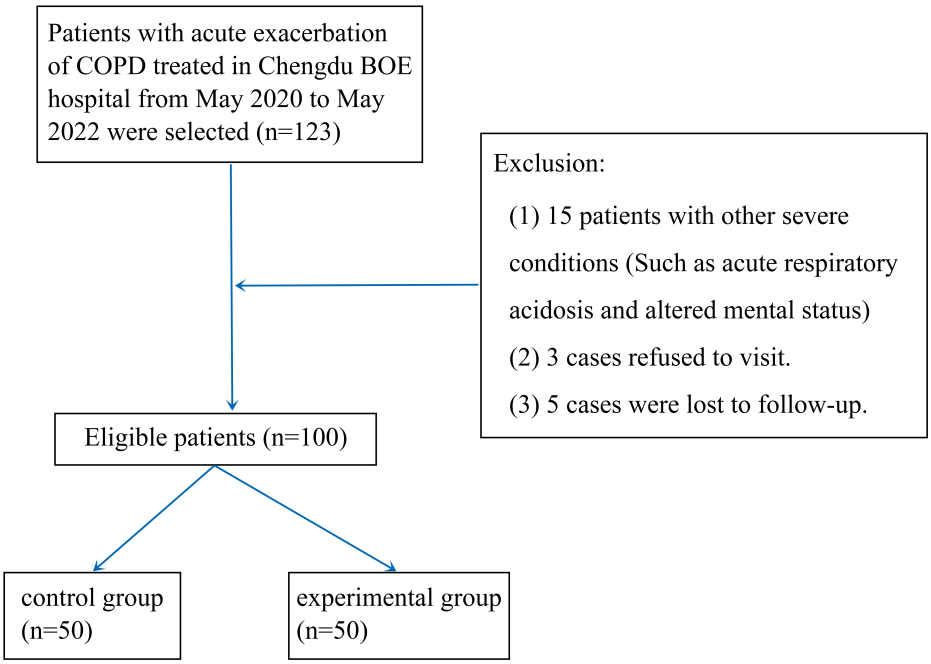

FIGURE 1. Flow chart of patients' inclusion. COPD: chronic obstructive pulmonary disease.

TABLE 1. Comparison of general information between both groups ($\bar{x} \pm s$).

Group	n	Age (yr)	Course of disease (yr)	Hypertension
Experimental group	50	62.64 ± 11.65	2.45 ± 1.37	5
Control group	50	63.20 ± 10.92	2.68 ± 1.31	6
χ^2/t	-	0.248	0.858	0.102
p	-	0.805	0.393	0.749
Group	n	History of drinking	History of smoking	Diabetes mellitus
Experimental group	50	33	40	9
Control group	50	34	35	3
χ^2/t	-	0.045	1.333	3.409
p	-	0.832	0.248	0.065

stable phase. (6) Other lung diseases (such as interstitial lung diseases).

2.2 Methods

Control group inhaled terbutaline nebulization twice daily for 15 minutes at a dosage of 2 mL (5 mg). Western medical therapy: (1) Controlled oxygen therapy: Hospitalized acute exacerbation of chronic obstructive pulmonary disease (AECOPD) patients receive oxygen therapy as a fundamental treatment. After oxygen therapy patients without severe complications can easily reach satisfactory oxygenation levels (PaO_2 >60 mmHg or SaO_2 >90%). However, inhaled oxygen concentration should not be too high to avoid potential CO_2 retention and respiratory acidosis. There are two methods of oxygen delivery: nasal cannulas and Venturi masks, with Venturi masks regulating inhaled oxygen concentration more precisely. Arterial blood gases should be checked again 30 minutes after starting oxygen therapy to ensure satisfactory oxygenation and to rule out CO_2 retention and respiratory acidosis. (2) Airway dilation: This includes the administration of β2-adrenergic receptor agonists and anticholinergics. In severe cases, a daily intravenous dose of aminophylline (0.25 g mixed in 250 mL of 5% glucose solution) once a day for 7 days. (3) Corticosteroids: To accelerate recovery, these are prescribed alongside bronchodilators for hospitalized AECOPD patients. Oral prednisone (30–40 mg/day for 10–14 days, with a gradual taper) or intravenous methylprednisolone (40 mg daily for 3–5 days, followed by an oral regimen) sre options.

Supportive Care: Monitoring and supplementing fluid and electrolyte balance is essential, as is nutritional support—*via* enteral or parenteral means if necessary. Prophylactic anticoagulation with heparin or low molecular weight heparin is recommended for patients immobilized, with polycythemia, dehydration or with thromboembolic disease. Additional treatments include facilitating sputum expectoration (stimulating coughs, chest percussion, postural drainage and humidifying airways), addressing comorbidities (coronary heart disease, diabetes, hypertension), and managing comorbidities (shock, disseminated intravascular coagulation or upper gastrointestinal bleeding).

Mechanical ventilation: During ventilation, arterial blood gas should be monitored. (1) Non-invasive Ventilation (NIV): Parameters are customized to the patient's needs, aiming to control spontaneous breathing with a backup rate of 12 breaths/min. Initial settings include an expiratory pressure of 3–4 cmH_2O and an inspiratory pressure of 7–8 cmH_2O, which are then gradually adjusted to 5–6 cmH_2O (every 3 hours/3 times daily) and eventually 15–20 cmH_2O as tolerated. Through a nasal mask with adjustable flow rates, oxygen is delivered to keep oxygen saturation above 90%. (2) Invasive Ventilation: With severe acid-base disturbances or altered consciousness who continue to have respiratory failure despite maximal medical and non-invasive measures should be considered for invasive ventilation. This involves intubation and modes like Synchronized Intermittent Mandatory Ventilation (SIMV) combined with Pressure Support Ventilation (PSV) and Positive End-Expiratory Pressure (PEEP). Frequency (10–12 breaths/min) and pressure (10–12 cmH_2O) are adapted to clinical status and blood gas analysis. Upon improving, the patient may be able to transition to NIV. Patients' and families' preferences should be respected when making decisions regarding mechanical ventilation, especially for end-stage COPD, as well as the potential benefits of intensive interventions.

Antibiotics: When patients exhibit exacerbated dyspnea, increased coughing, and purulent sputum active antibiotic therapy is initiated, based on local pathogen prevalence and antibiotic sensitivity.

Experimental group received the Qingre Lifei decoction on top of the control group's treatment. The prescription consists of 20 g Salvia miltiorrhiza, 15 g each of Pheretima, Polygonatum kingianum, Lepidium apetalum seed, Stemona tuberosa, Houttuynia cordata, Descurainia sophia seed, and 10 g each of Glycyrrhiza and Schisandra chinensis. Dosage and usage: One dose per day, add 1200 mL of water, decoct regularly for 30 minutes. Take 300 mL of the decoction divided into morning and evening doses of 150 mL each. Both groups underwent four consecutive 7-day courses.

2.3 Observation indicators

(1) Treatment Effectiveness: In 1 month after hospitalization, the doctor will evaluate the treatment effect comprehensively according to the following criteria. Significant effect: Significant symptom relief or disappearance of asthma and shortness of breath after treatment, and $\geq$70% improvement in lung function. Effective: Asthma and shortness of breath symptoms improved after treatment, 30%–70% improvement in lung function. Ineffective: No symptoms change or condition worsens, <30% improvement in lung function. Total effective rate = marked effectiveness + effectiveness rate. (2) Changes in lung function indicators between both groups, including Forced Vital Capacity (FVC), Forced Expiratory Volume in the first second (FEV1), and calculation of FEV1/FVC values, measured before treatment and one month after treatment. (3) Inflammatory markers: Comparing inflammatory markers before and after treatment for both groups, including C-reactive protein (CRP), white blood cell count (WBC), and neutrophils (N) percentage. CRP detection method: 4 mL of fasting elbow venous blood from patients is routinely centrifuged before immunoturbidimetry. WBC and N percentage were measured using standard blood tests. (4) Blood gas analysis: Using blood gas analyzers to measure arterial oxygen pressure (PaO_2), carbon dioxide pressure ($PaCO_2$), and oxygen saturation (SaO_2) before and after treatment in both groups. (5) Recording adverse reactions during treatment.

2.4 Statistical methods

Statistical analysis was performed using SPSS 18.0 (IBM, Armonk, NY, USA). Quantitative data were described by mean ($\bar{x} \pm s$) and compared using *t*-tests. Categorical data were described in percent (%) and compared using chi-square test. $p < 0.05$ indicates statistically significant difference.

3. Results

3.1 Comparison of treatment efficacy

The experimental group had a significantly higher total effective rate than the control group ($p < 0.05$) (Table 2).

3.2 Changes in lung function indicators

One month after treatment, the experimental group showed significantly higher FVC, FEV1 and FEV1/FVC compared to the control group ($p < 0.05$) (Table 3).

3.3 Inflammatory factors

One month after treatment, CRP, WBC and N were significantly in the experimental than the control group ($p < 0.05$) (Table 4).

3.4 Changes in blood gas indicators

One month after treatment, the experimental group had significantly higher PaO_2 and SaO_2, and lower $PaCO_2$ compared to the control group ($p < 0.05$) (Table 5).

3.5 Adverse reactions

Adverse drug reactions incidence did not differ between both groups ($p > 0.05$) (Table 6).

4. Discussion

COPD is a common respiratory condition characterized by bronchial smooth muscle spasms. By compromising gas exchange, leading to pulmonary hyperinflation, and tiring respiratory muscles, these spasms lead to hypoxia, carbon dioxide retention, and mutual exhaustion syndromes [8, 9]. COPD's high incidence among the elderly markedly deteriorates both pulmonary function and overall quality of life [10]. Contemporary clinical research focuses on developing effective strategies to ameliorate clinical symptoms and improve pulmonary ventilation, thereby elevating life quality. Traditional Chinese Medicine (TCM) categorizes COPD as "lung distension" and "asthma syndrome" which are characterized by both essential deficiencies and symptoms excess [11]. This pathological framework encompasses qi deficiency, depletion, or recurrent wind-cold infections harming yang qi, resulting in lung qi

TABLE 2. Comparison of treatment efficacy between both groups (n (%)).

Group	n	Significant effect	Effective	Ineffective	Total effective rate
Experimental group	50	26 (52.00)	21 (42.00)	3 (6.00)	47 (94.00)
Control group	50	18 (36.00)	22 (44.00)	10 (20.00)	40 (80.00)
χ^2					4.332
p					0.037

TABLE 3. Comparison of lung function indicators between both groups ($\bar{x} \pm s$).

Group	n	FVC (L)		FEV1 (L)		FEV1/FVC (%)	
		Before treatment	One month after treatment	Before treatment	One month after treatment	Before treatment	One month after treatment
Experimental group	50	1.25 ± 0.31	2.03 ± 0.44	0.69 ± 0.17	1.54 ± 0.33	55.33 ± 2.69	75.86 ± 3.81
Control group	50	1.31 ± 0.27	1.77 ± 0.37	0.73 ± 0.15	1.22 ± 0.25	56.25 ± 2.65	68.93 ± 3.25
t	-	1.032	3.198	1.248	5.466	1.723	9.785
p	-	0.305	0.002	0.215	<0.001	0.088	<0.001

Note: independent samples t-test was used for comparison between groups.
FVC: Forced vital capacity; FEV1: forced expiratory volume in the first second.

TABLE 4. Comparison of inflammatory factor levels between both groups ($\bar{x} \pm s$).

Group	n	CRP (mg/L)		WBC ($\times 10^9$/L)		N (%)	
		Before treatment	One month after treatment	Before treatment	One month after treatment	Before treatment	One month after treatment
Experimental group	50	16.65 ± 4.25	4.01 ± 0.21	10.23 ± 1.48	7.40 ± 1.40	79.63 ± 7.35	61.30 ± 5.24
Control group	50	16.30 ± 4.26	4.96 ± 0.34	10.56 ± 1.27	8.95 ± 1.92	80.36 ± 6.85	69.31 ± 6.05
t	-	0.411	16.810	1.197	4.612	0.514	7.708
p	-	0.682	<0.001	0.234	< 0.001	0.609	<0.001

Note: independent samples t-test was used for comparison between groups.
CRP: C-reactive protein; WBC: white blood cell count; N: neutrophils.

TABLE 5. Comparison of blood gas indicators between both groups ($\bar{x} \pm s$).

Group	n	PaO_2 (mmHg)		$PaCO_2$ (mmHg)		SaO_2 (%)	
		Before treatment	One month after of treatment	Before treatment	One month after of treatment	Before treatment	One month after of treatment
Experimental group	50	40.97 ± 1.45	85.64 ± 3.56	68.30 ± 7.26	46.34 ± 6.08	74.30 ± 4.14	97.05 ± 1.03
Control group	50	40.75 ± 1.51	55.31 ± 2.48	67.21 ± 7.43	51.37 ± 7.16	74.24 ± 4.31	87.31 ± 1.51
t	-	0.743	49.431	0.742	3.787	0.071	37.680
p	-	0.459	<0.001	0.460	<0.001	0.944	<0.001

PaO_2: Blood oxygen partial pressure; $PaCO_2$: carbon dioxide partial pressure; SaO_2: oxygen saturation.

TABLE 6. Comparison of adverse events between both groups (n (%)).

Group	n	Gastrointestinal discomfort	Headache	Palpitate	Nausea and vomiting	Adverse reactions
Experimental group	50	1 (2.00)	2 (4.00)	1 (2.00)	0	4 (8.00)
Control group	50	3 (6.00)	2 (4.00)	1 (2.00)	1 (2.00)	7 (14.00)
χ^2						0.919
p						0.338

fullness and primary manifestations such as asthma, coughing, oppression, swelling, and chronic pulmonary conditions—which are all based on a kidney yang deficiency [12]. Therefore, both the lungs and kidneys should be treated in clinical interventions.

Terbutaline, a β2-adrenergic agonist widely employed in COPD treatment, binds effectively to β2 receptors, improving bronchodilation and mucus clearance with pronounced permeability effects [13]. Despite this, its use as a standalone therapy is not optimal due to its limited anti-inflammatory properties [14]. The integration of TCM into COPD management has demonstrated promise owing to its holistic approach targeting underlying causes and symptoms, to its minimal side effects, and to its ability to adapt to the individual needs of patients. The treatment has been shown to significantly improve clinical COPD symptoms, reduce disease duration, and improve prognoses [15]. In this study, the experimental group had a significantly higher total effective rate than the control group. One month after treatment, the experimental group's FVC, FEV1 and FEV1/FVC were significantly higher than the control group. Accordingly, Qingre Lifei decoction, along with Western medical approaches, has a substantial therapeutic effect on COPD. With the Qingre Lifei decoction, COPD symptoms are addressed comprehensively with a combination of principal, minister, adjuvant and messenger drugs. Salvia miltiorrhiza and Houttuynia cordata are the primary herbs, with Salvia miltiorrhiza promoting circulation and dispelling blood stasis. Houttuynia cordata has the ability to relieve wind-heat, detoxify and produce a cooling effect, making it particularly effective in treating lung heat accompanied by coughing [16]. Minister drugs include Semen Raphani, Lepidium apetalum seed, and Stemona tuberosa. Semen Raphani reduces qi and phlegm, while Lepidium apetalum seed soothes coughs, relieves asthma and promotes diuresis. Stemona tuberosa suppresses phlegm production and coughing, moisturizes the lungs and descends qi [17, 18]. Schisandra chinensis, Polygonatum kingianum, and Pheretima act as adjuvants. Generally indicated for depleted asthma and chronic cough cases, Schisandra chinensis is known for its benefits to qi, fluid generation, cough cessation, and lung moisturization. Polygonatum kingianum provides lung nourishment and qi enrichment, also aiding the spleen, whereas Pheretima facilitates the opening of collaterals and veins, lung clearance, wind extinction, asthma stabilization, and heat reduction [19, 20]. In this formula, licorice acts as a harmonizing agent, ensuring synergy between the herbs. TCM deals with underlying causes as well as manifest symptoms, while Western medicine provides complementary treatment support that halts disease progression and maintains physiological functions. In comparison to Western medicine monotherapy, this integrative approach can improve patients' physiological status and improve their prognosis [21, 22]. One month after treatment, the experimental group showed lower levels of CRP, WBC and N than the control group. Inflammation and inflammatory markers can be significantly decreased by combining TCM and Western medicine. Analytically, this therapeutic synergy may be attributed to the herbal constituents' coordinated action on blood circulation, dissolving stasis, eliminating heat, transforming phlegm, stabilizing asthma, and quelling coughs. Efforts to address root causes and symptoms concurrently have shown that this regimen exhibits anti-inflammatory properties, opposes pro-inflammatory mediators, ameliorates capillary permeability, mitigates bodily inflammation and exudation, dilutes sputum, attenuates airway hyperresponsiveness, and balances immune and respiratory dysfunctions. In the experimental group, inflammatory markers were significantly lower than in the control group post-treatment, indicating a significant reduction in inflammation. One month after treatment, the experimental group had significantly higher PaO_2 and SaO_2, and lower $PaCO_2$ than the control group. Based on these results, it appears that the combination with Qingre Lifei decoction is more effective than Western medicine alone at mitigating hypoxic conditions. The efficacy is partly attributed to the Salvia miltiorrhiza's bioactive constituents: lipid-soluble tanshinone and water-soluble

salvianolic acid compounds. These agents offer resistance to pulmonary fibrosis, preempt emphysema development, lower pulmonary hypertension, repair lung tissue lesions, and reduce capillary permeability [23, 24]. Salvia miltiorrhiza is also notable for its antispasmodic properties on vascular smooth muscle. It dilates pulmonary vessels to enhance gas exchange, thus improving respiratory distress symptoms. Pheretima relaxes bronchial smooth muscle spasms, thus alleviating asthma symptoms. These drugs act synergistically to increase blood circulation, resolve stasis, suppresses coughs, and ease asthmatic symptoms, thereby reducing patients' hypoxic states. Adverse drug reactions did not differ significantly between both groups, indicating that the combination of Qingre Lifei decoction and Western medicine. By treating COPD patients with the Qingre Lifei decoction in conjunction with terbutaline nebulization, it is concluded that not only is pulmonary function enhanced, but also hypoxia is alleviated, and the anticipated clinical outcomes is achieved. However, the small sample size of this study may result in biased results. Future research should expand the sample size and incorporate multicenter studies to bolster the robustness of the results.

5. Conclusions

In conclusion, the combination of Qingre Lifei decoction and terbutaline nebulization offers considerable therapeutic benefits to men suffering from acute exacerbations of COPD disease. Pulmonary ventilation function and blood gas parameters improve significantly after treatment. It facilitates patients' overall health restoration and demonstrates favorable therapeutic effects that make it worthy of wider clinical promotion.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

HZ—designed the study and carried them out, prepared the manuscript for publication and reviewed the draft of the manuscript; HZ, LW, AL, LBX, XG—supervised the data collection, HZ, LW, AL, LBX—analyzed the data, HZ, LW, AL—interpreted the data. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Chengdu BOE Hospital (Approval no. 2019059). Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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