

Uterine Perforation with the Levonorgestrel Releasing Intrauterine Device; Analysis of Reports from Four National Pharmacovigilance Centres

Kees van Grootheest,^{1,2} Bernhardt Sachs,³ Mira Harrison-Woolrych,⁴ Pia Caduff-Janosa⁵ and Eugene van Puijenbroek¹ 1 Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, the Netherlands 2 Department of Pharmacy, Section Pharmacotherapy and Pharmaceutical Care, University of Groningen, Groningen, the Netherlands 3 Division of Pharmacovigilance, Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany 4 Intensive Medicines Monitoring Programme, Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand 5 Unit Vigilance, Division of Safety of Medicines, Swissmedic, Swiss Agency for Therapeutic Products, Bern, Switzerland

Abstract

Background: Levonorgestrel-releasing intrauterine devices (LNG-IUD) are commonly used for contraception and other indications in many countries. National pharmacovigilance centres have been receiving reports from healthcare professionals and patients of uterine perforation associated with the use of these LNG-IUDs.

Methods: National pharmacovigilance centres in the Netherlands, New Zealand, Switzerland and Germany did a search on their adverse drug reaction databases for reports of cases of uterine perforation after insertion of a LNG-IUD received between the introduction of the LNG-IUD onto the market in the late 1990s and 15 July 2007. The number of women affected and patient characteristics such as age, parity and breastfeeding status were examined. In addition, the method of detection of the perforation and the time until discovery of the perforation were analysed.

Results: Between the introduction of the LNG-IUD onto the market in each country and 15 July 2007, 701 cases of uterine perforation with a LNG-IUD were reported; 8.5% of the perforations were detected at the time of insertion. Abdominal pain and control/check-up visits were the most common events that lead to the detection of a perforation. Of 462 women known to be parous, 192 (42%) were breastfeeding at the time the perforation was discovered.

Conclusions: Uterine perforations can be asymptomatic and may remain undetected for a long time after IUD insertion. Abdominal pain, control/ check-up visits or changes in bleeding patterns are triggers for detection of perforation and should therefore be taken seriously.

For more information, please contact info@lareb.nl