

Case Report





# Yousiyue induced pulmonary embolism: a case report

#### **Abstract**

We evaluate a case report of Yousiyue induced pulmonary embolism in order to provide reference for safety use of oral contraceptives.

Keywords: Yousiyue, oral contraceptives, pulmonary embolism

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#### Introduction

Drospirenone and ethinylestradiol tablets (II) was approved by the State Food and Drug Administration in 2014, officially landed in Chinese market in April 2015 and the product name is Yousiyue. The main components of Yousiyue are drospirenone 3mg with ethinylestradiol 0.02mg. Drospirenone is called the fourth generation pregnancy hormone. It has Progestogen, Antiandrogen and Antimineralocorticoid activities. Not only does it have efficient contraceptive effect, but it can also stabilize hormone levels in women's bodies. But it still can cause some general and serious adverse reactions during usage process. Among these serious adverse reactions, the risk of thromboembolism has caused widespread controversy internationally.1 It has been reported a case of a young Japanese woman who died of pulmonary embolism after taking drospirenone and ethinylestradiol tablets (II) for 17 months due to dysmenorrhea. Three cases of death caused by thrombotic disease after taking drospirenone ethinylestradiol tablets within one year, the relevant department in Japan issued a safety alert for this drug.<sup>2</sup> In this paper, one case of adverse reaction of pulmonary embolism caused by the use of Yousiyue in the treatment of polycystic ovary syndrome was analyzed in order to provide a reference for the safety research of oral contraceptives in China.3

## **Case report**

On May 19, 2022, a 29-year-old female patient began to take drospirenone and ethinylestradiol tablets (II)(Yousiyue) orally due to "polycystic ovary syndrome", 2 tablets per day. (Since Yousiyue is non-prescription drug in China, most of them may be purchased through social pharmacies, which may lead to off-label uses.) On November 1st, she came to our hospital due to "chest pain accompanied by asthma for 10 days" for treatment and voluntarily stopped taking Yousiyue. At admission, the main symptoms and signs are: slight cough and phlegm, with a small amount of blood in the sputum, normal body temperature, no chest tightness, no dizziness, headache, no nausea and vomiting, no fever or chills, good sleep, normal bowel movements, clear consciousness, good mental health, flat breathing, clear respiratory sounds in both lungs, no obvious dry or wet rales, regular heart rhythm, no pathological murmurs, soft abdomen, no tenderness or rebound pain, and no edema in both lower

limbs. Pulmonary embolism and pulmonary infarction were diagnosed by computer tomography pulmonary angiography (CTPA). After admission, urine routine, blood routine, thyroid function, coagulation function, etc. were checked, and the results were all normal. Considering the serious adverse reactions caused by Yousiyue. low molecular weight heparin calcium injection was administered for anti-coagulation treatment. On the third day of admission, the patient's chest pain symptoms improved and fever appeared. C-reactive protein (CRP) was found to be elevated, and the patient was considered to be complicated with pulmonary infection. Anti-infection treatment was continued. After treatment for 16 days, the patient had no obvious discomfort and abnormal signs and was permitted to be discharged from the hospital.

# **Discussion**

Compared with Yasmin, the estrogen content of Yousiyue drops to 20 µg/tablet. At present, it is the lowest estrogen daily dose in China. It can reduce the occurrence of estrogen related adverse reactions and reduce the fluctuation of endogenous hormones to a greater extent through the "24+4" drug administration mode. Studies have shown that in hormone free interval of the traditional "21+7" mode, follicle stimulating hormone (FSH) increases, causing follicles to grow and produce estrogen, leading to follicle escape and bleeding problems. Reducing the hormone free interval from 7 days to 4 days can reduce fluctuations in endogenous hormones, thereby better inhibiting ovarian activity and ovarian hormone synthesis.

Although the adverse reactions of low-dose Drospirenone and ethinylestradiol tablets (II) were less, there are still risks of venous thromboembolism. Pulmonary embolism is a life-threatening disease. There were evidences that estrogen in oral contraceptives, especially Ethinylestradiol, can increase prothrombin activity, thus inducing resistance to the blood's natural anticoagulant system.<sup>6</sup> There were also evidence that drospirone/Ethinylestradiol can affect the morphology and biochemical characteristics of red blood cells, promote platelet activation, and lead to the transformation of blood to a hypercoagulable state.<sup>7</sup> To ensure safe medication, it is necessary to thoroughly inquire about the patient's past history, allergy history, personal history, and family history before using the drug, and evaluate the medication risks in detail. It can be used only when it is confirmed that the benefits of taking the drug outweigh the risks,



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and patients should be followed up as much as possible. Although the incidence of serious adverse reactions of Pulmonary embolism caused by Yousiyue is very low and rare, once it occurs, it must be actively rescued to avoid life danger. Chinese clinical safety research on its post marketing needs to be strengthened. This case report will provide a reference for the safety research of oral contraceptives in China.

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#### **Conflicts of interest**

Authors declare that there is no conflict of interest exists.

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Study on the mechanism of drug procurement and rational drug use.

### References

 Jiangping D. FDA: drospirenone containing contraceptives may increase the risk of blood clots in women. Modern Medicine and Clinical Practice. 2011;26(4):293 □

- Idota N, Kobayashi M, Mivamori D, et al. Drospirenone detected in postmortem blood of a young woman with pulmonary thromboembolism a case report and review of the literature. Leg Med Tokyo. 2015;17(2):109–115.
- 3. http://www.jsadr.org.cn/
- Yue T, Zhigang Z. Clinical application status and evaluation of drospirenone and ethinylestradiol tablets (II). *Drug Evaluation*. 2017;14(16):42–58.
- Spona J, Binder N, Hoschen K, et al. Suppression of ovarian function by a combined oral contraceptive containing 0.02mg ethinyl estradiol and 2mg chlormadinone acetate given in a 24/4-day intake regimen over three cycles. Fertil Steril. 2010.94(4):1195–1201.
- Lima A, Martins L, Lopes M, et al. Influence of hormonal contraceptives and the occurrence of stroke: integrative review. Rev Bras Enfemi. 2017;70(3):647–655.
- Emmerson O, Bester J. Lindeque BG, et al. The impact of two combined oral contraceptives containing ethinyl estradiol and drospirenone on whole blood clot viscoelasticity and the biophysical and biochemical characteristics of erythrocytes. *Microsc Microanal*. 2018;24(6):713– 728