



Project to Collect Medical Near-Miss/
Adverse Event Information

Medical Safety
Information

No.125, April 2017

Insufficient Understanding of Drugs to be Halted Pre-operatively —Oral Contraceptives—

Two cases have been reported in which medical personnel were unaware that the package insert specified that the drug was contraindicated in the case of surgery or that the patient was taking the drug, resulting in surgery being postponed (information collection period: from January 1, 2013 to February 28 2017). The information is compiled based on “Individual Theme Review” (p.130) in the 44th Quarterly Report.

Cases have been reported in which surgery was postponed because a patient did not stop taking an oral contraceptive which the package insert specified to be contraindicated for women due to have surgery within four weeks.

Drug Name	Background
Ange 28 Tablets	Physician A, who saw the patient at her first consultation, had ascertained that the patient was taking the drug, but failed to tell Physician B
Triquilar 28	Neither the physician nor the nurse knew that the drug is contraindicated for pre-operative patients

- Oral Contraceptives**
- Ange 21/28 Tablets
 - Ortho 777-21 Tablets
 - Ortho M-21 Tablets
 - Synphase T28 Tablets
 - Triquilar 21/28
 - Favoir 21/28
 - Marvelon 21/28
 - Labellefile 21/28
- *From PMDA, Information on Package Inserts for Prescription Drugs (as of February 28, 2017)

- ◆ The contraindications section on the package insert states, “Patients due to have surgery within the next four weeks, patients who have had surgery within the last two weeks, patients who gave birth within the last four weeks, and patients who require bed rest for a long period [There can be a higher risk of cardiovascular side-effects due to increased blood coagulability].”
- ◆ Some therapeutic agents for treating dysmenorrhea also carry a contraindication for patients due to have surgery within four weeks.

Insufficient Understanding of Drugs to be Halted Pre-operatively —Oral Contraceptives—

Case 1

Physician A, who saw the patient as an outpatient at her first consultation six months earlier, had ascertained from the medical history form that the patient was taking Ange Tablets, but failed to tell Physician B when the latter took over the patient's care. Physician B knew that Ange Tablets are contraindicated for a period of four weeks before surgery, but had not ascertained that the patient was taking this drug, so did not order the patient to stop taking them during her outpatient consultation. After admission, information provided by the patient herself resulted in discovery of the fact that the patient was taking Ange Tablets and surgery was postponed.

Case 2

The patient had an outpatient consultation in the surgical department and was scheduled for surgery about a month later. At the time of the consultation, the patient told the physician that she was taking Triquilar, but the physician did not realize that the drug is contraindicated for a period of four weeks before surgery and therefore did not order the patient to stop taking Triquilar. When the patient came for her pre-admission orientation six days before admission, the nurse learned that the patient was taking Triquilar, but did not know that it is a drug that must be stopped before surgery. After admission, the pharmacist noticed that Triquilar had not been stopped and surgery was postponed.

Preventive measures taken at the medical institutions in which the events occurred

- Staff will be made fully aware that oral contraceptives are contraindicated for patients due to have surgery within four weeks.
- Pharmacists will identify the patient's oral medications on the day of the outpatient consultation at which the patient's surgery is decided and provide information to the physician.

Complementary comment by the Comprehensive Evaluation Panel

- Indicate contraindicated oral medications on the pre-operative checklist and ensure thorough adherence to checks thereof.

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project.

<http://www.med-safe.jp/>

* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.

* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.



Department of Adverse Event Prevention
Japan Council for Quality Health Care

1-4-17 Kandamisaki-cho, Chiyoda-ku, Tokyo 101-0061 JAPAN
Direct Tel: +81-3-5217-0252 Direct Fax: +81-3-5217-0253
<http://www.med-safe.jp/>