Application to Add Glucagon to the Model List of Essential Medicines

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1. Summary: Application is made to add glucagon, 1 mg powder for injection, to treat hypoglycemia when glucose cannot be administered.

2. WHO Focal Point: none

3. Organizations consulted: none

4. INN: glucagon

5. Formulation: ampoules containing 1 mg, with diluent.

6. Available in North America, many European countries and elsewhere

7. Listing as specific medicine

8. Public Health relevance:

The drug glucagon is genetically engineered to be identical to human glucagon. Like the hormone, it stimulates adenylate cyclase to increase cyclic AMP. It increases blood glucose levels by promoting hepatic glycogenolysis and gluconeogenesis. It also has positive inotropic and chronotropic effects independent of alpha- and beta-adrenergic receptors.

Glucagon is primarily used in the management of hypoglycemia in adults, children, and pregnant women. It also has an unlabeled use as a cardiac stimulant after beta-blocker or calcium channel blocker overdose. In addition, glucagon is used to inhibit gastrointestinal motility to assist in radiologic examinations. It may also be used to help make a diagnosis of insulinoma.

Hypoglycemia

Severe hypoglycemia is dangerous because it can result in central nervous system damage, coma, and death. For example, there is an association between severe hypoglycemia and dementia for type 2 diabetics (Whitmer et al, 2009). In addition, a study in Dhaka, Bangladesh, found hypoglycemia to be a major cause of mortality in association with diarrhea in children (Bennish et al, 1990). Four percent of deaths of
people with insulin-dependent diabetes mellitus have been attributed to hypoglycemia. (Cryer, 1994).

In U.S. emergency departments from 1993-2005, there were around 5 million visits for hypoglycemia, with a quarter of these patients being admitted (Ginde et al., 2008). In Kayseri, Turkey, hypoglycemia was detected in about 1% of all hospital admissions to a teaching hospital (Güven et al., 2000).

Neonates and children are also affected by hypoglycemia. In a government maternity hospital in Kathmandu, 41% of newborns had mild hypoglycemia and 11% had moderate hypoglycemia (Pal, 2000). In Iran, a 15.15% incidence of neonatal hypoglycemia was found in the Tehran Children’s Hospital (Dashti et al., 2007). A rural Kenyan district hospital found hypoglycemia on admission in 23.0% of neonates and 7.3% of children over 28 days old (Osier et al., 2003). Meanwhile, the prevalence of hypoglycemia was 6.4% among pediatric emergency admissions at a teaching hospital in Nigeria (Elusiyan et al., 2005). In a hospital in Mozambique, 7.1% of pediatric admissions had hypoglycemia (Solomon et al., 1994).

Patients with insulin-treated diabetes are at particular risk for severe hypoglycemia (The DCCT Research Group, 1991). This is particularly concerning given the increasing global burden of diabetes, which is projected to increase from 285 million people in 2010 to 439 million in 2030 (IDF, 2009). It was recommended that all diabetics being treated with insulin have a glucagon kit available to them (Pearson, 2008).

A survey of U.S. hospitals found a 12%-18% prevalence of hypoglycemia in diabetic patients. Hypoglycemia was more common in patients with more severe diabetes and those being treated with insulin (Wexler et al., 2007). Another study found that 30% of diabetic outpatients using insulin had at least one episode of hypoglycemic symptoms or low blood glucose (Miller et al., 2001). One UK study found that 73% of type 2 diabetics had experienced hypoglycemia since beginning treatment with insulin (Henderson et al., 2003). Meanwhile, in Alexandria, Egypt, a quarter of diabetic children seen in an ambulatory setting had a history of hypoglycemic coma (Bassili et al., 2001).

Hypoglycemia is also a consequence of severe falciparum malaria. 8-30% of those with severe falciparum malaria have hypoglycemia, particularly in children with cerebral malaria as well as in pregnant women with quinine therapy (Thien et al., 2006). A recent study in Mali also found that more severe hypoglycemia defines a worse prognosis (Willcox et al., 2010).

Beta Blocker Toxicity

According to animal studies, glucagon has positive inotropic and chronotropic effects after β–blocker and calcium channel blocker overdose. Yet its effect on survival rate is still unclear, and there have been no studies with human subjects (Bailey, 2003). Still, glucagon is widely accepted as an antidote, particularly as first-line agent in β-blocker
overdose (Shepherd, 2006). It is recommended that hospitals with emergency admissions stock glucagon for this purpose (Dart, 2000).

The American Association of Poison Control Centers found that in 2008, cardiovascular drugs were the fifth most frequently involved substance in adult exposures and accounted for 2% of pediatric exposures. Fifty percent of the cardiovascular drugs involved were β-blockers and calcium channel blockers. Cardiovascular drug overdose was the fourth leading cause of mortality in this database (Bronstein et al, 2009). Similarly, in 2003 at the Loghman-Hakim Hospital Poison Center in Tehran, Iran, cardiovascular drugs were responsible for 4.4% of drug overdoses. Cardiovascular drugs were responsible for 2.2% of all deaths due to any cause of poisoning (Shadnia et al, 2007). These numbers are likely to increase due to the growing prevalence of cardiovascular disease globally, followed by an expected increase in the use of beta-blockers.

9. Treatment details:

Directions for Treatment of Severe Hypoglycemia:
Severe hypoglycemia should be treated initially with intravenous glucose, if possible.
1. If parenteral glucose can not be used, dissolve the lyophilized glucagon using the accompanying diluting solution and use immediately
2. For adults and for pediatric patients weighing more than 20kg (44 lbs), give 1 mg (1 unit) by subcutaneous, intramuscular or intravenous injection.
3. For pediatric patients weighing less than 20 kg (44 lbs), give 0.5 mg (0.5 unit) or a dose equivalent to 2-30 µg/kg.
4. Discard any unused portion.
5. An unconscious patient will usually awaken within 15 minutes following the glucagon injection. If the response is delayed, there is no contraindication to the administration of an additional dose of glucagon; however, in view of the deleterious effects of cerebral hypoglycemia, emergency aid should be sought so that parenteral glucose can be given.
6. After the patient responds, supplemental carbohydrate should be given to restore liver glycogen and to prevent secondary hypoglycemia.

10. Comparative Effectiveness

It is estimated that 8-15% of insulin treated diabetics experience severe hypoglycemia and resulting episodes, at least once a year (MacCuish, Munro, Duncan, 1970). Furthermore, hypoglycemia is related to approximately 4% of the deaths of elderly diabetic patients. Severe hypoglycemia is associated with acute (Cohen S, 1976) and chronic alcohol, severe hepatic and renal dysfunction, endocrinologic tumors, and malnutrition. If not remedied, severe hypoglycemia can result in permanent neurological damage (Auer RN), coma, seizures and death. (Heller, M.B and Vukmir R.B., 1993)
Summary of Available Data
Several clinical trials have shown the effectiveness of glucagon as treatment for hypoglycemia. In 1985, Mühlhauser et al. utilized home glucagon (subcutaneous or intramuscular) injections in an 18 month long consecutive series in a clinical trial; there were 434 adult participants (Mühlhauser I, Koch J, Berger M, 1985). Fifty-three severe hypoglycemic episodes were treated with 1mg glucagon injections by relatives of patients. All therapy was successful except for one case, a 98% success rate. In four cases a second 1 mg injection of glucagon was administered. Other clinical studies (Casparie AE, Elving LD, 1983, Collier A, et al, 1987) reported successful use of glucagon in a large series of diabetic patients. In these studies, intramuscular or subcutaneous injection of 1 mg of glucagon by either relatives or medical personnel was a highly reliable method of restoring normal blood glucose levels or very slight hyperglycemia within 15 minutes of injection, similar to results of Mühlhauser I, Koch J, Berger M’s clinical trials.

Available Estimates of Clinical Effectiveness
Patients with hypoglycemia able to ingest fluids have long used the obvious enteric treatment of ingestion of glucose-containing foods like orange juice or other sugar solutions. Granulated sugar provides 4 grams of glucose per teaspoon. In 1964, in a study done by Shipp et al. (1964) of young campers, glucagon was deemed effective over oral glucose when given subcutaneously in either a 1 mg or 2 mg dose. Another common treatment of acute hypoglycemia is infusion of 50 or 25% dextrose solutions. However there are risks to this approach. Such infusions are both hypertonic and acidotic, which can cause pain and even tissue damage if extravasated (Heller and Vukmir, 1993). There are limitations to IV infusion of dextrose. There are patients without IV access due to lack of peripheral intravenous sites that occur in chronically ill diabetic patients (Pons, PT, Moore EE, Cusick JM et al., 1988). Central venous cannulation can be a solution to this problem, but this carries a complication rate, and access can be difficult particularly in patients with altered mental status or are actively seizing (Herbst, C., 1979).

Thus, all of these concerns would lead to a desire for an alternative treatment that would allow for hypoglycemia treatment that was neither enteral nor intravenous. In a clinical trial by Vukmar, Paris and Yealy, glucagon was proven to be safe and effective therapy for hypoglycemia in the pre-hospital setting for patients without IV access. In sum, glucagon injection is effective for mild and severe hypoglycemia. The complex effects of glucagon injection involve both glycogenolysis and gluconeogenesis, and may have clinical relevance in the patient with severe carbohydrate and/or protein depletion (Heller and Vukmir, 1993).

1. Summary of comparative evidence on safety

Safety and Tolerability

Numerous studies have demonstrated the efficacy and safety of glucagon in the treatment of severe hypoglycemia (Patrick, 1990; Howell, 1997; Elrick, 1958; Pearson
When compared to intravenous glucose treatment of hypoglycemia, intramuscular glucagon injection has been shown to be equally safe (Carstens, 1998). Both intravenous and intramuscular administration of glucagon have been shown to have comparable side effect profiles (Chernish, 1988). The most common adverse reactions are nausea, vomiting and headache, though some studies show the incidence of such effects to be equivalent to placebo (Chernish, 1975).

In a summary of 18 studies performed outside of the United States in which 438 adult patients were treated with glucagon, the major side effect was nausea (10%). When 164 healthy volunteers were exposed to glucagon in the same studies, the incidence of side effects were nausea (28%), dizziness (13%), vomiting (3.6%), headache (2.4%) and malaise (1.4%). There was only one incidence of hyperglycemia in all subjects studied therefore not constituting a significant risk of glucagon administration (Novo Nordisk, 1998). Another study performed in the U.S. involving 50 hypoglycemic subjects treated with glucagon showed headache to be the only side effect with a 4% incidence (Vukmir, 1991). Furthermore, perhaps due to glucagon’s short half life (8-18 minutes), most side effects noted subside within one hour of administration (Namba, 1993). Numerous studies have also demonstrated the safety and efficacy of glucagon use to treat hypoglycemia in the pediatric population (Gibbs, 1958; Cornblath, 1958; Carson, 1955; Shipp, 1964; Aman, 1988; Haymond, 2001).

In addition to treating severe hypoglycemia, glucagon is also used to treat beta-blocker and calcium channel blocker overdose. The evidence supporting use of glucagon in beta-blocker and calcium channel blocker overdose, however, is limited to animal studies leaving current antidotal therapy to be based on these as well as case reports (Bailey, 2003; Shepherd, 2006). Because no prospective human study evaluating optimal therapy has been performed, there are also no specific data elucidating the safety of glucagon in this setting. The dose of glucagon used for beta-blocker overdose is 50-150 µg/kg initial bolus followed by a continuous infusion at a rate of 2-5mg/hr (Shepherd, 2006). This is a significantly higher dose than the 1 mg subcutaneous or intramuscular injection given to treat hypoglycemia. More data is needed to confirm the safety of glucagon in this setting.

Safety in Pregnancy

Glucagon is a Pregnancy Category B drug in the United States. Reproduction studies have not been performed in humans, however, studies performed in rats at doses up to 2 mg/kg glucagon administered two times a day (up to 40 times the human dose based on body surface area) have revealed no evidence of impaired fertility or harm to the fetus (Eli Lilly, 1998). However, due to the lack of adequate and well-controlled studies in pregnant women and because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Contraindications and Warnings
Generalized allergic reactions have been reported with glucagon and use is contraindicated in patients with such known hypersensitivity. Glucagon is also contraindicated in patients with known pheochromocytoma (Eli Lilly, 1998). Because exogenous glucagon has been shown to stimulate the release of catecholamines, use in the presence of a pheochromocytoma may cause a sudden and marked increase in blood pressure. If a patient develops a sudden increase in blood pressure, 5 to 10 mg of phentolamine mesylate may be administered intravenously in an attempt to control the blood pressure (Eli Lilly, 1998).

A relative contraindication to glucagon use is in hypoglycemia caused by an insulinoma. In patients with insulinoma, glucagon may cause an initial increase in blood glucose, however because of glucagon’s hyperglycemic effect, subsequent hypoglycemia may be caused by exacerbated insulin release from the tumor (Eli Lilly, 1998). An attempt to give glucose either orally or intravenously should be made in any patient developing hypoglycemia post-glucagon administration.

Overdose of glucagon has rarely been noted. Because glucagon is a polypeptide, accidental ingestion into the gastrointestinal tract would result in rapid destruction of the recombinant hormone. The intravenous median lethal dose in mice and rats is approximately 300 mg/kg and 38.6 mg/kg respectively (Eli Lilly, 1998). Treatment of overdose is primarily symptomatic for nausea, vomiting and possible hypokalemia (Novo Nordisk, 1998; Eli Lilly, 1998).

Summary of comparative safety against comparators

Glucagon has no therapeutic equivalents.

12. Summary of available data on comparative cost and cost-effectiveness within the pharmacological class or therapeutic group:

It is estimated that 8-15% of insulin treated diabetics experience severe hypoglycemia and resulting episodes, at least once a year. Furthermore, hypoglycemia is related to approximately 4% of the deaths of elderly diabetic patients. If not remedied, severe hypoglycemia can result in permanent neurological damage, coma, seizures and death. (Heller, M.B and Vukmir R.B., 1993)

Since 1957, clinical experiments have demonstrated the effectiveness of glucagon injections to treat severe hypoglycemia. One study performed by Schulman et al. demonstrated the rapidity of glucagon onset of action as well as its potency. Blood sugar rose within 5 minutes of glucagon injection, and interestingly, the amount of insulin present does not interfere with the effectiveness of a given glucagon dose. Schulman et al. also discuss the advantages of glucagon injection, including a minimal volume to inject, and the absence of local reactions such as thrombosis. (Schulman, et al., 1957) In addition, glucagon injection is much easier, faster, less time consuming and leads to a decreased incidence of gastro-intestinal problems in comparison to a feeding tube.
Thus, this method of alleviating hypoglycemia is much more practical both in and away from the hospital. Another study performed by Muhlhauser et al. in 1985 reported that 98% success rate when 53 severe hypoglycemia episodes were terminated with 1 mg of glucagon. Subsequent studies have shown a similar success rate in the treatment of hypoglycemia with glucacons in diabetic patients. (Heller, M.B and Vukmir R.B., 1993) In addition, the maximum rise in glucose was independent of intramuscular, intravenous or subcutaneous route of injection. (Muhlhauser et al. 1985)

Current formulations of glucagon available are glucagon from Eli Lilly and GlucaGen from Novo Nordisk. Studies by Eli Lilly show that a maximum blood glucagon concentration of 7.9 ng/ml occurs 20 minutes after subcutaneous injection, and a maximum blood concentration of 6.9 ng/mL occurs 13 minutes after intramuscular injection. Glucose concentrations rose to 136 mg/dL by 30 minutes after a 1mg injection. Novo Nordisk reports that blood glucose concentrations begin to rise 10 minutes after intramuscular injection of 1 mg of GlucaGen, and a maximum concentration of approximately 110 mg/dL is reached by 30 minutes post injection. Price per dose of drug, paid by the individual, ranges from 0 to 27,88 euro. Details are in Appendix A.

For comparisons, the U.S. published (The Red Book) wholesale list price for dextrose 5% in water, 500 ml, is $9.25 - $14.86 and for glucagon, 1 mg, is $84 - $112. This gives a cost ratio of glucagon being 8 times more costly than dextrose for commercially prepared formulations. Oral glucose is cheaper.

From a cost-effectiveness standpoint, oral glucose is the best and is the preferred treatment of hypoglycemia. For hypoglycemic patients who cannot ingest oral glucose, IV glucose is effective therapy. For patients with severe hypoglycemia who cannot ingest oral glucose and in whom IV access is not possible, then IM glucagon is cost-effective if compared to the cost of long term care if the severe hypoglycemia persists long enough to cause meaningful irreversible brain damage.

13: Regulatory Status:

Glucagon is a drug used to increase blood sugar levels. In a recombinant form, glucagon has been approved for use in the United States by the Food and Drug Administration since 1998. It is also approved for use in Canada and in the UK, where it is approved as glucagon hydrochloride.

References


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Shipp JC, Delcher HK, Munroe JF. Treatment of insulin hypoglycemia in diabetic campers; a comparison of glucagon (1 and 2 mg) and glucose. Diabetes 13;645-8, 1964


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