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The Advantages and Disadvantages of Pharmacological Treatment for Hypertension in Children and Adolescents

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Title: The Advantages and Disadvantages of Pharmacological Treatment for Hypertension in Children and Adolescents

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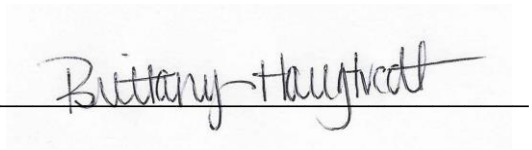
Signature 

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Abstract

Obesity in children continues to rise, causing an increase in hypertension in children and adolescents. Uncontrolled hypertension in children can lead to end organ damage to the renal and cardiovascular system at a much earlier age than we are seeing now. Pediatric primary hypertension, also called essential hypertension, has been proven to increase cardiovascular disease and hypertension as an adult. First line treatment in pediatric primary hypertension is lifestyle modification, diet and exercise. When those modalities are not enough, clinicians need to know the next steps in treating pediatric hypertension. Treating primary hypertension in children and adolescents seems unheard of, but proper evaluation and treatment is imperative to preventing further future organ damage. The newest guidelines for assessing and treating hypertension will be discussed as well as the clinical trials on anti-hypertensive agents used in treating pediatric hypertension will be reviewed. Based on the research, ACE inhibitors, thiazide diuretics and calcium channel blockers are thought to be a reasonable first line medication for children requiring drug treatment for hypertension.

A case report on a 67-year-old female who came into the clinic for hypertension follow up after first being diagnosed and started on an anti-hypertensive medication will be referenced throughout. She developed a common anti-hypertensive medication side effect. I will review the changes in her plan on care as well as review her significant family health history in correlation to her hypertension.

The Advantages and Disadvantages of Pharmacological Treatment of Hypertension in Children

Background

Studies have shown that children and adolescents who have pre-hypertension or hypertension are more likely to be hypertensive as adults. The attached case study (see Appendix A) demonstrates uncontrolled hypertension in an adult. Although it is undetermined if this patient had pediatric primary hypertension in her younger years, children with primary hypertension often has a positive family history of hypertension or cardiovascular disease. This 67-year-old female has a strong family history of cardiac disease. Her mother passed away from an abdominal aortic aneurism and her father during a coronary artery bypass graft (CABG) procedure and small cell lung cancer. Her brother is currently alive, however has already had a CABG as well. I don't have further documentation on this patient's pediatric history, but the current data I have points to a follow up appointment for her hypertension. This was her second appointment from when she was started on an anti-hypertensive medication Lisinopril. The CDC's latest data from the 2015 National Ambulatory Medical Care Survey indicates "the prevalence of hypertension increases with age, from 7% among those aged 18-39 to 65% among those aged 60 and over" (Yoon, Frayar, & Carrol, 2015, p. 2). I expect these statistics to increase at the next survey due to the increase in child and adult obesity.

"The percentage of childhood obesity in the United States has more than tripled since 1970. Today, one in five school aged children (ages 6-19) has obesity per the Centers for Disease Control and Prevention (CDC)" (Fryar, Carroll, & Ogden, 2014, p. 2-4). Childhood obesity is increasing the cases of early onset primary hypertension and atherosclerosis as well as the risk for developing left ventricular hypertrophy. Early studies indicated that primary hypertension was a rare concern in children and adolescents with estimated incidences of 1-2%

(Flynn, 2011). In the past few years the situation has changed and we are seeing more pre-hypertensive or elevated blood pressures in children and adolescents. Screening studies in early 2000's have shown an increase of 3-5% (Flynn, 2011). This proves early intervention in pediatric hypertension is imperative to decreasing a much earlier onset of cardiac and renal disease and other long term health effects.

Based on the current research, I will review the current recommendations for assessing and treating pediatric primary hypertension. A thorough literature review was done on the current pediatric anti-hypertensive pharmacological options. I will also discuss the advantages and disadvantages to each medication.

Literature Review

In 2004, the National High Blood Pressure Education Program (NHBPEP) came out with the fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. The 2004 NHBPEP recommends children three years of age or older should have their blood pressure measured during medical facility visits. However, the U.S. Preventative Service Task Force (USPSTF) does not find sufficient evidence to recommend for or against routine screening for childhood hypertension. NHBPEP recommends three separate readings of elevated blood pressure (an average systolic blood pressure (SBP) and/or diastolic blood pressure (DBP) greater than or equal to 90th percentile for age, height, and sex) on separate visits are needed to make the diagnosis of hypertension in children. Once the child has been diagnosed with primary hypertension, the child should have a comprehensive assessment for cardiovascular risk factors including a lipid profile, fasting glucose, and body mass index (BMI). First line treatment of primary hypertension in children includes non-pharmacologic treatment including weight loss, dietary modifications, and exercise (Luma & Spiotta, 2006). "Prehypertension is defined as average SBP or DBP levels on one occasion, that are less than the 95th percentile but greater than or equal to either the 90th percentile or 120/80 mmHg, whichever is lower. Hypertension is classified as Stage I if the average SBP or DBP is between the 95th percentile and the 99th percentile + 5 mmHg. Stage II is classified if the average of either SBP or DBP exceeds the 99th percentile + 5 mmHg" (National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, 2004, p. 4). These guidelines are a movement in the right direction, however they lack a single target goal for blood pressure readings as seen in adults.

Prior to 1997, pharmaceutical companies rarely conducted pediatric trials, and even more rare were trials of anti-hypertensive agents conducted in children. The Food and Drug Administration Modernization Act (FDAMA) was passed in 1997, creating an increase in trials of anti-hypertensive medications in children.

> The FDAMA mandated that the Food and Drug Administration (FDA) identify drugs with potential health benefits in children and request manufactures to conduct pediatric trials. In exchange, the manufactures can receive an additional 6 months of market exclusivity. The Best Pharmaceuticals for Children Act (BPCA), was passed in 2002, which renewed and amended section 111 of the FDAMA. In addition to renewing the exclusivity provision, it provided a process for "off-patent" drug development requiring public posting of results of all pediatric trials and requires reporting of all adverse events for 1 year after granting of exclusivity. The BPCA also added an Office of Pediatric Therapeutics at the FDA to assist with all activities affecting children. In 2003, the Pediatric Research Equity Act (PREA) was passed and required all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration must contain a pediatric assessment unless the manufacture obtains a waiver or deferral of pediatric studies. (Flynn, & Daniels, 2006, p. 747-748).

These legislative initiatives have helped improve the safety information in the manufacturers' drug labels as well as provided an increase in medication dosing for pediatrics. However, many of the older anti-hypertensive medications prior to 1997 have not been formally studied in children, which has led to an increased use of anti-hypertensive medications without FDA- approved pediatric labeling. The older anti-hypertensive medications missed out on the incentives for industry sponsored trials. (Misurac et al., 2016). Many of the studies were of short

duration and did not assess the target organ damage or other health outcomes. Regardless, an increase in pediatric studies had increased the amount of data regarding the pediatric use of anti-hypertensive medications. The remaining sections of this paper will consist of an anti-hypertensive medication review for pediatrics as well as point out areas in which further research and trials are needed.

A first line medication commonly used in adults and now pediatrics are angiotensin-converting enzyme inhibitors (ACEI). ACE inhibitors work by preventing the body from creating a hormone called angiotensin II. This is done by the medication blocking a chemical called angiotensin converting enzyme which relaxes blood vessels and helps to reduce the amount of water reabsorbed by the kidneys. ACE inhibitors provide beneficial effects on cardiac function and remodeling, thus is considered the drug of choice for patients with compromised cardiac function or left ventricular hypertrophy (Misurac et al., 2016). They have also been found to provide renal protection for patients with chronic kidney disease and diabetes mellitus (Dhull et al., 2016). One studies' preliminary data indicated improvement in cholesterol and insulin resistance in obese children with metabolic syndrome (Misurac et al., 2016).

Many of the ACE inhibitors have been systematically studied in children due to the FDAMA trials. ACEI's come in long and short acting forms. Captopril is the oldest ACE inhibitor and best studied in pediatrics for the treatment of hypertension in infants and children. It's a shorter acting ACEI needing to be given three times a day creating an inconvenience to the child and parents (Flynn, 2011). The longer-acting ACE inhibitors have been more favorable for this reason. Published efficacy results are available for the longer acting ACE inhibitors enalapril, fosinopril, and lisinopril, but not for benazepril or quinapril (Flynn, 2011). Enalapril and Lisinopril have both been studied in double-blind placebo-controlled pediatric studies

(Misurac et al., 2016). Both studies used the "same dose-response design that established minimum effective doses for these compounds of 0.08 mg/kg/day" (Flynn, 2011, p. 112). The blood pressure was reduced in a dose-dependent manner with minimal side effects. The fosinopril was trialed in 2003 via prospective, double-blind, placebo-controlled trial, proving greater blood pressure reduction, but failed to establish a dose-response effect (Dhull, Baracco, Jain, & Mattoo, 2016). The results of the benazepril trial from the FDA are available, but they indicate that no dose-response was established either. In other words, many of the ACE inhibitors have been trialed in pediatrics, but lack efficacy (Flynn, 2011).

ACE inhibitors are generally well tolerated. A common side effect also seen in adults was a chronic cough. They should also not be used in patients with bilateral renal stenosis as they can cause acute kidney injury. They also are teratogenic and should not be used in females of child bearing age at risk for becoming pregnant or pregnant women.

Angiotensin receptor blockers (ARBs) are the newer anti-hypertensives on the market, which have allowed them to be studied in pediatrics due to the FDAMA sponsored trials. They were developed to overcome several of the deficiencies found in ACE inhibitors. ARB's do not inhibit the breakdown of kinins which caused the cough seen in ACEI's. ARBs block the action of angiotensin II receptor, blocking vasoconstriction and thus decreasing systemic vascular resistance. ARBs have variating half-lives, but are dosed once daily. Common side effects include headache, dizziness, blurred vision, fatigue, hyperkalemia, rash and anemia (Dhull, et al., 2016). As seen with ACE inhibitors, ARBS also are teratogenic, but exposure during pregnancy may be more harmful. ARB's have limited use in children under the age of 6 due to the increased adverse effects seen in this age group. Losartan is the oldest ARB, but was the first to be studied in hypertensive pediatrics (Misurac et al., 2016). "Short term treatment with losartan

in hypertensive children 6-17 years of age produced significant dose-dependent reductions in diastolic blood pressure" (Flynn, 2011, p. 113). Olmesartan included a noteworthy study with a separate cohort of black hypertensive children which proved to have decreased efficacy in black children as compared to white children. Candesartan and valsartan trials were conducted on children under the age of 6, however, despite data demonstrating efficacy within this age group, the FDA has not labeled either of these two medications for use in children under the age 6 due to safety concerns. Valsartan was found to have a dose-dependent response in children ages 6-16, however, children ages 1-6, failed to demonstrate a dose-response (Flynn, 2011). Overall, ARB's prove to be safe and effective in children and adolescents. They are often seen as the next best choice for patients who cannot tolerate ACEI's.

Calcium channel blockers have very minimal side effects and are used as first line treatment in pediatric primary hypertension. Calcium channel blockers inhibit calcium channels within smooth muscle cells in the vasculature, resulting in decreased vasoconstriction and reduced peripheral vascular resistance" (Misurac et al, 2016, p. 35). The most common side effects are headache and peripheral edema due to the vasodilatory effects of this medication Calcium channel blockers are divided into two classes; the nondihydropyrines and dihydropyridines. There are two nondihydropyrines calcium channel blockers, verapamil and diltiazem (Flynn, 2011). Verapamil and diltiazem are more commonly used for rate control and both have very little data or experience in children (Misurac et al., 2016). The dihydropyridine calcium channel blocker with the longest history of use in the pediatric population is nifedipine. Nifedipine is a short acting calcium channel blocker recommended for use in children 6 years of age and older, however cautiously, as it can potentially cause rapid drops in blood pressure. Nifedipine is unable to be used in small children under age of 6 because the medication can't be

crushed. Amlodipine was approved by the FDA in 2004 and has gained the most attention by pediatric investigators (Flynn, 2011). It has a long half-life of 36-45 hours requiring a higher mg/kg/day dosing in children under the age of 6 (Dhull et al, 2016). The long half-life of this medication held up even if the tablet was given whole, crushed, or placed into suspension (Flynn, 2011).

The next class of anti-hypertensive medications used in children are diuretics. Diuretics are a good first line choice for hypertension management, however they need to be used cautiously. They are designed to decrease left ventricular fill pressures through volume reduction, which can cause volume depletion in athletes and during exercise. There are many different types of diuretics; thiazide, loop, and potassium sparing diuretics, all which have a different mechanism of action on the body. Diuretics have been found to cause electrolyte imbalances, especially loop and thiazide diuretics. They are also contraindicated in the very young or developmentally delayed children because of volume depletion. This population is unable to voice thirst or get fluids to replenish if there are thirsty, increasing their risk for dehydration. Hydrochlorothiazide and chlorothiazide are thiazide diuretics available in tablet and liquid form. Loop diuretics are rarely used to treat hypertension alone. Potassium sparing diuretics, such as spironolactone and amiloride, are rarely used to treat hypertension, except in special circumstances and in resistant hypertension. They can cause hyperkalemia in patients (Misurac, et al., 2016).

The last popular class of anti-hypertensives used in children and adolescents are the beta blockers. “Beta-Adrenergic antagonists block the action of endogenous catecholamines and norepinephrine at their sites of action on vascular smooth muscle, myocardium, kidneys, bronchi, and other locations” (Misurac, et al., 2016, p. 38). Their high side effect profile places them

second or third in line for the treatment of pediatric primary hypertension. "Beta blockers are contraindicated in athletes as they can decrease maximum sports performance and endurance" (Misurac et al., 2016, p. 38). They are contraindicated in children and adults with asthma or chronic lung disease as they can cause bronchospasm in the lungs. Also, they should be avoided in diabetic children, as this agent can mask the signs of hypoglycemia. Abruptly stopping a beta blocker can cause rebound hypertension and tachycardia. The extended release metoprolol was FDA approved for use in pediatric hypertension in 2007, although it is available in immediate release and short acting drug forms (Dhull et al., 2016). "Bisoprolol/hydrochlorothiazide (HCTZ), a beta blocker combined with a diuretic, has been studied in a placebo controlled trial producing significant reduction in diastolic blood pressure but not SBP in children. Labetalol is a combination alpha and beta blocker, and is available in IV for enteral form. It has not been specifically studies in a randomized control study, limiting its data in children. Carvedilol has only been studied in children with heart failure" (Misurac et al., 2016, p. 39). Most of the beta blocker studies in children were for cardiac conditions and not in cases of hypertension. More data is needed to prove these medications are safe and effective in children and adolescents.

Direct vasodilators, alpha-blockers, and central alpha agonists are second and third line agents used to treat pediatric primary hypertension. They are often used with resistant pediatric hypertension and in cases of emergent elevated blood pressure. They come with a high side effect profile and no data regarding their efficacy in hypertensive children, limiting their use (Flynn, 2011).

Among the anti-hypertensive agents, uremic acid reduction medications recently have been studied as well. High uremic acid levels within the body has gained popularity as a predictor for the development of hypertension in children and adults. "Hyperuricemia is still

controversial as to whether it precipitates in the etiology of hypertension. In a randomized, double blind, placebo controlled trial, 30 untreated, primary hypertensive adolescents, were treated with allopurinol for 4 weeks and then placebo for 4 weeks. Twenty of the 30 adolescents achieved normal blood pressure with allopurinol. The same group of investigators recently performed a randomized control study in adolescent with prehypertension utilizing allopurinol and probenecid (an uricosuric agent) to see if blood pressure reduction in the previous study was due to uric acid reduction in the body. Both groups had a significant reduction in blood pressure. More research is needed to prove efficacy of uric acid reduction agents" (Lande & Kupferman, 2013).

The NHBPEP has recommended a step-care approach to starting anti-hypertensive medications in children and adolescents. Initial treatment includes one anti-hypertensive medication as well as nonpharmacological options. The first medication should be started at the lowest dose possible to achieve blood pressure control. If blood pressure control is not achieved, move into step 2. Increase the dose until desired blood pressure target is reached or a maximum dose is reached. If blood pressure control is still not achieved, proceed by adding a second medication with a complementary mechanism of action. In most cases, a diuretic will be the second agent unless contraindicated. Step 4 includes adding a third anti-hypertensive drug of a different class or referral to a specialist who treats childhood and adolescent hypertension (Flynn, 2011).

All types of medications come with advantages and disadvantages. A common complaint with anti-hypertensive medications in children is the lack of suspensions or child friendly drug formulations. Most anti-hypertensive medications only come in pill form, creating a challenge for medication administration in children. Of the medications discussed, commercially available

suspensions only exist in hydrochlorothiazide, chlorothiazide and propranolol. Providers have told parents to crush the tablets and give with applesauce or yogurt, but this raises concern and uncertainty for medication uniformity, unknown bioavailability and stability of the medication (Flynn, 2011). Another disadvantage is the lack of guidelines as to which class of anti-hypertensive agents should be used first to treat primary hypertension in children and adolescents. The adult population has clear cut recommendations, but it should not be assumed what works well in the adult population, will work great in children. Most pediatric anti-hypertensive studies have been conducted on newer anti-hypertensive medications due to the FDAMA financial incentives. The older anti-hypertensive drugs will likely never be tested in children due to the lack of funds granted (Lande & Kupferman, 2013). The older medications could have great potential and efficacy if reimbursement would be made available for testing in children.

Despite the disadvantages, pediatric anti-hypertension medication trials have provided pediatric specific medication information in the manufactures' drug labels and the clinical trials for anti-hypertensive agents in children are now available in scientific journals and on the internet (Flynn & Daniels, 2006). Based on the research, ACE inhibitors, thiazide diuretics and calcium channel blockers are thought to be a reasonable first line medication for children requiring drug treatment for hypertension. Although, a baseline of recommendations has been laid out, further knowledge and data are needed for the treatment of primary hypertension in children and adolescents. More trials are needed to compare the effectiveness of one class of anti-hypertensive medications to another. Very little research and trials have been done on combination anti-hypertensive medications in the pediatric population. More education is needed in the clinics and out of office facilities in regards to the correct time to start blood

pressure monitoring in children and how to assess for hypertension. "A survey performed in 2014 found that 71% of physicians measured blood pressure during ambulatory visits only if the child had risk factors for hypertension. After measuring blood pressure, 65% compared the reading with reference data only if they suspected it was elevated" (Bijlsma, Hester, Kaspers, & Bokenkamp, 2014, p. 173). Lastly, long term trials are needed to detect end organ damage to develop improved risk assessment monitoring and blood pressure treatment goals. The long-term effects of untreated hypertension in children are still unknown.

We know adequate blood pressure control reduces cardiovascular disease risk, but also delays kidney disease and damage in children. As the prevalence of hypertension continues to rise in the pediatric population, further clinical trials in children are needed to properly manage and understand pediatric primary hypertension.

Learning Points

- Further education is needed to improve the recommended guidelines of pediatric hypertension. In my practice, I will start blood pressure monitoring at age three and continue monitoring will be referenced against NHBPEP guidelines.
- Early pharmacological intervention will be used if lifestyle modifications, diet, and exercise are not improving the elevated blood pressure to prevent end organ damage.
- Pediatric anti-hypertensive medication clinical trials and manufactures' drug labels will be referenced for safety and efficacy of proper medication management prior to administration.

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Appendix A

Case Report

Chief Complaint: Hypertension follow up. Cough.

HPI: Kathy, a 67-year-old female comes into the clinic for her 3 week follow up on hypertension. 3 weeks ago, she was started on Lisinopril 20 mg PO daily. She states her blood pressure has not improved since starting the medication. She also reports a cough. The cough lasts all day and night and start approximately when she started the new blood pressure medication. She reports checking her BP at home and states her BP has been running 150-160 SBP, and 70-80 DBP.

ROS:
General: Denies fever, fatigue or un expected weight loss.
HEENT: Denies runny nose, stuffy nose, ear pain or drainage, or sore throat.
Respiratory: Denies shortness of breath, wheezing, or hemoptysis. Cough as per HPI. Cough is dry, does not improve or worsen with eating or drinking. Denies cough after eating spicy foods or laying down after eating. Denies burning sensation in chest or throat.
Cardiovascular: Denies chest pain, palpitations, dyspnea on exertion or swelling in extremities.
GI/GU: Denies nausea, vomiting, diarrhea, blood in stool, or bloating.
Skin: Denies any skin rashes or bruising.
Musculoskeletal: Denies any back pain or join pain or swelling.
Neuro: Denies numbness, tingling, seizures or tremors.

Allergies: No known drug allergies

Family Health History:
Mom- Abdominal aortic aneurism- deceased, unknown age
Dad- CABG, small cell carcinoma- deceased, unknown age
Brother- CABG- Alive
2 Children- Healthy- Alive

Social History:
Smoking- No
Alcohol- No
Illegal drug use- No

Medications:
Multivitamin 1 tablet PO daily
Lisinopril 20 mg PO daily

Physical Exam:
Vitals: BP: 160/98, HR: 80, Resp.: 20, Temp.: 98.6 F
General: Alert and oriented. Sitting in chair. Does not appear in any distress.
HEENT: Head normocephalic, atraumatic. PERRL. No erythema or drainage to bilateral eyes. TM clear, no erythema, fluid or drainage to bilateral ears. Nares patent, pink and no inflammation or drainage. Pink, moist oral mucosa. No erythema, exudate or adenopathy to posterior pharynx. No lymphadenopathy or enlarged thyroid.
Respiratory: Lungs clear throughout.
Cardiovascular: Normal rhythm and normal rate. S1 and S2 heard on auscultation. No murmurs, clicks or rubs. No edema to lower extremities.
GI/GU: Soft, round, non-tender. Bowel sounds active x 4. No CVA tenderness.
Skin: Warm, dry. No rashes, bruising or breakdown.

Differential Diagnosis: Asthma, GERD, Upper respiratory infection, Bronchitis

Diagnosis: Ace inhibitor Cough, uncontrolled hypertension

Plan:

1.) Discussed switching to another blood pressure medication due to ace inhibitor cough and uncontrolled hypertension.
2.) Stop Lisinopril. Start Losartan 50 mg PO daily. Side effects discussed. She will call the office if she has any side effects or is not tolerating the new medication.
3.) Follow up in 2-4 weeks.
4.) CBC and CMP lab work prior to follow up appointment.
5.) Discussed continuing to exercise and healthy eating plan.
6.) Recommend continuing to check BP at home. She will bring a BP log to her next appointment.
7.) She agrees with the above plan, and will call the clinic with any questions or concerns.

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