

Probiotics May Reverse Antibiotic-Related Diarrhea

BY JEFF EVANS
Senior Writer

ORLANDO, FLA. — Daily intake of a lactobacilli-fermented milk may help prevent antibiotic-associated diarrhea in hospitalized patients, Natalie A. Fortier reported at the annual meeting of the American College of Gastroenterology.

Few of the published studies on the use of probiotics to prevent antibiotic-associated diarrhea have had a strong randomized, placebo-controlled design, said Ms. Fortier of the University of Montreal.

The daily drink, which contained 50 billion colony-forming units of live *Lactobacillus acidophilus* and *L. casei*, was associated with significantly fewer cases of antibiotic-associated diarrhea (7 of 41 patients) than was a placebo drink composed of lactoserum devoid of any microorganisms (16 of 43 patients).

Ms. Fortier and her colleagues at the university defined antibiotic-associated diarrhea as three or more liquid stools in a 24-hour period in the randomized, double-blind trial.

The researchers provided the active treatment or placebo daily to adult patients with an average age of 70 years on the 7-10 days that they were taking antibiotics and obtained follow-up from the

patients for 21 days after they stopped taking antibiotics.

The patients began prophylactic treatment in the first 48 hours after starting antibiotics, which were primarily for upper respiratory tract infections.

Those with active diarrhea, GI bleeding, inflammatory bowel disease, *Clostridium difficile* infection in the last 3 months, a high risk of an immunocompromised state, lactose intolerance, or a regular intake of probiotics were excluded from the trial.

Diarrhea associated with *C. difficile* occurred less often in patients who received the active treatment (1 of 41) than in placebo patients (7 of 43), although the difference did not reach statistical significance.

Actively treated patients had a significantly shorter median length of stay in the hospital, compared with patients who received placebo (8 days vs. 10 days).

Ms. Fortier and her associates obtained their results from a multivariate analysis after controlling for risk factors for anti-

biotic-associated diarrhea and *C. difficile*-associated diarrhea as well for the fact that significantly more placebo patients received β -lactam antibiotics (67%) than did actively treated patients (41%).

Side effects—mostly of a GI nature—occurred in nearly half of patients in each group, she said.

The active and placebo preparations were provided by Bio-K+ International Inc., Laval, Que., which manufactures and markets the active treatment. ■

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE: ZOMIG is indicated for the acute treatment of migraine with or without aura in adults. ZOMIG is not indicated for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. ZOMIG is contraindicated. Safety and effectiveness of ZOMIG have not been established for cluster headache, which is present in an older, predominantly male population.

CONTRAINDICATIONS: ZOMIG should not be given to patients with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia) or to patients who have symptoms or findings consistent with ischemic heart disease, coronary artery vasospasm, including Prinzmetal's variant angina, or other significant underlying cardiovascular disease (see WARNINGS). ZOMIG should not be given to patients with uncontrolled hypertension (see WARNINGS). ZOMIG should not be given to patients with a history of cerebrovascular disease, peripheral vascular disease, or a history of stroke.

WARNINGS: ZOMIG should not be used where a clear diagnosis of migraine has been established. Risk of Myocardial Ischemia and/or Infarction and Other Adverse Cardiac Events: ZOMIG should not be given to patients with documented ischemic or vasospastic coronary artery disease (see CONTRAINDICATIONS). It is strongly recommended that zolmitriptan not be given to patients in whom uncontrolled coronary artery disease (CAD) is present, as indicated by the presence of risk factors (e.g., hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, female with surgical or hysterectomy, or male over 40 years of age) unless a cardiovascular evaluation provides satisfactory clinical evidence that the patient is reasonably free of coronary artery and ischemic myocardial disease or other significant underlying cardiovascular disease. The sensitivity of cardiac diagnostic procedures to detect cardiovascular disease or predisposition to coronary artery vasospasm is modest at best. If, during the cardiovascular evaluation, the patient's medical history, electrocardiogram, or other investigations reveal findings indicative of, or consistent with, coronary artery vasospasm or myocardial ischemia, zolmitriptan should not be administered (see CONTRAINDICATIONS). For patients with risk factors predictive of CAD, who are determined to have a satisfactory cardiovascular evaluation, it is strongly recommended that administration of the first dose in the setting of a physician's office or similar medically staffed and equipped facility unless the patient has previously received zolmitriptan. Because cardiac disease can occur in the absence of clinical symptoms, consideration should be given to obtaining on the first occasion of use an electrocardiogram (ECG) during the interval following the first ZOMIG dose. It is recommended that patients at high risk for CAD, who are determined to be free of CAD, and who have or acquire risk factors predictive of CAD, as described above, undergo periodic interval cardiovascular evaluation (see CONTRAINDICATIONS). The systematic approach described above is intended to reduce the likelihood that patients with unrecognized cardiovascular disease will be inadvertently exposed to zolmitriptan.

Cardiac Events and Fatalities: Serious adverse cardiac events, including acute myocardial infarction, have been reported within a few hours following administration of zolmitriptan to patients with a history of cardiac disease. In one case, a patient died following the administration of other 5-HT₁ agonists. Considering the extent of use of 5-HT₁ agonists in patients with migraine, the incidence of these events is extremely low. ZOMIG can cause coronary vasospasm; at least one of these events occurred in a patient with no cardiac history and with increased absence of coronary artery disease. Because of the potential of the events to ZOMIG use as a causal relationship cannot be excluded. In the cases where there has been known underlying coronary artery disease, the relationship is uncertain. Patients with symptomatic Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders should not receive ZOMIG.

Pre-marketing experience with zolmitriptan: Among more than 2,500 patients with migraine who participated in premarketing controlled clinical trials of ZOMIG Tablets, no deaths or serious cardiac events were reported. Post-marketing experience with zolmitriptan: Serious adverse cardiac events have been reported in association with the use of ZOMIG Tablets, and in very rare cases, these events have occurred in the absence of known cardiovascular disease. The uncontrolled nature of post-marketing surveillance, however, makes it impossible to determine definitively the proportion of the reported cases that were actually caused by zolmitriptan or to establish an association with individual cases.

Cerebrovascular Events and Fatalities with 5-HT₁ agonists: Cerebral hemorrhage, subarachnoid hemorrhage, stroke, and other cerebrovascular events have been reported with 5-HT₁ agonists. Because these events have occurred with 5-HT₁ agonists, it is possible that the cerebrovascular events were primary, the agonist having been administered in the incorrect belief that the symptoms experienced were a consequence of migraine, when they were not. It should be noted that patients with migraine may be at increased risk of certain cerebrovascular events, including stroke, subarachnoid hemorrhage, and other cerebrovascular events.

Other Vasospasm-Related Events: 5-HT₁ agonists may cause vasospastic reactions other than coronary artery vasospasm such as peripheral and gastrointestinal vasospasm. As with other serotonin 5-HT₁ agonists, very rare gastrointestinal ischemic events including ischemic colitis and gastrointestinal infarction or necrosis have been reported with ZOMIG Tablets; these may present as bloody diarrhea or abdominal pain.

Increase in Blood Pressure: As with other 5-HT₁ agonists, significant elevations in systemic blood pressure have been reported on rare occasions with ZOMIG Tablet use in patients with a history of hypertension; very rarely these increases in blood pressure have been associated with significant clinical events. Zolmitriptan is contraindicated in patients with uncontrolled hypertension. In volunteers, an increase of 1 and 5 mm Hg in the systolic and diastolic blood pressure, respectively, was seen as 15. In the headache trials, vital signs were measured only in the small number of patients who had an effect on blood pressure was seen. In a study of 10 mg of ZOMIG Tablets, liver disease, 7 of 2 experienced 20 to 80 mm Hg elevations in systolic and/or diastolic blood pressure after a dose of 10 mg of zolmitriptan (see CONTRAINDICATIONS). An 18% increase in mean pulmonary artery pressure was seen following dose with another 5-HT₁ agonist in a study evaluating subjects undergoing cardiac catheterization.

PRECAUTIONS
General: As with other 5-HT₁ agonists, sensations of tightness, pain, pressure, and heaviness have been reported after treatment with ZOMIG Tablets in the presence of cardiovascular disease. Because these symptoms have occurred with 5-HT₁ agonists, it is possible that the symptoms or signs or symptoms suggestive of angina following should be evaluated for the presence of CAD or a predisposition to Prinzmetal's variant angina before receiving additional doses of medication, and should be monitored electrocardiographically if desired to ensure a satisfactory response to treatment. Similar to other 5-HT₁ agonists, patients with symptoms or signs suggestive of angina should be treated with caution. Similar to other 5-HT₁ agonists, patients with Raynaud's syndrome or Raynaud's syndrome following the use of any 5-HT₁ agonist are candidates for further evaluation (see WARNINGS). Zolmitriptan should also be administered with caution to patients with diseases that may alter the absorption, metabolism, or excretion of drugs, such as impaired renal or hepatic function (see PHARMACOLOGY). For a complete list of contraindications, see the full prescribing information for ZOMIG Tablets and ZOMIG-ZMT Tablets. The orally disintegrating tablet is contraindicated in patients with uncontrolled hypertension, the radioactivity in the diagnosis of migraine headache should be reconsidered before administration of a second dose.

Use in Patients with Renal Impairment: In a study of 10 mg of zolmitriptan in patients with renal impairment, zolmitriptan, the radioactivity in the urine after 7 days, the latest time tested, was still 75% of the value measured after 4 hours. This suggests that zolmitriptan and/or its metabolites may bind to the melanin of the eye. Because there could be accumulation in melanin rich tissues over time, this raises the possibility that zolmitriptan could cause toxicity in these tissues after extended use. However, no effects on the retina related to treatment with zolmitriptan were noted in any of the toxicity studies. Although no systematic monitoring of ophthalmologic function was undertaken in clinical trials, and no specific recommendations for ophthalmologic monitoring are offered, prescribers should be aware of the possibility of long-term ophthalmologic effects.

Phenylethanolamines: Phenylethanolamines should be informed that ZOMIG-ZMT contain phenylethanolamine (a component of aspartame). Each 2.5 mg orally disintegrating tablet contains 2.5 mg phenylethanolamine. Each 5 mg orally disintegrating tablet contains 5.0 mg phenylethanolamine.

Information for Patients: See PATIENT INFORMATION at the end of this labeling for the text of the separate leaflet provided for patients. ZOMIG-ZMT Orally Disintegrating Tablets: The orally disintegrating tablet is packaged in a blister. Patients should be instructed not to remove the tablet from the blister until just prior to dosing. The blister pack should then be peeled open, and the orally disintegrating tablet placed on the tongue, where it will dissolve and be swallowed with the saliva.

Laboratory Tests: No monitoring of specific laboratory tests is recommended.
Drug Interactions: Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because there is a theoretical basis that these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine or methysergide) and zolmitriptan within 24 hours of each other should be avoided (see CONTRAINDICATIONS). MAOA-A inhibitors increase the systemic exposure of zolmitriptan. Therefore, the use of zolmitriptan in patients receiving MAOA-A inhibitors is contraindicated (see CLINICAL PHARMACOLOGY and CONTRAINDICATIONS). Non-opioid analgesics used within 24 hours of zolmitriptan treatment is not recommended (see CONTRAINDICATIONS). Following administration of zolmitriptan, the half-life and AUC of zolmitriptan and its active metabolites were approximately doubled (see CLINICAL PHARMACOLOGY). Selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline) have been reported, rarely, to cause weakness, hyperreflexia, and incoordination when coadministered with 5-HT₁ agonists. If concomitant treatment with zolmitriptan and an SSRI is clinically warranted, appropriate observation of the patient is advised.

Drug/Laboratory Test Interactions: Zolmitriptan does not lead to in vitro mammalian cell mutagenicity (CHO/HGPRT assay). Zolmitriptan is clastogenic in an in vitro human lymphocyte assay both in the absence of and in the presence of metabolic activation; it was not clastogenic in an in vivo mouse micronucleus assay. It was also not genotoxic in a bacterial mutagenicity assay (Ames test).
Impairment of Fertility: Studies of male and female fertility were conducted in humans after a single 10 mg dose of the maximum recommended total daily dose. There was no effect of zolmitriptan on sperm count, sperm motility, sperm morphology, or sperm function. In a study of 10 mg of zolmitriptan, there was no effect on human exposure to human exposure (AUC and C_{max}) of 10 mg. When female subjects were given zolmitriptan during gestation, parturition, and lactation, an increased incidence of hypoprothrombinemia was found in the offspring at the maximum recommended total daily dose of 400 mg/kg/day (1100 times human exposure).

Pregnancy, Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women; therefore, zolmitriptan should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In reproductive toxicity studies in rats and rabbits, oral administration of zolmitriptan to pregnant animals was associated with embryofetal and fetotoxic abnormalities. When pregnant rats were administered oral zolmitriptan during the period of organogenesis at doses of 100, 400, and 2000 mg/kg/day, there was a dose-related increase in embryomortality which became statistically significant at the high dose. The maternal plasma exposures at these doses were approximately 286, 1100, and 5500 times the exposure in humans receiving the maximum recommended total daily dose of 10 mg. The high dose was maternally toxic, as evidenced by a decreased maternal body weight gain during gestation. In a similar study of rats, maternally toxic doses of 10 and 20 mg/kg/day (maternal plasma exposures equal to 286 and 5500 times human exposure) and 42 times exposure in humans receiving the maximum recommended total daily dose of 10 mg, and increased incidences of fetal malformations (fused sternabrae, rib anomalies) and variations (major blood vessel variations, irregular ossification pattern of ribs) were observed at 20 mg/kg/day. Three mg/kg/day was a no-effect dose (equivalent to human exposure of 10 mg). When female subjects were given zolmitriptan during gestation, parturition, and lactation, an increased incidence of hypoprothrombinemia was found in the offspring at the maximum recommended total daily dose of 400 mg/kg/day (1100 times human exposure).

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Nursing Mothers:

It is not known whether zolmitriptan is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when zolmitriptan is administered to a nursing woman. Lactating rats dosed with zolmitriptan had milk levels equivalent to maternal plasma levels at 1 hour and 4 times higher than plasma levels at 4 hours.

Pediatric Use: Safety and effectiveness of ZOMIG in pediatric patients have not been established. ZOMIG is not recommended for use in patients under 18 years of age. Postmarketing experience with other triptans includes a limited number of reports that describe pediatric patients who have experienced clinically serious adverse events that are similar in nature to those reported rarely in adults. **Geriatric Use:** Although the pharmacokinetic disposition of the drug in the elderly is similar to that seen in younger adults, there is no information about the safety and effectiveness of zolmitriptan in this population because patients over age 65 were excluded from the controlled clinical trials. (see CLINICAL PHARMACOLOGY: Special Populations)

ADVERSE REACTIONS: Serious cardiac events, including myocardial infarction, have occurred following the use of ZOMIG Tablets. These events are extremely rare and most have been reported in patients with risk factors predictive of CAD. Events reported, in association with drugs of this class, have included coronary artery vasospasm, transient myocardial ischemia, myocardial infarction, ventricular tachycardia, and ventricular fibrillation (see CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS).

Incidence in Controlled Clinical Trials: Among 2,633 patients treated with ZOMIG Tablets in the active and placebo controlled trials, no patients withdrew for reasons related to adverse events, but as patients treated a single dose had the opportunity for discontinuation was limited. In a long-term, open label study where patients were allowed to take multiple migraine attacks for up to 1 year, 8% (107 of 1300) from the trial because of adverse events. The most common adverse events were dizziness, headache, dry mouth, constipation, dyspepsia, pain, chest or neck tightness or heaviness, somnolence and warm sensation. Table 1 lists the adverse events that occurred in 2% of the 2,074 patients in any one of the ZOMIG 1 mg or ZOMIG 5 mg Tablets dose groups of the controlled clinical trials. Only events that were more frequent in a ZOMIG Tablet group compared to the placebo group are included. The events cited reflect experience gained under closely monitored conditions of clinical trials in a highly selected patient population. In actual clinical practice in or through clinical trials, these frequencies may not apply, as the conditions of use, reporting behavior, and the kinds of patients treated may differ. Several of the adverse events appear dose related, notably paresthesia, sensation of heaviness or tightness in chest, neck, jaw, and throat, dizziness, somnolence, and possibly asthenia and nausea.

Table 1. Adverse Experience Incidence in Five Placebo-Controlled Migraine Clinical Trials: Events Reported By ≥ 2% Patients Treated With ZOMIG Tablets

Adverse Event Type	Placebo (n=401)	ZOMIG 1 mg (n=163)	ZOMIG 5 mg (n=98)	ZOMIG ZMT (n=1072)
ATYPICAL SENSATIONS				
Hypesthesia	1%	12%	12%	18%
Paresthesia (all types)	2%	5%	7%	9%
Sensation without pain	1%	1%	1%	2%
PAIN AND PRESSURE SENSATIONS				
Chest-pain/tightness/pressure and/or heaviness	1%	2%	3%	4%
Neck/throat/jaw-pain/tightness/pressure	1%	1%	2%	10%
Heaviness other than chest or neck	1%	1%	2%	5%
Pain-location specified	0%	0%	0%	2%
Other-pressure/tightness/heaviness	0%	2%	2%	2%
DIGESTIVE				
Dry mouth	2%	11%	16%	14%
Dyspepsia	1%	3%	2%	1%
Dysphagia	0%	0%	0%	2%
Nausea	1%	4%	4%	3%
NEUROLOGICAL				
Dizziness	4%	6%	8%	10%
Somnolence	0%	0%	0%	2%
Vertigo	0%	0%	0%	2%
OTHER				
Asthenia	3%	5%	3%	9%
Palpitations	1%	0%	<1%	2%
Myalgia	<1%	1%	1%	2%
Myasthenia	<1%	1%	1%	2%
Sweating	1%	0%	2%	3%

ZOMIG is generally well tolerated. Across all doses, most adverse reactions were mild and transient and did not lead to long-lasting effects. The incidence of adverse events in controlled clinical trials was not affected by gender, weight, or age of the patients; use of prophylactic medications; or use of other drugs. There were insufficient data to assess the impact of race on the incidence of adverse events.

Other Events: In the paragraphs that follow, the frequencies of less commonly reported adverse events are presented. Because the reports include information on open and uncontrolled studies, the role of ZOMIG in their causation cannot be reliably determined. Furthermore, variability associated with adverse event reporting, the terminology used to describe adverse events, etc., limit the value of the quantitative frequency estimates provided. Event frequencies are calculated as the number of patients who used ZOMIG Tablets (n=4,027) reported an event divided by the total number of patients exposed to ZOMIG Tablets. All reported events are included except those already listed in the previous table, those too general to be informative, and those not reasonably associated with the use of the drug. Events are further categorized by body system categories and enumerated in order of decreasing frequency using the following definitions: infrequent adverse events are those occurring in 1/100 to 1/1,000 patients and rare adverse events are those occurring in fewer than 1/1,000 patients.

Atypical sensations: Infrequent was hypesthesia. General: Infrequent were allergic reaction, chills, facial edema, fever, malaise and photosensitivity. **Cardiovascular:** Infrequent were arrhythmias, hypertension and syncope. Rare were bradycardia, extrasystoles, postural hypotension, QT prolongation, tachycardia and thrombocytopenia. **Digestive:** Infrequent were increased appetite, tongue edema, esophagitis, gastroenteritis, liver function abnormality and thirst. Rare were anorexia, constipation, gastritis, hematemesis, pancreatitis, melena and ulcer. **Hemic:** Infrequent was ecchymosis. Rare were cyanosis, thrombocytopenia, eosinophilia and leukopenia. **Metabolic:** Infrequent was edema. Rare were hyperglycemia and alkaline phosphatase increase. **Musculoskeletal:** Infrequent were back pain, leg cramps and tenosynovitis. Rare were arthritis, asthenia, tetany and twitching. **Neurological:** Infrequent were agitation, anxiety, depression, emotional lability and insomnia. Rare were akathisia, amnesia, apathy, ataxia, dystonia, euphoria, hallucinations, cerebellar ataxia, hyperkinesia, hypotonia, hypertonia and irritability. **Respiratory:** Infrequent were bronchitis, bronchospasm, epistaxis, hiccup, laryngitis, and yawn. Rare were apnea and voice alteration. **Skin:** Infrequent were pruritus, rash and urticaria. **Special Senses:** Infrequent were dry eye, eye pain, hyperacuity, ear pain, parosmia, and tinnitus. Rare were diplopia and lacrimation. **Urogenital:** Infrequent were hematuria, cystitis, polyuria, urinary frequency, urinary urgency. Rare were miscarriage and gynecorrhea.

The adverse experiences profile seen with ZOMIG-ZMT Tablets was similar to that seen with ZOMIG Tablets.
Postmarketing Experience with ZOMIG Tablets: The following section enumerates potentially important adverse events that have occurred with ZOMIG Tablets and which have been reported spontaneously to various surveillance systems. The events enumerated represent reports arising from both domestic and non-domestic use of oral zolmitriptan. The events enumerated include all except those already listed in the ADVERSE REACTIONS section above or those too general to be informative. Because the reports cite events reported spontaneously from worldwide postmarketing experience, frequency of events and the role of zolmitriptan in their causation cannot be reliably determined.

Cardiovascular: Coronary artery vasospasm; transient myocardial ischemia, angina pectoris, and myocardial infarction.
Digestive: Very rare gastrointestinal ischemic events including ischemic colitis, ischemic colitis, and gastrointestinal infarction or necrosis have been reported; these may present as bloody diarrhea or abdominal pain (see WARNINGS).

Neurological: As with other acute migraine treatments including other 5-HT₁ agonists, there have been rare reports of headache.
General: As with other 5-HT₁ agonists, there have been very rare reports of anaphylaxis or anaphylactoid reactions in patients receiving ZOMIG. There have been few reports of hypersensitivity reactions, including angioedema.

DRUG ABUSE AND DEPENDENCE: The abuse potential of ZOMIG has not been assessed in clinical trials.
OVERDOSAGE: There is no experience with clinical overdose. Volunteers receiving single 50 mg oral doses of zolmitriptan commonly experienced sedation. The elimination half-life of ZOMIG is 15 hours (see CLINICAL PHARMACOLOGY), and therefore monitoring of patients after overdose with ZOMIG should continue for at least 15 hours or until symptoms or signs persist. There is no specific antidote to zolmitriptan. In the event of overdose, patients should be monitored closely for respiratory depression, establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation, and monitoring and support of the cardiovascular system. It is unknown what effect hemodialysis or peritoneal dialysis has on the plasma concentrations of zolmitriptan.

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Early Colorectal Ca Screening in Minorities

ORLANDO, FLA. — Colorectal cancer occurs at a high enough rate in African Americans and Hispanics under 50 years of age to warrant screening starting at age 40, according to Jaydutt Vadgama, Ph.D., of the Charles R. Drew University of Medicine and Science, Los Angeles.

In a retrospective study, Dr. Vadgama found that of 148 patients who had been diagnosed with colorectal cancer at the Martin Luther King/Drew Medical Center during 1996-2004, 38 (26%) were younger than 50 years of age. At diagnosis, the 38 patients had a median age of 42 years. Half of the patients under age 50 had a family history of colorectal cancer.

During 1993-1997, 46% of the 11,615 cases of colorectal cancer in African Americans and Hispanics in California occurred in patients younger than 50 years.

"Colorectal cancer screening should be considered in African Americans and Hispanics beginning at age 40 regardless of family history," the researchers suggested in a poster presentation at the annual meeting of the American College of Gastroenterology.

The college's guidelines on colorectal cancer screening, published in 2000, recommend that patients at higher than average risk for colorectal cancer should be screened by colonoscopy at an age of 40 years or 10 years younger than the age of the youngest affected relative at diagnosis, whichever is earlier.

—Jeff Evans

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