



MADRAC *Bulletin*

For healthcare professionals only

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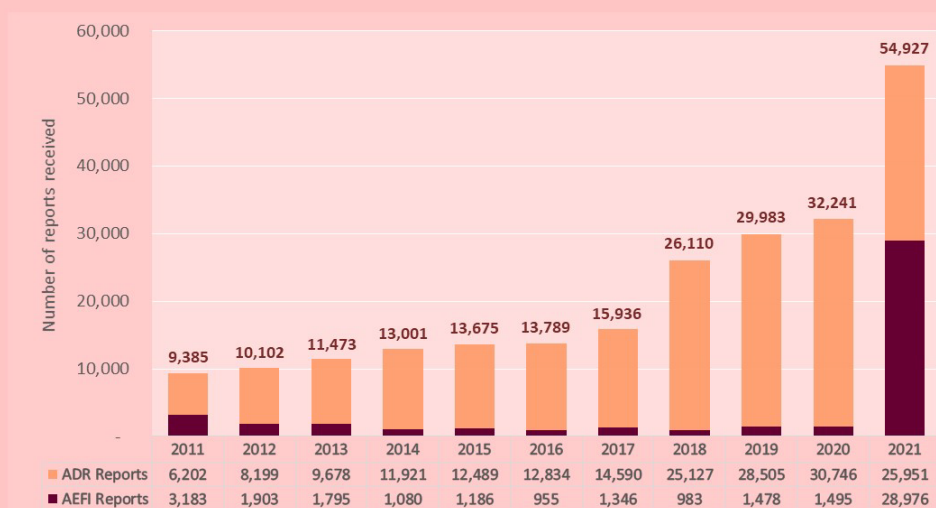
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Features

Adverse Event Reports for 2011-2021

In 2021, the Centre for Adverse Drug Reaction Monitoring, NPRA received total 54,927 adverse drug reaction (ADR) and adverse event following immunisation (AEFI) reports, with an 70.4% increase compared to 2020. In particular, the number of AEFI reports received in 2021 has increased nearly 20-fold in comparison to 2020. The apparent surge was largely resulted from the increased awareness of adverse event (AE) reporting as well as a massive influx of AEFI reports following the mass vaccination roll-out under the National Immunisation Program for COVID-19 (PICK) in Malaysia since 24th February 2021.

Total Adverse Drug Reaction (ADR) and Adverse Event Following Immunisation (AEFI) Reports Received Annually (2011-2021)



DISCLAIMER:

Figure 1 shows the total reports received by NPRA before full evaluations were carried out. These adverse events are not necessarily causally related to the product/vaccine.

Features

Summary Report on Adverse Events Following Immunisation of COVID-19 Vaccines in Malaysia #2

The NPRA monitors the safety of COVID-19 vaccines to ensure that they remain safe for use and the benefits of these vaccines continue to outweigh the risks in the Malaysian population. As part of our monitoring efforts, NPRA is publishing key findings of this safety monitoring.

The current summary report is based on data up to 31st December 2021.

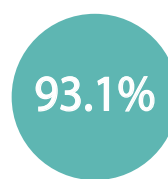
[Read the summary report here.](#)



Minor AEFI responses
per 1,000 doses



Overall AEFI reports
per 1,000 doses



Percentages of
non-serious AEFI reports



Serious AEFI reports
per 1,000 doses

Similar to global scenario, the vast majority of the reported AEFIs in Malaysia are non-serious. The most common reactions included injection site pain, headache, fatigue, muscle or joint pain, lethargy and fever.

The rate of serious AEFIs reported via the NPRA Reporting System is small at 0.03 per 1,000 doses, most requiring short-term hospitalisation for observation and treatment.



Based on the current data, the benefit-to-risk-ratio of COVID-19 vaccines registered in Malaysia remains very favourable.

The NPRA encourages all healthcare professionals and patients to report any suspected AEFIs so that potential new risks can be identified, and appropriate safety measures and regulatory actions can be taken to mitigate the risk, if deemed necessary.

Features

Welcome MADRAC 2022-2024

The 181th Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) meeting, which was held virtually on 24th February 2022, marked the first MADRAC meeting for the 2022-2024 session.



NPRA extends our utmost welcome to all respectable MADRAC members

NPRA believes that the shared expertise of MADRAC 2022-2024 from a variety of fields and practices will benefit and advance the national pharmacovigilance system for safety monitoring of medicines and vaccines in Malaysia.

Information of the members and alternates of MADRAC 2022-2024 is available on the NPRA website > About NPRA > MADRAC Members

COVID-19 Vaccine Special Pharmacovigilance Committee (JFK)

As part of the pharmacovigilance preparedness for the National Immunisation Program for COVID-19 (PICK) in Malaysia, the Ministry of Health (MOH) has set up the COVID-19 Vaccine Special Pharmacovigilance Committee (JFK - *Jawatankuasa Farmakovigilans Khas Vaksin COVID-19*) in early 2021.

JFK is chaired by the NPRA Director and comprises of relevant health experts from cardiology, immunology, haematology, neurology, internal medicine, pathology, infectious diseases, geriatrics and forensics from MOH facilities, public and private universities. The primary functions of JFK are to evaluate the causality of serious AEFI reports specific to COVID-19 vaccine, to communicate insights from AEFI reporting to the National Immunisation Policy and Practice Committee (JDAIK - *Jawatankuasa Dasar dan Amalan Imunisasi Kebangsaan*), to make recommendations on COVID-19 vaccine safety issues, including any necessary policy changes, as well as to provide essential information to the Special Financial Assistance on Adverse Effects of COVID-19 Vaccine Committee (BKK - *Bantuan Khas Kewangan Kesan Mudarat Vaksin COVID-19*).

The JFK meeting is held virtually once a month.



Articles Based on Case Reports

Myocarditis in Adolescents Following COVID-19 Vaccination

by Nur Ayuni binti Ahmad

Case Report 1ⁱ

A 14-year-old male with no known medical illnesses received his first dose of Comirnaty vaccine. The next day after vaccination, he developed left-sided chest pain that was described as pricking in nature but non-radiating. The symptom was present on and off for a few days but claimed to be bearable. As the symptom persisted, he sought treatment at a health facility. Upon investigations, an electrocardiogram (ECG) examination showed ST elevation at leads II, III, aVF and V5, V6 with PR inversion and the creatine kinase (CK)-MB level was elevated at 47 U/L. Besides that, his echocardiogram (ECHO) showed no abnormalities, with an ejection fraction at 58%. Cardiac magnetic resonance imaging (MRI) revealed myocardial oedema, inflammation of basal inferior and mid inferolateral walls at the left ventricle, as well as subepicardial fibrosis of the basal inferolateral/inferior wall. The patient was diagnosed with **acute myocarditis post COVID-19 vaccination** and treated with ibuprofen tablets 600 mg three times a day for 1 week followed by a five-week taper, colchicine tablet 0.5 mg once daily, and omeprazole capsule 20 mg once daily. The patient was recovering well at the point of reporting.

Case Report 2ⁱ

A 16-year-old male received his second dose of Comirnaty vaccine. He developed chest pain two days after vaccination, which increased with inspiration. He was subsequently admitted to the hospital for further investigation. Troponin T, CK, and CK-MB levels were found to be elevated at >2000 ng/L, 743 U/L and 17.6 ng/mL, respectively. ECG showed ST elevation in leads V3-V6, while echocardiogram appeared normal with an ejection fraction at 56%. The patient was diagnosed with **acute myocarditis secondary to COVID-19 vaccination** and treated with diclofenac tablets 50 mg three times a day, pantoprazole tablets 40 mg two times a day, paracetamol tablets three times a day, and potassium chloride in normal saline intravenous drip. The patient was recovering well at the point of reporting.

Discussion

According to the World Health Organisation (WHO), myocarditis is one of the adverse events of special interest that needs to be closely monitored post COVID-19 vaccination.^{2,3} As reported by the US Centers for Disease Control and Prevention (CDC), the rate of myocarditis/pericarditis was approximately 12.6 cases per million doses after the second dose of mRNA vaccination among individuals aged 12 to 39 years. Rare cases of myocarditis have been reported, primarily in adolescent males and young adult.³



Myocarditis is a condition in which the myocardium becomes inflamed as a result of the immune system's response to a specific infection or trigger.⁴⁻⁵ According to the US CDC, myocarditis symptoms usually appear within a week after the second vaccination dose.⁴ In any case, further assessment is required prior to initiating any medical intervention.²⁻³ The severity of the reported cases varies; however, most of them recover rapidly and completely following treatment and rest.⁶

As stated in the Clinical Guidelines on COVID-19 Vaccination in Malaysia², individuals who develop myocarditis after the first dose are advised to postpone their second dose, especially if they are at high risk of infection or severe disease. The second dose can be administered once they have recovered from the acute illness. Although vaccine-induced myocarditis is less harmful and self-limiting than myocarditis caused by other agents (including SARS-COV-2 infection), it can lead to more serious complications. Thus, it is recommended to discuss with the treating physician or cardiologist before making any decisions.

To date, NPRA has received **29 local reports of myocarditis following COVID-19 vaccination**, mostly involving Comirnaty vaccine, with the exception of two (2) reports following AstraZeneca vaccine.¹ All the received reports were carefully reviewed by the expert committee members in light of the mentioned criteria by the US CDC.⁵ Of total 29 reports, 20 cases occurred among adolescents, of which 17 cases involved male adolescents. Nine (9) cases were reported following the first dose administration, while the remaining 11 cases were observed after the second dose. As of 22nd December 2021, the overall reporting rate for myocarditis following the first and second dose of mRNA-containing vaccines in Malaysia was 0.87 reports per million doses.¹ Meanwhile, in the United Kingdom, 12 reports per million doses of suspected myocarditis across all age groups were reported following mRNA COVID-19 vaccination.⁸ Despite the risks of myocarditis associated with vaccination, the benefits of vaccination still outweigh risks in adolescents.^{2,3,7}

***DISCLAIMER**

This information comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases. This information does not represent the opinion of WHO.

Advice for Healthcare Professionals

- 1** Consider myocarditis in adolescent and young adults present with acute chest pain, shortness of breath, palpitations, fainting, abdominal pain, low grade fever or a combination of these symptoms following COVID-19 vaccination.
- 2** When myocarditis is suspected, always consult a cardiologist for further assistance and guidance. The management may differ depending on the patient's age, clinical manifestation, or possible causes.
- 3** It is important to rule out all the other possible causes of myocarditis such as viral infection (including prior SARS-CoV-2 infection) and non-infectious aetiologies. Consider consultation with infectious disease team to assist in this evaluation.

- 4** For initial assessment, obtain urgent electrocardiogram, echocardiogram, troponin and inflammatory markers such as C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). If all the investigations reveal no significant findings, myocarditis is unlikely.
- 5** Check the latest Clinical Guidelines on COVID-19 Vaccination in Malaysia for the diagnosis and management algorithm for vaccine-induced myocarditis.
- 6** Communicate with the young persons, their family, or their caregivers that the condition is very rare, usually mild, and often self-limiting.
- 7** Report any suspected cases of myocarditis related to COVID-19 vaccination to the NPRA.

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Articles Based on Case Reports

Ciprofloxacin-Induced Thrombocytopenia

by Ng Jia Mean

Case Report¹

A 32-year-old Bajau male with no known medical illness was admitted to the emergency department due to a motorbike accident. He had a severe traumatic brain injury with haematoma and multiple skull fractures, and he underwent a decompressive craniectomy.

He developed an intraparenchymal brain abscess from the surgical site infection and was started on intravenous (IV) ceftriaxone on day 8. Following the culture and sensitivity results of the wound swab, which revealed *Enterobacter cloacae*, the antibiotic was subsequently changed to IV meropenem. Unfortunately, the patient developed allergic skin rashes to meropenem, and his treatment was reverted back to IV ceftriaxone in combination with IV metronidazole. In view of the lack of significant clinical response to the antimicrobial given, the patient's treatment was switched to IV ciprofloxacin 400 mg every 12 hours on day 50 and later, his platelet count dropped drastically to $17.7 \times 10^9/L$. As **ciprofloxacin-induced thrombocytopenia** was suspected, ciprofloxacin was withheld and IV ceftriaxone was recommenced until he was discharged. His platelet count was normalised to $253 \times 10^9/L$ three days after the discontinuation of ciprofloxacin. His other inpatient medications included oral levetiracetam, propranolol, pantoprazole, and quetiapine. **Figure 1** shows the overall trend of the patient's platelet count in relation to the usage of antibiotics.

Discussion

Ciprofloxacin is a fluoroquinolone antibiotic that is indicated to treat a wide variety of infections, including skin and soft tissue infections, bone and joint infections, lower respiratory tract, gastrointestinal as well as urinary tract infections.²⁻³ Ciprofloxacin is the most potent among the fluoroquinolone class against gram-negative bacilli bacteria (for example, *Enterobacteriaceae* such as *Escherichia coli*, *Salmonella* spp., *Shigella* spp., and *Neisseria*) and *Pseudomonas aeruginosa*, in addition to its effectiveness against some gram-positive bacteria.³ Ciprofloxacin exhibits its bactericidal effect by inhibiting bacterial DNA topoisomerase and DNA-gyrase, hence restraining bacterial DNA replication.²⁻³

Thrombocytopenia, characterised by an abnormally low platelet count, is a rare documented side effect associated with ciprofloxacin use.^{2,4} There are several potential mechanisms for this phenomenon, but the exact mechanism by which ciprofloxacin affects the platelets is unknown.⁵⁻⁷ While ciprofloxacin shares a similar chemical structure with quinine, which is well-known to cause platelet-reactive, antibody-mediated immune thrombocytopenia, the

Legends:

Area shaded in light yellow	Normal platelet count range ($150 - 400 \times 10^9/L$)
I	IV Ceftriaxone
II	IV Meropenem
III	IV Ceftriaxone + IV Metronidazole
IV	IV Ciprofloxacin
V	IV Ceftriaxone

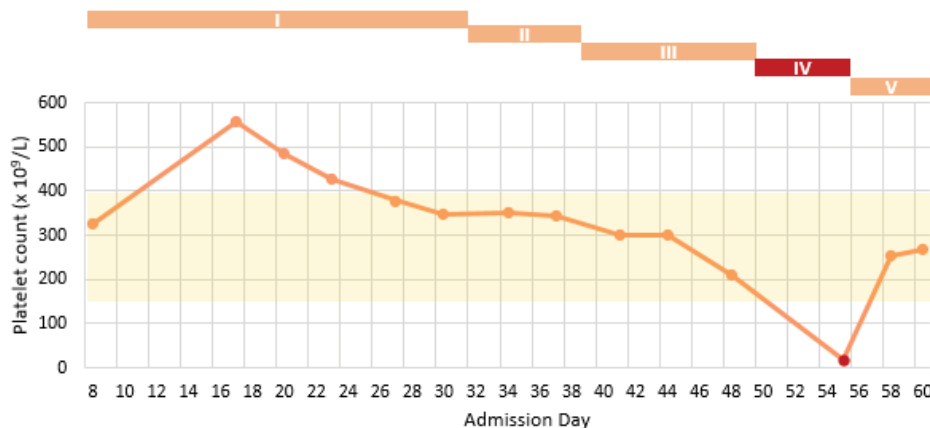


Figure 1: Patient's platelet count in relation to the usage of antibiotics

identification of fluoroquinolone-dependent antibodies against platelets that cause destruction of platelets in some literature reports could explain the action of fluoroquinolones.⁵⁻⁸

While a more reliable method like platelet-reactive antibodies test is not widely available⁶⁻⁸, the gold standard for suspecting drug-induced thrombocytopenia is the observation of an increase in platelet count after discontinuation of the drug.⁸ According to findings from a randomised controlled trial (RCT) and several case reports published, ciprofloxacin-induced thrombocytopenia occurs between 12 hours and four (4) days after initiation and returns to normal within one (1) week, with no active intervention required in most cases.⁵⁻⁷ Platelet transfusion may be necessary in patients suffering from active bleeding or when platelet count is less than $20 \times 10^9/L$.⁶ Findings of the RCT also suggested that the resulting platelet count decrease could affect the prognosis in critically ill patients.⁷

In Malaysia, there are currently 45 registered products containing ciprofloxacin, which include products in the form of oral tablet, injection, ear and eye drops.⁹ The NPRA had received 1,247 adverse drug reaction (ADR) reports with 2,350 adverse events (AEs) related to ciprofloxacin. Skin reactions [pruritus (397), rash (237), and urticaria (153)], dyspnoea (97) and vomiting (38) are among of the most common AEs reported. There were only **two (2) local cases of thrombocytopenia** reported.¹ As of December 2021, a search in the World Health Organisation (WHO) global ADR database^{10*} revealed a total of 905 cases suspected to be associated with ciprofloxacin.

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Advice for Healthcare Professionals

- 1 Be aware of the possible relationship between thrombocytopenia and the use of ciprofloxacin, and monitor the platelet count accordingly especially in critically ill patients with impaired kidney function, advanced age, and concurrent severe infection.
- 2 Discontinue ciprofloxacin if it is the suspect cause of an acute drop in platelet counts, and consider alternative therapy. In most cases, platelet counts will return to normal promptly or within a week after the drug withdrawal.
- 3 Report any adverse drug reactions suspected to be related to the use of ciprofloxacin to the NPRA.

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Articles Based on Case Reports

Cyclopentolate Eye Drops in Children: Risk of Psychotic Reaction

by Wo Wee Kee

Case Report¹

A 6-year-old Malay girl with no known medical illnesses was given cyclopentolate 1% eye drops to dilate her pupils in preparation for a refraction test at an ophthalmology clinic. Each eye received a total of four (4) drops of cyclopentolate over a 30-minute course: the second drop was given five (5) minutes after the first drop, followed by the third drop twenty (20) minutes later, and the last drop five (5) minutes after the third drop. The child developed acute delirium following the fourth drop, which manifested as visual hallucinations, as well as mood and behavioural changes. The mother sought treatment for the child at a hospital later that afternoon. However, these symptoms resolved gradually and spontaneously without treatment, as she was already back to normal behaviour upon reaching the hospital. Additionally, local allergic reactions were noted over her face (periorbital oedema of both eyes, rashes, and itchiness of bilateral cheeks), which resolved after being given prednisolone and chlorpheniramine at the hospital.

Discussion

Cyclopentolate is commonly used in the paediatric population as eye preparations for fundoscopy, retinopathy of prematurity (ROP) examination, and refraction testing, to name a few.²⁻³ It exerts mydriatic and cycloplegic effects by inhibiting acetylcholine activity on the iris sphincter muscle and the accommodative muscle of the ciliary body in the eyes.^{2,4} Given its relatively rapid onset (15-60 minutes) and shorter duration (within 24 hours) of mydriasis and cycloplegia, cyclopentolate is generally preferred in practice over atropine, which is similarly classified under anticholinergic agents.²⁻³

Aside from ocular side effects, cyclopentolate as an eye drop preparation may also produce systemic adverse effects.²⁻⁸ This is primarily due to the drug can be absorbed transconjunctivally or drained into the nasolacrimal duct and then diffused into systemic circulation through the highly vascularised nasal mucosa.⁵⁻⁹ A small amount of drugs entering the nasolacrimal system may be swallowed and absorbed via the digestive system.^{6,7,9} Cyclopentolate produces reactions similar to other anticholinergic drugs, but the central nervous system (CNS) manifestations, such as incoherent speech, restlessness, hallucinations, hyperactivity, and seizures, are more commonly reported.²⁻⁸ Other systemic anticholinergic adverse effects include abdominal distention, tachycardia, urinary retention, and hypersalivation.²⁻⁷

Systemic toxicity with topical cyclopentolate is usually rare, dose-related, and more prone to occur in infants and young children.^{3,5,7,8} It is documented that psychotic reactions and behavioural disturbances in children occur more frequently with 2% concentration.² This could be explained by children having a smaller body mass, less blood volume, and immature nervous, cardiovascular, and drug elimination systems compared to adults.^{3,5,7} Systemic adverse effects are generally seen within 15-60 minutes after the instillation of cyclopentolate eye drops.³ They usually improve without sequelae within 2 hours in adults and within 4-6 hours in infants/children.^{5,7} Treatment is essentially symptomatic or supportive, with physostigmine being reserved for serious toxicity.^{3,5-8}



In Malaysia, there are currently two (2) registered products that contain cyclopentolate as a single agent or combination product in eye drop preparations.¹⁰ To date, the NPRA has received 82 adverse drug reaction (ADR) reports with 137 adverse events suspected to be associated with cyclopentolate (including all single and combination products). Apnoea (25), neonatal apnoea (11), and cyanosis (9) were the most frequently reported adverse events. There were only two (2) reports describing psychotic reactions in children, which included the case described above. The adverse events observed were abnormal behaviour (2), acute delirium (1), hallucination (1), visual hallucination (1) and altered mood (1).¹ A search of the World Health Organisation (WHO) global ADR database^{11*} revealed 15 cases of delirium, 18 cases of visual hallucinations, one (1) case of altered mood, and 13 cases of abnormal behaviour suspected to be caused by cyclopentolate.

***DISCLAIMER**

This information comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases. This information does not represent the opinion of WHO.

Advice for Healthcare Professionals

- 1** Be aware of the potential risk of psychotic reaction when prescribing of cyclopentolate eye drops in infants and young children.
- 2** Recommend to use the lower concentration of cyclopentolate eye drops in infants and young children as they are more susceptible to systemic adverse effects. The recommended dosage for children is one (1) drop of 0.5-1% into the eye, followed by a second drop of 0.5-1% after 5-10 minutes if needed.
- 3** Advise patients to apply slight pressure over the nasolacrimal sac for 2-3 minutes after instillation of eye drop to minimise systemic absorption.

- 4** Closely monitor for systemic adverse effects 30 minutes following instillation of cyclopentolate eye drop in infants and young children.
- 5** Inform caregivers of the possibility of further reactions to anticholinergic medications if necessary.
- 6** Report any ADR suspected to be related to cyclopentolate to the NPRA.

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Articles Based on Case Reports

Neonatal Gynaecomastia and Galactorrhoea with Prolonged Use of Morphine

by Syifa' Izzati Mohd Zainul Arifien

Case Report¹

A female neonate was started on syrup morphine 0.2 mg 8 hourly on the 9th day of life (DOL) to treat opioid withdrawal syndrome following fentanyl infusion for sedative procedures in neonates. Her reported underlying conditions included congenital diaphragmatic hernia, chronic lung disease, and moderate patent ductus arteriosus (PDA). Inotropes (intravenous dopamine/noradrenaline/adrenaline), intravenous hydrocortisone, and syrup sildenafil were given concomitantly. After 18 days, the neonate developed breast enlargement and whitish milk discharge from her right nipple was observed. She was clinically diagnosed with neonatal gynaecomastia and galactorrhoea secondary to prolonged use of morphine, and syrup morphine was weaned off. No prolactin level was taken during the event and she was recovering at the time of reporting. Both reported adverse events were given causalities of possibly-related to the drug.

Discussion

Neonatal breast enlargement (commonly denoted as gynaecomastia or thelarche) is frequently seen in 60-90% of newborns and can be accompanied by galactorrhoea (non-lactational milk secretion) due to increased prolactin levels in 5-20% of cases.²⁻⁴ These neonatal problems usually occur secondary to the transplacental transfer of maternal oestrogens.²⁻⁶ The subsequent drop in neonatal blood oestrogen levels after birth triggers the secondary secretion of prolactin hormone in the pituitary gland, leading to hyperprolactinaemia which causes breast enlargement and/or milk secretion (popularly known as Witch's milk).²⁻⁸ These enlarged breasts are hard and tender as compared to the soft and painless gynaecomastia of older children and adolescents.²

Uncomplicated, physiological gynaecomastia and galactorrhoea in newborns are usually transient and resolve within a few weeks.^{3,5,6} Whereas, nonphysiological breast problems associated with hyperprolactinaemia may occur at any age as a consequence of medical conditions (e.g. pituitary disorders, tumours or severe hypothyroidism) or use of medication and substance (e.g. antipsychotics, antidepressants, metoclopramide or opioids).⁵⁻⁷

Morphine belongs to the opioid group and is mainly indicated for relief of moderate-to-severe pain and as an analgesic adjunct in general anaesthesia.⁸⁻⁹ There are currently nine (9) registered products containing morphine in Malaysia, available in tablets and parenteral formulations.¹⁰ However, there are also extemporaneous preparations of morphine prepared at healthcare facilities for patients with special needs, as in the case discussed above.

Exogenous opioids can have effects on various levels of the endocrine system.⁸ Evidence from both human and animal studies has shown that chronic administration of opioids can lead to an increase in plasma prolactin levels, although the frequency of hyperprolactinaemia and the impact of dose and route of administration have not been clearly established. The presence of opioid receptors in the hypothalamus may have a role in the stimulatory effect of opioids on prolactin secretion. While the exact underlying mechanism remains unclear, studies suggest that opioids' complex interactions with dopaminergic and serotonergic pathways may be involved.⁷⁻⁸



Figure 2: bilateral breast swelling in a newborn⁴

A review of literature also discovered a rare case report of **neonatal gynaecomastia complicated by morphine-induced hyperprolactinaemia**.⁴ A 1-month-old female infant on mechanical ventilation, who was administered midazolam, diazepam, pancuronium, phenobarbital and morphine infusion (15 mcg/kg/hr), developed bilateral breast swelling after two weeks [Figure 2]. She was initially treated as mastitis, but the swelling did not improve despite a 10-day antibiotic treatment. Further examination revealed milk secretion on pressure with elevated prolactin levels and she was diagnosed with morphine-induced hyperprolactinaemia. As she was gradually weaned off intravenous morphine, her breast swelling and prolactin level improved, and the milk secretion stopped.

To date, NPRA has received 836 local adverse drug reaction (ADR) reports with 1,356 adverse events associated with products containing morphine. The most common reported adverse events were skin reactions, namely urticaria (243), pruritus (233) and rash (95). There is only **one (1) report of galactorrhoea and gynaecomastia**, which is discussed above.¹ As of February 2022, the World Health Organisation (WHO) global ADR database^{11*} contains 17 reports of gynaecomastia, five (5) reports of galactorrhoea and two (2) reports of breast enlargement suspected to be associated with morphine but none of these reports involved infants or children. Based on the extended global search on opioids drug class (ATC: N02A), there were 182 reports of gynaecomastia, 88 reports of galactorrhoea and 28 reports of breast enlargement. Of these reports, only one (1) report of breast enlargement related to methadone in 1-month-old male infant and one (1) report of gynaecomastia linked with codeine in 9-year-old female.

Overall, looking at the relatively small number of ADR reports received locally and globally, there is a possibility that these adverse events may be overlooked and under-reported especially in the younger population.

*DISCLAIMER

This information comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases. This information does not represent the opinion of WHO.

Advice for Healthcare Professionals

- 1 Gynaecomastia and galactorrhoea in newborns are common physiological conditions that resolve spontaneously; however, it is important to rule out other possible causes, such as medication use, to minimise further complications.
- 2 Be aware of the endocrine effects of opioids. Monitor possible clinical manifestations of hormonal imbalance especially in patients on long-term use of opioids and consider laboratory evaluations if needed.
- 3 Consider discontinuation or reduction of the opioids and in cases of chronic pain, consider an alternative for pain relief.
- 4 Avoid repeated expression of witch's milk by manual squeezing as it will prolong milk secretion and introduce infection.
- 5 Report any ADR suspected to be related to the use of morphine or other opioids to the NPRA.

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How to report adverse drug reactions?

NPRA encourages all healthcare professionals to report all suspected adverse drug reactions to medicines, including vaccines, over-the-counter medicines, as well as traditional and health supplements.

To report adverse drug reactions:

1. Visit www.npra.gov.my
2. Report ADR **as healthcare professional**.
 - a) Choose **Online Reporting** or
 - b) Download the **ADR manual form** and submit the completed form via email or post:

fv@npra.gov.my



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