



Medicating Young or Very Young Patients — Part I

Beatrice B. Turkoski

Children enter an orthopaedic treatment environment for a variety of reasons. Some of these pediatric patients will be seen in practices specializing in pediatric orthopedics.

However, many young patients with less demanding problems will be seen in family practice settings and general orthopaedic areas. Medicating these children safely and effectively and educating parents about a child's medications are important aspects of good nursing care. In this first discussion about pediatric medications, the unique considerations about medicating children at different ages are addressed. Adherence considerations are identified, guidelines for talking with children about medications are identified, and improvements in the regulations that are designed to increase knowledge about safety and efficacy in pediatric pharmacology are reviewed. The second part of this discussion addresses examples of drugs used to address selected common health problems in pediatric patients and will be published in the May/June 2007 issue of *Orthopaedic Nursing*.

Children enter an orthopaedic treatment environment for a variety of reasons. These can include accidental trauma, abuse, birth defects or genetic anomalies, and neuromuscular and musculoskeletal disorders. Some of these pediatric patients will be seen in practices specializing in pediatric orthopaedics, especially those with long-term and chronic or highly complicated conditions. However, many young patients with less demanding problems will be seen in family practice settings and general orthopaedic areas. Medicating these children safely and effectively and educating parents about a child's medications are important aspects of good nursing care.

Pediatric pharmacology is a distinct and special branch of pharmacology, and specific questions about individual medications for pediatric patients should always be referred to experts. However, there are some guidelines about medicating children that are basic. In this article, some of the unique considerations about medicating children at different ages are addressed. Adherence considerations and guidelines for talking with children about their medications are identified. Safety issues relating to pediatric medications and the Food and Drug Administration (FDA) rules designed to increase the knowledge about safety and efficacy in pediatric pharmacology are also reviewed. Part II of

this discussion addresses examples of drugs used to address selected common health problems in pediatric patients.

*Children are not just small adults,
children are unique.*

Children Are Unique

Pediatric patients are classed in different age ranges from birth through adolescence; premature infant <38 weeks' gestation, newborn (neonate) birth to 1 month, infant 1 to 24 months, young child 2 to 4 years; older child 6 to 12 years, and adolescent 13 to 18 years (Herfindal & Gourley, 2000). With children at all ages (just as with adults) consideration of any medication must include general nutritional status, size, medical status, and other prescription or nonprescription products being used. However, each of the pediatric age groups also has age-dependent considerations. With young children, before prescribing any drug, the maturity of organ function must be considered. Developmental stage can affect both pharmacokinetics and pharmacodynamics. With older children, growth pattern and prepubertal development may be important factors. In adolescents, additional considerations may relate to hormonal levels and lifestyle habits (e.g., smoking and/or use of nonprescription or illicit drugs).

ABSORPTION

Age-related differences in the gastrointestinal system affect the way some drugs are absorbed. At birth, the gastric pH is low and does not increase to adult levels until a child is about 1 year old. Acidic drugs will, therefore, have decreased absorption in infants. Intestines are shorter in children under 2 years old, gastric enzyme activity is generally lower than in adults, and gastrointestinal transit time is increased until about 5 years of age. Thus, doses of

Beatrice B. Turkoski, PhD, RN, Kent State University College of Nursing, Kent, OH.

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some drugs may not be sufficiently absorbed (e.g., Theodor Sprinkles are only about 50% absorbed in children younger than 5 years) (Herfindal & Gourley, 2000).

Topical absorption changes as children mature. Although children absorb at about the same rate as adults, infants and young children have a greater body surface relative to total body mass and skin thickness is less than in older children and adults. As a result, they are more likely to experience adverse reactions to topical drugs.

DISTRIBUTION

Water-soluble drugs are essentially distributed into the aqueous portion of the body. Percentage of fluid relative to body weight and the composition of that fluid affect the volume of distribution, the concentration of drug (the concentration of drug at receptor sites), and the elimination of many drugs. Approximately 75% of body weight in neonates is in the form of water, and by 1 year, the percentage of body water reaches 60%, similar to that of adults. The higher percent of water in infants may require higher mg/kg dosages to achieve therapeutic drug concentration levels in the blood. Conversely, in elderly patients who have decreased fluid volumes, the mg/kg dose may need to be less than with younger persons to reduce the potential for drug toxicity (Katzung, 2003).

ADVERSE REACTIONS

Drug sensitivity also differs between young children and adults. The central nervous system does not reach adult levels until about 8 years of age, and the temperature-regulating system is less stable. Doses of drugs that normally lower temperature must be carefully adjusted for age to reduce the potential for increased temperature and toxicity, e.g., aspirin products, nonsteroidal antiinflammatory drugs (NSAIDs) (ibuprofen, indomethacin, naproxen, etc.), anticholinergics (atropine, scopolamine, belladonna, propantheline, etc.), sympathomimetics (amphetamine, ephedrine, epinephrine, cocaine, etc.), and antihistamines (diphenhydramine, hydroxyzine, etc.), and most antipsychotics can cause adverse temperature response in young children if doses are not adjusted for age. In addition, the immaturity of thermal regulation, along with increased skin permeability, and larger surface are all contributing factors to the potential for exaggerated skin reactions in young children (Herfindal & Gourley, 2000).

Some drugs also have other adverse effects on children such that the benefits of use must be weighed against the potential for damage; for instance, corticosteroids suppress growth, sexual precocity may develop with androgens, and levodopa affects prepubertal development. Corticosteroids, vitamins A and D, and nitrofurantoin, may increase intracranial pressure (Katzung, 2003).

Adherence to Recommended Drug Regimens

When talking about medication-taking behavior in children or in adults, the word “adherence” is preferable to “compliance.” Compliance suggests that a patient is passively acquiescing or complying with a set of orders; thus, “noncompliance” suggests the deliberate choice not to follow those orders. Adherence implies that there is a

contract or an alliance between professional and patient (or patient’s caregivers). Whereas, as Osterberg and Blaschke (2005) suggest, neither term is perfect, and healthcare providers are increasingly using the term “adherence” as is used in this discussion.

Difficulties in adherence are as common with pediatric patients as they are with older patients (Kirchner, 2000; Liptak, 1996; Matsui, 1997; Winnick, Lucas, Hartman, & Toll, 2005). However, the confounding variable when medicating children is that success depends on both the child’s adherence and the parent’s adherence, in addition to all of the other influencing variables, such as culture, home environment, family finances, experience with the healthcare system, etc. Children of any age may resist having to take medication, they may resent frequent dosing, often they dislike the taste or texture of a medication (palatability is a major factor with children), and they may have difficulty swallowing oral doses but be fearful of injections. Parents may not understand the importance of adherence or, as in the case of antibiotics, they may not realize the importance of completing the full regimen when after a half of that time the child seems to be “cured.”

With infants or toddlers, adherence is basically a parental responsibility because an adult will administer the medication (usually liquid). Parents will be more likely to adhere to medicine regimens for infants and toddlers if they understand the reason for the choice of medication and have been instructed in safe administration. Teaching parents (or caregivers) how to use a calibrated syringe (or a calibrated medicine cup) and how to draw up the exact amount is paramount—the common household teaspoon can vary between 2 and 10 mL and use could result in dangerous underdosing or overdosing of medication (Madlon-Kay & Mosch, 2000). Parents need to know how to squirt small amounts at a time into the buccal pouch, wait until the child swallows, and then squirt in a little more until all the medication is administered. (Administering the medication directly on the tongue may increase the potential for choking.) Additionally, parents of infants or small children may not recognize the need to give a further dose if a child has spilled or spit out half of what was given; this will happen less with a calibrated syringe than with a spoon.

With school-age children, the child is mature enough to be included in medication discussions, including the rationale for the medication. When possible, allowing children in this age group to choose the formulation they prefer (pills, liquids, or chewable tablets) may be just the step that will ensure their adherence. Children in this age group may be capable of administering their own medications (with parental supervision) and should be instructed the same as any adult about timing doses, crushing or mixing with food or liquids, and other safety factors.

When medicating adolescents, the healthcare professional has all the adherence considerations of the child plus those of an adult (Herfindal & Gourley, 2000). Teenagers are beginning to exert their independence and individuality and are approaching adulthood. They are capable (usually) of self-administering their own medications and need to be informed, consulted, and in control of any treatment plan. As they are reaching for adulthood, adolescents place a high value on their privacy; obtaining the necessary medical and medication history from an ado-

lescent may be more difficult when a parent is continually present. Tact when communicating with both parent and child is necessary to help ease the transition of responsibility. In addition, each state has laws governing the confidentiality of minors, and parents may not be aware of these laws (Wynne, Woo, & Millard, 2002).

Children are busy people, especially adolescents who often have not only a school schedule but also a work schedule. Most children will prefer not to have to take medicine at school or in the case of many older adolescents—at school or work. Considering the practical and convenience aspects of the patient's daily life, adjusting dosing schedules to meet their busy schedule will have a positive influence on adherence. When it is necessary to schedule medications during the school day, arrangements should be made with the school health professional about appropriate timing, the need for the medication, and any potential adverse reactions. Today's rules of zero-tolerance for any drugs in the school environment make it vital that both students and parents are fully aware of the importance of informing school authorities of any necessary medication.

When considering adherence to a medication regimen for any child, just as with any adult, the more convenient the schedule, the more palatable the drug formulation and the more understanding the patient has about the rationale for the medication, the greater will be the adherence. Respecting a child's capabilities and thoughtful honest communication about his or her medications is an important part of the partnership between health-care professional and patient that fosters adherence rather than just compliance. (See Table 1 for guidelines about educating older children and adolescents about medications).

Is this the Right Dose?

Despite the availability of improved dosing information about pediatric dosing for drugs that are approved for

pediatric use, the majority of drugs available today—prescription and nonprescription—have not been tested for use with children. When pediatric dosing information is not available, appropriateness of using that drug must be questioned. When a drug without pediatric information must be used and there is no pediatric dosing information, the dose must be calculated as a proportion of the adult dose.

There are formulas available for calculating pediatric dosage based on age or weight. However, calculating pediatric doses based on just the child's age or weight in comparison to average adult age or weight often results in underestimating the therapeutic dose (Katzung, 2003). Body surface calculations are more accurate and take into consideration both the height and the weight of the patient. Body surface of the pediatric patient is considered as a proportion of the average adult body surface area (1.73 m²), and that figure is used to identify the proportion of an approved adult dose. Most drug references today include nomograms for calculating pediatric doses according to actual body surface area of the patient.

Improving the Amount and Safety of Pediatric Drug Information

Using calculations of any kind for determining pediatric doses of a drug may eventually be unnecessary. During the past decade, FDA regulations governing clinical trials and approval for age appropriate pediatric use have been strengthened. Old drugs are being examined for use in pediatric populations, and most new drugs must contain some information about use with pediatric patients.

This increased attention to the safety and efficacy of drugs for pediatric use is a major improvement in FDA regulations. For most of the 20th century, requirements for determining efficacy and safety of a drug were based only on clinical trials with adults. Any pediatric dosing was based on calculations from adult information. After

TABLE 1. EDUCATING THE SCHOOL-AGE AND OLDER CHILD ABOUT MEDICATIONS

1. Children have a right to know:
They have a right to accurate and appropriate information about their medicines, according to their health condition and capabilities for understanding.
2. Children want to know:
Healthcare professionals should communicate directly with children about their medications, according to their health condition and capabilities for understanding.
3. Children grow in independence:
Transfer of responsibility for medicine use should respect parental responsibilities and the health condition and growth and capability of the child.
4. Children learn by example:
The actions of healthcare professionals and parents should exemplify the correct use of medicines.
5. Children need to be safe:
They have a right to accurate information that will enable them to make wise choices about use and misuse of prescription and nonprescription medicines.

Excerpted from: 'Talking to Children about Their Medicines, Pfizer and U.S. Pharmacopeia.' www.usp.org/audiences/consumers/children/principles.html (accessed 11/6/06).

1979, the FDA mandated that only drugs approved for pediatric use after controlled clinical studies with children were allowed to include dosing information for pediatric. Because trials with children were rare, most drugs (by some estimates as high as 80%) were prescribed "off label" for children and had no pediatric information in the manufacturer's packaging.

Regulation of drugs for pediatric use remained inadequate until 1994, when the Pediatric Labeling Rule was passed (FDA, 2006). The 1994 regulation was not mandatory but rather encouraged manufacturers to extrapolate clinical trial information with adults and include information for pediatric dosing if that particular drug had similar effects on the course of the disease between children and adults. In 1999 FDA Modernization Act was passed to increase and improve information about use of drugs in pediatric populations. This act made it mandatory for manufacturers of all new drugs to submit their data on studies with children unless they had received an exemption on the basis that the drug would not be used with pediatric patients. Of equal importance, this law also required that pediatric studies be conducted with already marketed drugs that were being used in substantial numbers of children and the FDA published a priority list that identified those drugs (e.g., "modernizing" the information on existing drugs). Exemptions from the regulations for pediatric studies are granted if the product is likely to be either unsafe or ineffective in children, pediatric studies are impossible or impractical because the sample size is too small, or pediatric formulations of the drug in question cannot be formulated for pediatric use.

In 2002 and 2003, after extensive ongoing consultation with the pediatric research experts and the American Academy of Pediatrics, Congress passed further FDA legislation related to pediatric drugs. Both the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act (FDA, 2002) were enacted to strengthen the rules about marketing and labeling drugs used with pediatric populations, strengthening support for research in pediatric drugs (including a focus on research with minority and underprivileged children) and establishing the Office of Pediatric Therapeutics in the FDA. Today, all labeling for new drugs (unless granted an exclusion by the FDA) must include information about safety and efficacy for pediatric use and, in addition, any change in indication, dosage regimen, new ingredi-

ents, or new route of administration for currently marketed drugs requires safety and efficacy information about pediatric use.

Conclusion

There has been considerable improvement in the FDA regulations that govern safety and efficacy of medications approved for use with children. However, it is ultimately the healthcare professionals who prescribe and administer medicine to pediatric patients who are responsible for ensuring that both child and parent are knowledgeable about the rationale for the medication and the importance of adherence to a medication regimen. Nurses who are aware of the unique challenges of medicating pediatric patients will play a major role in safely treating health problems in children.

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