REGLAN IS A DANGEROUS PSYCHIATRIC DRUG: THE FACTS YOU NEED TO KNOW

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The drug Metoclopramide also known primarily by its brand name Reglan, is a pharmaceutical drug that is heavily used in nearly every patient suffering from Gastroparesis. Reglan is marketed as just another anti-nausea medication with no mention of the fact that Reglan is a psychiatric drug (Neuroleptic Dopamine Antagonist) that has some very serious side effects associated with it that I will break down further in this scientific research article. I recommend to anyone who is thinking of taking this medication or who knows someone who is to please share this document with them and/or your prescribing physician as many people, even physicians, are not necessarily aware of what Reglan (Metoclopramide) truly is and what it does to the body. They see it as purely being a pharmaceutical drug for the alleviation of nausea.

Drugs that contain metoclopramide include: Reglan tablets, Reglan oral disintegrating tablets, metoclopramide oral solution, and Reglan injection. More than 2 million Americans use these products, according to the FDA.

In recent years there has been a growing trend to identify drugs according to the conditions that they are being used to treat rather than by their pharmacological category or characteristics, including their impact on the brain. A long-standing problem, for example, has been the identification of metoclopramide (Reglan) as an anti-nausea drug rather than as a neuroleptic drug being used to treat nausea. Many unfortunate cases of tardive dyskinesia have resulted from the poorly informed prescription of this dangerous drug.

The problem has become particularly serious regarding the identification or naming of neuroleptics in psychiatry when they are being used to treat something other than schizophrenia. Quetiapine (Seroquel) is a so-called atypical neuroleptic with many adverse effects associated with the older neuroleptics, such as tardive dyskinesia, as well as additional adverse effects more closely associated with the atypicals, such as diabetes.

Yet, patients are commonly told that Seroquel is a “sleep aid” or “bipolar drug,” in effect misleading them into believing that they are not taking a neuroleptic or antipsychotic drug. Neuroleptics approved for antidepressant augmentation, such as aripiprazole (Abilify), are
similarly being called “antidepressants” in a misleading fashion. This euphemistic naming of drugs not only misleads patients and their families; it also lulls the prescriber and clinician into a false sense of security and makes it increasingly impossible for patients and families to identify the class to which a drug belongs, and hence the risks associated with it.

So, what exactly are Neuroleptic drugs (dopamine blockers) and what is it that they do? A dopamine antagonist (antidopaminergic) is a type of drug which blocks dopamine receptors by receptor antagonism. Most antipsychotics are dopamine antagonists, and as such they have found use in treating schizophrenia, bipolar disorder, and stimulant psychosis. Several other dopamine antagonists are antiemetics used in the treatment of nausea and vomiting.

So, what are some uses of Neuroleptic drugs (Dopamine Blockers) and examples? Dopamine receptor antagonists are used for some diseases such as:

- Schizophrenia,
- Bipolar disorder
- Nausea and vomiting.
- Hypersexuality and increased orgasmic activity.
- Used as antiemetics: metoclopramide, and droperidol.
- Used as tricyclic antidepressants: amoxapine, clomipramine, trimipramine. By using Dopamine Blockers Choline can antagonize dopamine directly or interfere with receptor function Melatonin suppresses dopamine activity as part of normal circadian rhythm functions, although pathological imbalances have been implicated in Parkinson's disease.

Neuroleptic drugs (dopamine blockers) used for non-psychiatric purposes can cause the same adverse effects. Prochlorperazine (Compazine) and metoclopramide (Reglan) are used to control nausea and vomiting during pregnancy, the flu, gastroparesis, delayed gastric emptying, and both present serious risks including tardive dyskinesia. Tardive dyskinesia (TD) is a disorder that results in involuntary, repetitive body movements. This may include but not be limited to grimacing, sticking out the tongue or smacking of the lips. TD also causes rapid jerking movements or slow writhing movements. In about 20% of people, decreased functioning results which can be and usually is permanent. The FDA recently published analyses suggesting that metoclopramide (Reglan) is the MOST common cause of drug-induced movement disorders. Another analysis of study data by the FDA showed that about 20% of patients in that study who used metoclopramide took it for longer than three months.
Tardive Dyskinesia (TD) can occur as a result of “long-term” use of Metoclopramide (Reglan) which typically develops within just a few months of treatment but can also take years to fully develop or develop to a point at which its symptoms become so strong that it becomes noticed by the patient, the patient's family, the patient's doctor, and/or a combination. Due to the high risk of TD associated with Reglan the FDA has placed what is known as a “black box warning” on this medication. An FDA black box warning is essentially placed upon medications that are associated with such dangerous side effects that it is one step below being banned from the market. Many of the pharmaceutical drugs that the FDA puts a black box warning on eventually go on to be removed from the market either willingly by the manufacturer, unwillingly due to the level of complaints received by the FDA, or due to accumulation of lawsuits and reports of injury linked to the black boxed drug.

Tardive dyskinesia is often misdiagnosed as a mental illness rather than a neurological disorder, and as a result patients are prescribed neuroleptic drugs, which increase the probability that the patient will develop a severe and disabling case, and shortening the typical survival period.

Children are frequently given metoclopramide (Reglan) for nausea and gastroesophageal reflux. I am in agreement with a scientific study completed by Mejia and Jankovic in 2010 that this drug is inducing many more cases of TD in children than is suggested by the literature and/or acknowledged by the FDA and the Pharmaceutical company. They report the case of a 12-month-old girl who developed orofaciolingual TD at only 2 months of age after 2 weeks of treatment with metoclopramide for gastroesophageal reflux disease. It persisted for at least 9 months after the medication was discontinued (Mejia & Jankovic, 2005). In my research, I have evaluated several cases of infants who developed abnormal movements in reaction to metoclopramide. In these cases, the abnormal movements were accompanied by flaccidity and failure to thrive. Recovery over many years was incomplete with most never fully recovering from the damage caused by Reglan.

Another severe side effect associated with metoclopramide (Reglan) is neuroleptic malignant syndrome (NMS), which can be fatal in 20% of cases. Any dopamine blocking agent used for other purposes, such as metoclopramide and prochlorperazine for nausea, can also cause NMS. The disease strongly resembles a viral disorder, lethargic encephalitis, which occurred in epidemic form during and shortly after World War I. Both strike the basal ganglia especially hard, causing a similar impact. NMS typically includes impaired consciousness and mental deterioration, elevated temperature (102 F+), autonomic nervous system instability (increased respiratory rate, blood pressure, heart rate, or sweating), and neurological impairments in the
form of extrapyramidal signs (EPS). NMS can present in varied and confusing ways and with varying intensity.

In my research and medical experience, even severe and life-threatening cases are sometimes misdiagnosed as “schizophrenia” or “catatonia.” The clinician must be alert for any symptoms that resemble NMS. Any report of fever should raise a suspicion. Early recognition with immediate termination of the causative agent and supportive measures in a hospital setting can be lifesaving as the longer the delay in treatment the more likely the patient is to suffer either permanent severe bodily harm or death. Some diagnostic analyses describe “rigidity” as the main neurological sign associated with NMS, and I have seen cases misdiagnosed because rigidity was not apparent. In my medical and research experience, rigidity may not be a symptom or may be a symptom when in comparison to the other occurring symptoms go unnoticed or unreported by the patient. Parkinson’s symptoms have also shown up in cases of NMS. Also, the condition Tardive dyskinesia which we just discussed can become a lasting sequela of nonfatal NMS as shown in research by (Zarrouf & Bhanot, 2007). Usually described as “rare” in the literature, NMS is common—occurring in as many as 2.4% of patients in a retrospective chart review by (Addonizio, Susman, & Roth, 1986). I suspect that many mild cases go unnoticed and that more research into this area is needed as the 2.4% statistic came from a 1986 study.

Europe Recommends Restrictions for Metoclopramide (Reglan) due to the symptoms of TD and NMS as described above but also due to cases of cardiovascular reactions, mainly associated with intravenous formulations given to patients with underlying risks for cardiac disease; they include hypotension, shock, syncope, bradycardia or atrioventricular block, and cardiac arrest.

Here’s more information on the Restrictions of metoclopramide (Reglan) use that have been recommended by the European Medicines Agency (EMA) Committee on Medicinal Products for Human Use (CHMP) that were first announced by the European Union in July of 2013. The recommendations are aimed at minimizing the known risks of potentially serious neurologic adverse effects. They include restricting the daily dose to a maximum of 30 mg and the duration of use to 5 days.

The review of metoclopramide was conducted at the request of the French medicines regulatory agency (ANSM), after continued safety concerns about adverse effects and efficacy. The ANSM asked the CHMP to review the benefits and risks of these medicines in all age groups and to recommend consistent indications for the European Union. The review confirmed the well-known risk for neurologic effects, such as short-term extrapyramidal disorders and tardive...
dyskinesia, the EMA notes in a press release. The risk for acute neurologic effects is higher in children, although tardive dyskinesia is reported more often in the elderly, and the risk is increased at high doses and with long-term treatment. The evidence indicates that these risks outweigh the benefits of metoclopramide in conditions requiring long-term treatment, according to the EMA.

The CHMP announced that metoclopramide is now contraindicated in children younger than 1 year of age; in children older than 1 year, it should only be used as a second-choice treatment for the prevention of delayed nausea and vomiting after chemotherapy and for the treatment of postoperative nausea and vomiting.

In adults, metoclopramide can be used for the prevention and treatment of nausea and vomiting associated with such things as chemotherapy, radiotherapy, surgery, and migraine. However, it should no longer be used in chronic conditions such as gastroparesis, dyspepsia, and gastroesophageal reflux disease, and should not be used as an adjunct in surgical or radiologic procedures. In addition, the daily maximum dose is now 0.5 mg/kg body weight; for adults, the maximum is 30 mg daily (administered as 10 mg 3 times daily).

Products containing higher doses should be removed from the market, the committee ruled. Oral liquid formulations have been particularly associated with overdose in children, the CHMP noted. Oral liquids containing more than 1 mg/mL will be withdrawn from the market, and oral doses of remaining formulations should be administered using an appropriately designed graduated oral syringe to ensure accuracy. Intravenous formulations with concentrations above 5 mg/mL and suppositories containing 20 mg will also be withdrawn.

The CHMP provides some details of the adverse events that have been reported with metoclopramide. The 1749 extrapyramidal disorders constituted nearly half of the 4005 spontaneously reported adverse effects in a manufacturer database as of December 2011. The reporting rate for these disorders was calculated to be 6 times higher in children than in adults, although it was not possible to accurately account for usage patterns in different age groups.

Extrapyramidal disorders were more likely to occur after several doses, although usually early in treatment, and were less likely at slower infusion rates when metoclopramide was given intravenously. Elderly patients seem to be at higher risk for potentially irreversible tardive dyskinesia after longer-term treatment. There were also a significant number of reports of overdose in children, particularly with oral liquid formulations.
The CHMP also described very rare cases of cardiovascular reactions, mainly associated with intravenous formulations given to patients with underlying risks for cardiac disease; they include hypotension, shock, syncope, bradycardia or atrioventricular block, and cardiac arrest.

If you are currently taking Metoclopramide (Reglan) then please talk to your doctor before going off this medication and please feel free to print a copy of this document to give to your doctor. This document has been made available for free personal use by Dr. Josh Ferguson.

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