SELF-TEST QUESTIONS

True or false?

3. An INR below 2.0 is effective in preventing stroke in an elderly patient being anticoagulated for atrial fibrillation.

4. Diuretics should not be prescribed for patients over 80 years old with fluid retention due to heart failure.

Answers on page 219

everyday practice. There is no evidence that a lower target INR (<2) is effective or has a lower risk of bleeding than a target of 2–3.

The newer oral anticoagulants, such as dabigatran, may seem to be an attractive alternative to warfarin in older people as regular blood tests are not required. However, there is no antidote or reversal drug if bleeding occurs. In addition, severe renal impairment is a contraindication and any decrease in renal function can increase the risk of bleeding.

Conclusion

Appropriate and safe prescribing of cardiovascular drugs for older people can be challenging. There are many things to take into account when prescribing for older people, especially if they are frail. Tailoring treatment to the individual patient with the aim of doing more good than harm, should be the guiding principle when prescribing cardiovascular drugs to older people.

Conflict of interest: none declared

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FURTHER READING

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Medicinal mishap

When is child-resistant packaging not child resistant?

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Case

A six-year-old boy presented to hospital after accessing his father's lithium tablets. It was unclear how many tablets were in the container and whether the child had taken any.

The lithium was stored in a plastic bottle with a child-resistant cap. On examining the cap, it was noted that the child-resistant mechanism would not engage unless downward pressure was applied while closing the cap. Without the downward pressure, the cap spun freely and would not engage to a fixed closure point. When this occurred, the cap could then be opened in the same manner as a simple screw cap. There were no instructions on the cap to say that downward pressure was required to activate the child-resistant mechanism. This procedure is not required for the majority of other child-resistant caps used on the Australian market.

The child needed to be observed for six hours. No adverse events emerged so he was discharged.

Comment

Young children gaining access to medicines is a frequently overlooked aspect of medication safety. The use of child-resistant packaging is a proven strategy for preventing poisoning, but it is only one layer of a multifaceted approach which includes supervision and limiting access.

Personal clinical experience suggests that families are not given preventive advice by the prescribing doctor or dispensing pharmacist about the potential toxicity to young children of drugs within their household. To compound this, there is confusion in the general

population about the effectiveness of child-resistant packaging in preventing poisoning in young children and in particular the functionality of child-resistant closures. There are several problems:

- child-resistant closures are used on products which have toxicity ranging from mild (such as penicillin-based syrups) to major
- the Therapeutic Goods Administration (TGA) Order 80 determines products requiring child-resistant packaging, yet a number of potentially toxic drugs fall outside this order and are marketed in non-child-resistant packaging (such as essential oils sold in bottles with standard screw caps, and calcium channel blockers sold in blister packs)
- child-resistant closures are often referred to as 'child-proof' caps, even by medical professionals, yet the Australian Standard AS 1928-2007 effectively allows up to one in five children in the testing range (42–51 months) to access the product. This is a compromise between keeping children out and making child-resistant closures so effective that adults cannot access them. The child-resistant closures are tested to ensure that 80% of adults can get in.
- the child-resistant mechanism is often assumed to be engaged, when it is not, either due to failure to fully close the cap or a dysfunction of the child-resistant closure.

An ad hoc survey of local and interstate pharmacies in relation to this incident revealed that several other batches of lithium tablets had similarly dysfunctional child-resistant closures. This matter has been reported to the manufacturer and the TGA.

With an increasing number of drugs stored in the home, it is important that child-resistant packaging performs as well as intended. Product failures need to be identified by appropriate surveillance and then promptly addressed.

Recommendations

Currently, there is no requirement for companies marketing medicines in Australia to perform post-production quality assurance testing of the functionality of child-resistant caps, although a few companies do perform these tests. Minor alterations to the bottle, cap or wadding can have significant impacts on the functionality of the child-resistant cap, and these defects can only be discovered at the end of the manufacturing chain. Ideally, they should be detected before the product is marketed.

The collation of reports of failures of child-resistant packaging is hampered by the lack of national standardisation of poisons information data in Australia and the inconsistency of product and packaging specific detail within those data. There are currently efforts underway to address this.

Patients should ensure that their medicines are kept out of reach of children, for example by storing the drugs in a locked container. However, this is only feasible when medication is not in use, and anecdotally, some exposures occur in the brief interval when the medication is being accessed to take a dose, or when it is being packed for travel. Effective child-resistant packaging is an important secondary prevention strategy in these scenarios. Consumer awareness of medication toxicity and poisoning prevention in young children could also be improved at the point of prescription and dispensing.

Conflict of interest: none declared

Comment by the Therapeutic Goods Administration

The TGA and the sponsor company investigated this case and found no evidence that the packaging of the relevant batch was defective when released for sale. As such, the reported issue of the child-resistant mechanism failing to engage unless downward pressure was applied while closing was found to be an isolated defect, the cause of which is unknown and may have occurred after purchase.

Child-resistant closures for medicines marketed in Australia are manufactured and tested to very high standards. However, like any mass-produced good, there may be the occasional defective unit.

All suspected child-resistant packaging defects should be reported to the TGA or sponsor so that they can be investigated.

Scheduled medicines are required to carry the warning 'KEEP OUT OF REACH OF CHILDREN' in bold text, placed prominently at the top of the label. The container of the lithium carbonate tablets referred to in the report carried this warning.

It is important to note that child-resistant closures are not child-proof. If they were, it would be difficult or impossible for many elderly people and arthritis sufferers to open them.

Child-resistant closures are tested on four-year-old children. The child in the report was six years old.

The requirements for child-resistant packaging of medicines are set out in Therapeutic Goods Order No. 80 'Child-Resistant Packaging Requirements for Medicines'.

Health professionals who receive a report of a suspected child-resistant packaging defect from a patient should consider sending the packaging to the TGA or sponsor so that the defect can be verified and properly assessed.