

Substantial Bone Loss Seen with Depo-Provera Use

*Limit use of Depo-Provera to 2 consecutive years only
Black Box Warning from the FDA*

FDA STATEMENT

“Women who use Depo-Provera Contraceptive Injection (CI) may lose significant bone mineral density (BMD). Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use Depo-Provera CI during adolescence or early adulthood, a critical time of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life. Depo-Provera CI should be used as a long term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate.”

OBJECTIVE

To compare longitudinal changes in bone mineral density (BMD) among first-time depot medroxyprogesterone acetate (DMPA) users to women using no hormonal contraception, and evaluate user characteristics associated with that BMD change.

DESIGN

Prospective longitudinal study.

PATIENT(S)

Women, aged 18 to 35, choosing DMPA for contraception (n = 178) and women using no hormonal contraception (n = 145).

MAIN OUTCOME MEASURE(S)

Hip and spine BMD measured, at three-month intervals for 24 months, by dual energy x-ray absorptiometry. RESULT(S): Mean hip BMD declined 2.8% (SE = 0.034) 12 months following DMPA initiation and 5.8% (SE = 0.096) after 24 months. Mean spine (L1-L3) BMD declined 3.5% (SE = 0.022) and 5.7% (SE = 0.034), respectively, after one and two years of DMPA use. Mean hip and spine BMD of control participants changed less than 0.9% over the same period. Among DMPA users, body mass index (BMI) change was inversely associated with BMD change at the hip, but not at the spine. Calcium intake, physical activity, and smoking did not influence BMD change in either group.

CONCLUSION(S)

Hip and spine BMD declined after one DMPA injection and this decline continued with each subsequent injection for 24 months. With the exception of increasing BMI among DMPA users, no user characteristics offered protection against DMPA-related BMD loss.

Clark MK, et al Bone mineral density changes over two years in first-time users of depot medroxyprogesterone acetate. *Fertil Steril.* 2004 Dec;82(6):1580-6.

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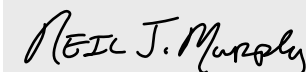
ALSO ON LINE...

This publication is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter which is available on the Internet at

www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm

You welcome to subscribe to the listserv and receive reminders about this service. If you have any questions, please contact me at nmurphy@scf.cc.

I am looking forward to hearing from you.



Dr. Neil Murphy
Ob/Gyn Chief
Clinical Consultant
(OB/GYN C.C.C.)

IHS Child Health Notes

Jan 2005

ARTICLES OF INTEREST

Managing Acute Gastroenteritis Among Children: Oral Rehydration, Maintenance and Nutritional Therapy

MMWR November 21, 2003/52(RR16):1-16

- A terrific summary of the development, physiology and clinical use of oral rehydration solution (ORS)

Oral rehydration therapy for diarrhea: an example of reverse transfer of technology.

Pediatrics. 1997 Nov;100(5):E10.

- Summary of a symposium held at Johns Hopkins in 1996
- Reviewed demonstrated efficacy of ORS
- Reviewed widespread and successful use of ORS around the world
- Pointed out that ORS is still grossly underused in the United States because it is seen as too simple compared to intravenous fluid

Barriers to use of oral rehydration therapy.

Pediatrics. 1994 May;93(5):708-11.

- Pointed out that barrier to use of ORS was often related not only to MD but to staff reluctance
- Staff perceived frequent, small feedings of ORS as too time consuming

A comparison of rice-based oral rehydration solution and "early feeding" for the treatment of acute diarrhea in infants.

J Pediatr. 1990 Jun;116(6):868-7

- Feeding of milk and solids in the first 24 hours of illness was associated with decreased stool output and decreased length of illness.

Oral rehydration therapy of infantile diarrhea: a controlled study of well-nourished children hospitalized in the United States and Panama.

N Engl J Med. 1982 May 6;306(18):1070-6.

- The first use of ORS in the United States was done in the Indian Health Service on the Whiteriver Apache Reservation in Arizona
- Demonstrated that the "simpler technology" of ORS was effective and far easier and cheaper than intravenous therapy

EDITORIAL COMMENT

The development of ORS has probably saved more lives worldwide than any other medical device in the past 30 years. It was rapidly adopted overseas but there was initial resistance to its use in the United States. Much of the resistance was based on the assumption that intravenous fluid (more sophisticated and intensive technology) must be better than something so simple as drinking salt and sugar water. Numerous studies in the past thirty years have shown not only the safety, but the superiority of ORS over intravenous therapy except in cases of severe diarrhea or children with decreased levels of consciousness.

The CDC article is a great summary for anyone not familiar with ORS; its development, scientific rationale and clinical use. I would like to point out that much of the early work on the use of ORS in this country was done by Dr. Matu Santosham of Johns Hopkins University. Much of his work was done with the Indian Health Service on the Whiteriver Apache reservation in Arizona. Dr. Santosham has also done many other studies of tremendous benefit to American Indians and Alaskan Natives through his work on development of vaccines against Hemophilus influenza type B and pneumococcus

RECENT LITERATURE ON AMERICAN INDIAN/ALASKAN NATIVE HEALTH

Racial/Ethnic Disparities in Neonatal Mortality – United States, 1989 – 2001

MMWR July 30, 2004;53:655-658

- Neonatal mortality accounts for two thirds of infant deaths in the U.S.
- Neonatal mortality of AI/AN in 2001 was 4.1/1,000 which is equal to that of whites and below the US average of 4.5/1,000
- AI/AN showed the greatest annual decrease in neonatal mortality of all ethnic groups during this time period with a decrease of 5% per year.
- This improvement may be related to better access to neonatal intensive care for rural populations such as AI/AN

From Your Colleagues

GEORGE GILSON, ANCHORAGE

Q. Which fetal heart rate and contraction patterns are worrisome with misoprostol?

A. The hyperstimulation syndrome is worrisome and contraindicates further use of the drug.

There are 3 types of uterine contraction patterns associated with misoprostol use, only one of which is worrisome:

- 1) tachysystole refers to the occurrence of more than 7 uterine contractions in any 15 minute monitoring window,
- 2) hypertonus refers to 2 or more uterine contractions lasting more than 120 seconds in any 15 minute monitoring window,
- 3) the hyperstimulation syndrome refers to any instance of 1) or 2) accompanied by a nonreassuring fetal heart tracing (i.e., tachycardia, decreased variability, repetitive variables or lates).

Only the hyperstimulation syndrome is worrisome and contraindicates use of the drug for further attempts at ripening or induction. It's incidence in most studies is usually under 5%. Tachysystole in early labor after use of misoprostol is a common finding and is usually not a cause of either maternal discomfort or fetal intolerance of the process, and does not contraindicate further usage.

JUDY THIERRY, HQE

Birth Simulator for Shoulder Dystocia—Rubin's maneuver requires the least traction

Without expeditious and appropriate management, both mother and fetus are at risk for injury, even death. Up to 27% of shoulder dystocia deliveries are associated with brachial plexus palsy, of which 10% are permanent. A novel birth simulator designed by biomedical engineers at Johns Hopkins University in Baltimore, Maryland, helps identify the least traumatic delivery procedure for shoulder dystocia and other problem deliveries and assists in physician training. See details below. Conclusion: In a laboratory model of initial maneuvers for shoulder dystocia, anterior Rubin's maneuver requires the least traction for delivery and produces the least amount of brachial plexus tension. Further study is needed to validate these results clinically.

Gurewitsch ED et al Comparing McRoberts' and Rubin's maneuvers for initial management of shoulder dystocia: An objective evaluation. Am J Obstet Gynecol. 2005 Jan;192(1):153-60.

OB/GYN CCC EDITORIAL COMMENT:

Shoulder dystocia is rare, but can be a devastating problem. Timely application of known maneuvers can reverse the problem instantly. I recommend everyone who provides obstetric care, directly or indirectly, complete the Advanced Life Support in Obstetrics Course (ALSO) at least every 5 years.

Cesarean Delivery

Highest percentage ever reported in the United States

Preliminary CDC data for 2003 indicated that 27.6% of all births in the United States resulted from cesarean deliveries, an increase of 6% from 2002 and the highest percentage ever reported in the United States. After declines during 1989-1996, the total cesarean rate and the primary cesarean rate (i.e., percentage of cesareans among women with no previous cesarean delivery; 19.1% in 2003) have increased each year.



Hot Topics

Obstetrics Gynecology Child Health Chronic Disease and Illness

OBSTETRICS

Preterm premature rupture of membranes: is there an optimal gestational age for delivery?

CONCLUSION: Our findings suggest that expectant management of women at 34 weeks and beyond is of limited benefit.

Lieman JM, Brumfield CG, Carlo W, Ramsey PS. Preterm premature rupture of membranes: is there an optimal gestational age for delivery?

Obstet Gynecol. 2005 Jan;105(1):12-7.

GYNECOLOGY

Passive smoking increases the risk of cervical neoplasia

CONCLUSION: The associations were in the direction of increased risk for both passive smoking and current active smoking in both the 1963 and 1975 cohorts, but were stronger in the 1963 cohort. The results of this long-term, prospective cohort study corroborate the association between active cigarette smoking and cervical neoplasia and provide evidence that passive smoking is a risk factor for cervical neoplasia. Trimble CL et al Active and passive cigarette smoking and the risk of cervical neoplasia.

Obstet Gynecol. 2005 Jan;105(1):174-81.

CHILD HEALTH

Role of Social Norms and Friends' Influences on weight control behavior: Adolescent girls

Social influences—perceptions of friends dieting and, to a lesser extent, the prevalence of trying to lose weight throughout a school—are associated with UWCBs [unhealthy weight-control behaviors] for a large group of adolescent girls. Dieting is common among adolescent girls, and many practice UWCBs such as fasting, using diet pills/powders/liquids, and vomiting or taking

laxatives. School-wide prevalence of girls trying to lose weight was significantly, although modestly, related to UWCBs for normal-weight and moderately overweight girls. Friends' dieting was significantly related to UWCBs among normal-weight and moderately overweight girls.

Eisenberg ME, Neumark-Sztainer D, Story M. 2005. The role of social norms and friends' influences on unhealthy weight-control behaviors among adolescent girls. *Social Science & Medicine* 60(6):1165-1173.

CHRONIC DISEASE AND ILLNESS

Bariatric Surgery May Be a Viable Treatment Option for Severe Obesity

CONCLUSIONS: As compared with conventional therapy, bariatric surgery appears to be a viable option for the treatment of severe obesity, resulting in long-term weight loss, improved lifestyle, and, except for hypercholesterolemia, amelioration in risk factors that were elevated at baseline.

Sjostrom L, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med.* 2004 Dec 23;351(26):2683-93.

Bariatric surgery: majority had complete resolution or improvement of co-morbidities

CONCLUSIONS: Effective weight loss was achieved in morbidly obese patients after undergoing bariatric surgery. A substantial majority of patients with diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea experienced complete resolution or improvement.

Buchwald H, et al Bariatric surgery: a systematic review and meta-analysis. *JAMA.* 2004 Oct 13;292(14):1724-37.

Events to Note

17th Annual IHS Research Conference:

International Meeting on Inuit and Native American Child Health:

Innovations in clinical care and research

- April 29-May 1, 2005
- Seattle, WA

3rd Western MCH Epidemiology

- May 12-13, 2005
- Portland, OR

Advances in Indian Health

- May 11-13, 2005
- Albuquerque, NM

National Summit on Preconception Care

- June 21-22, 2005
- Atlanta, Georgia

2005 U.S. Public Health Conference/Global Health Summit

- June 5-9, 2005
- Philadelphia, PA

Ask a Librarian

Diane Cooper, M.S.L.S. / NIH

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You now have access to journals and also electronic medical reference textbooks in MD Consult.

If you haven't tried MD Consult, here is how:

- 1) Go to HSRL site: <http://hsrl.nihlibrary.nih.gov/>
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- 3) A drop down box will show ACCESSING BOOKS AND JOURNALS (click this)
- 4) Next click on CONNECT TO MD CONSULT
- 5) You can use either the generic account which does not give you everything OR you can set up an individual account.

Have Questions? Contact :

cooperd@mail.nih.gov

Midwives Corner

Marsha Tahquechi, CNM, GIMC

Midwives Serving Indian Country

The American College on Nurse Midwives (ACNM) has profiled Native American midwives and nurse midwives serving Indian Country. In September of 2004 in conjunction with the opening of the Museum of the American Indian and the 2004 Indian Health Summit the ACNM set up an exhibit at the summit highlighting the work of midwives serving Indian Country. They also provided a booklet profiling some of the Indian Health Service midwifery

practices across the country. Booklet and other information:

<http://www.midwife.org/prof/display.cfm?id=457>

Relevant links that address some of the health concerns and initiatives to eliminate health disparities among Native Peoples:

<http://www.acnm.org/prof/midwivesindians.cfm>

STD Corner

Laura Shelby, Albuquerque

A Community-Based Intervention Designed to Increase Preventive Health Care Seeking Among Adolescents: The Gonorrhea Community Action Project

This intervention is noteworthy because the researchers employed a different approach to STD control by embedding STD prevention within a larger message about the importance of comprehensive prevention/reproductive health among adolescents and young adults.

The goal of the intervention was to increase preventive health care seeking among female adolescents.

Females participants were more likely to make an appointment for a check-up, to have undergone a check-up, and discuss the importance of having a check-up with family and friends.

The intervention, however, was less successful on male participants. Vandevanter NL et al A community-based intervention designed to increase preventive health care seeking among adolescents: the gonorrhea community action project.

Am J Public Health. 2005 Feb;95(2):331-7.

The Recognition of Depression: The Primary Care Clinician's Perspective

CONCLUSIONS: The likelihood of accurately diagnosing depression and the timeliness of the diagnosis are highly influenced by the conditions within which clinicians practice. Productivity expectations in primary care will continue to undermine the identification and treatment of depression if they fail to take into consideration the factors that influence such care.

Baik SY, et al The Recognition of Depression: The Primary Care Clinician's Perspective. Ann Fam Med. 2005 Jan-Feb;3(1):31-7.

Office of Women's Health, CDC

Marriage may be good for you

Regardless of population subgroup or health indicator, married adults were generally found to be healthier than adults in other marital status categories. Never married adults were among the least likely to be overweight or obese. Marital

Status and Health: United States, 1999–2002 presents prevalence estimates by marital status for selected health status and limitations, health conditions, and health risk behaviors among U.S. adults, using data from the 1999–2002 National Health Interview Surveys.

Family Planning

Consumer Reports Magazine Rates Condoms, Reviews 16 Other Contraceptive Methods

The group used “standardized tests”, including filling condoms with air, to rate the products it examined. Consumer Reports also included a “Guide to Contraceptives,” which discusses and charts 16 other contraceptive choices, including birth control pills, intrauterine devices and

vasectomy. The report says that IUDs, oral contraceptives and emergency contraception have become “safer than in previous years. However, Consumers Union said in a statement that “[c]ondoms remain the only family planning and pregnancy prevention method that can help prevent sexually transmitted diseases.

Consumer Reports, February 2005

ACOG

Intrauterine Device (IUD)

ACOG Practice Bulletin NUMBER 59

Conclusions

- Pelvic inflammatory disease complicating IUD insertion is uncommon, and the risk of PID decreases to the background risk after the first 20 days after insertion.
- Nulligravid and multiparous women at low risk of STDs who desire long-term reversible contraception are good candidates for IUDs.

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Routine use of prophylactic antibiotics at the time of IUD insertion confers little benefit.
- The copper T380A is very effective for postcoital emergency contraception and is most effective if inserted within 5 days after unprotected intercourse.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Intrauterine devices may be offered to women with a history of ectopic pregnancy.
- The levonorgestrel intrauterine system may be an acceptable alternative to hysterectomy in women with menorrhagia.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- The FDA recommends that IUDs be removed from pregnant women when possible without an invasive procedure.
- An IUD placed for contraception should be removed in a woman who has become menopausal.
- Contraception counseling should include information about risk factors for STDs and PID.

CCC Editorial comment

IUD's are a vastly underutilized contraceptive method. In light of the FDA Black Box warning about long term use of Depo-Provera, we should strongly consider IUDs in properly selected patients who desire a longer term contraceptive alternative.

(continued from page 1)

Substantial Bone Loss Seen with Depo-Provera Use

CCC EDITORIAL COMMENT

The FDA Black Box warning was based on one controlled clinical trial in adults and one ongoing open label, non-randomized clinical trial in adolescent females. The loss increases with duration of use and may not be completely reversible. There is evidence, in both adults and adolescents, that the decrease in BMD is at least partially reversible after Depo-Provera CI is discontinued and ovarian estrogen production increases. Long term studies on BMD loss in adolescents are not available at this time, but are ongoing.

Please note the FDA does not have data to address whether calcium or Vitamin D may lessen BMD loss in women using Depo-Provera CI. All patients should have adequate calcium or Vitamin D intake. There is also randomized clinical data that estrogen supplementation is protective in adolescent girls. (See below)

Another approach, if long term Depo-Provera CI is deemed essential, is to measure BMD. In adolescents, interpretation of BMD results should take into account patient age and skeletal maturity. Also see other citations below

BOTTOM LINE

Until further data is available, use of Depo-Provera CI for longer than 2 years should be limited, while adequate intake of calcium and Vitamin D should be encouraged. If other forms of birth control are inadequate, then BMD should be measured and should take into account patient age and skeletal maturity. Estrogen supplementation can also be considered.

We should strongly consider IUDs in properly selected patients who desire a longer term contraceptive alternative. Please see ACOG: IUD on page 6 of this newsletter.

Additional Related Information

CONCLUSION

Our results suggest that estrogen supplementation is protective of bone in adolescent girls who receive depot medroxyprogesterone acetate injections.

Cromer BA et al Double-blinded randomized controlled trial of estrogen supplementation in adolescent girls who receive depot medroxyprogesterone acetate for contraception. Am J Obstet Gynecol 2005 Jan;192(1):42-7

CONCLUSIONS

Depot medroxyprogesterone contraception was associated with a greater risk of diabetes compared with combination oral contraceptive use only. Risk was associated with length of use and persisted after adjustment for body mass index. Additional research is needed for confirmation, but this risk should be considered in contraceptive choice for women at high risk for diabetes.

Kim C; Seidel KW; Begier EA; Kwok YS Diabetes and depot medroxyprogesterone contraception in Navajo women. Arch Intern Med 2001 Jul 23;161(14):1766-71

CONCLUSION

Women who use depot medroxyprogesterone acetate through to menopause have attenuated rates of bone loss from the lumbar spine and femoral neck, presumably because they have already lost the estrogen-sensitive component of bone.

Cundy T; Cornish J; Roberts H; Reid IR Menopausal bone loss in long-term users of depot medroxyprogesterone acetate contraception. Am J Obstet Gynecol 2002 May;186(5):978-83

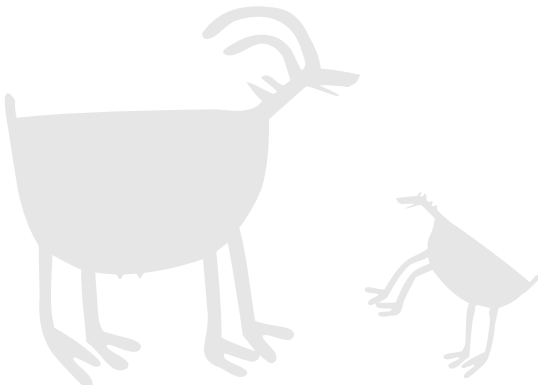
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Emergency Contraception does not increase promiscuity or unprotected sex, nor does it cause women to abandon their regular BC Method.

CONCLUSIONS:

While removing the requirement to go through pharmacists or clinics to obtain EC increases use, the public health impact may be negligible because of high rates of unprotected intercourse and relative underutilization of the method. Given that there is clear evidence that neither pharmacy access nor advance provision compromises contraceptive or sexual behavior, it seems unreasonable to restrict access to EC to clinics.

Raine TR, et al Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. JAMA. 2005 Jan 5;293(1):54-62

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START PLANNING NOW

March 30 - April 1, 2005

Albuquerque, New Mexico

IHS Advanced Colposcopy course and Refresher Workshop.

Ideal for non-OB/GYN and OB/GYN performing colposcopy.

Contact Roberta Paisano at (505) 248-4431

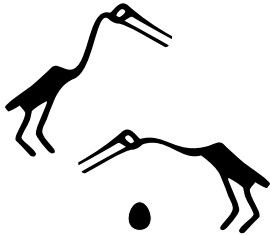
June 19 - 23, 2005

Denver, Colorado

IHS / ACOG. Postgraduate Course: Obstetric, Neonatal, and Gynecologic Care.

The basics of all AI/AN women's health, plus a good update.

Contact Yvonne Malloy at YMalloy@acog.org or (202) 863-2580



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JANUARY 2005

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From Your Colleagues

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- Birth Simulator for Shoulder Dystocia—Rubin's maneuver requires the least traction

Hot topics

- Obstetrics—Preterm premature rupture of membranes: Is there an optimal gestational age for delivery?
- Gynecology—Passive smoking increases the risk of cervical neoplasia
- Child Health—Role of Social Norms and Friends' Influences on weight control behavior: Adolescent girls

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