Cases of sudden death, most often in the elderly with dementia-related psychosis, have also been reported with haloperidol. In general, haloperidol is considered to have a lower incidence of extrapyramidal reactions than other antipsychotic drugs and less likely to cause neuroleptic malignant syndrome, hyperpyrexia, or other malignant reactions.

Altered body temperature, hyperthermia, and extrapyramidal symptoms may be indications of neuroleptic malignant syndrome. This syndrome, characterized by altered consciousness, hyperpyrexia, hyperkinesia, muscular rigidity, and autonomic instability, is potentially fatal.

The diagnosis of neuroleptic malignant syndrome should be made early and treatment instituted promptly. If neuroleptic malignant syndrome is suspected, haloperidol should be discontinued and supportive treatment administered promptly. If haloperidol is used in patients with dementia-related psychosis, the physician should be alert to the possibility of drug-induced extrapyramidal symptoms and neuroleptic malignant syndrome and should institute appropriate supportive measures.

Other important considerations in the differential diagnosis of extrapyramidal symptoms include drug fever, which is often seen in patients treated with neuroleptic agents; serotonin syndrome, which may be caused by the concomitant use of certain monoamine oxidase inhibitors and other drugs that enhance the activity of serotonin; and a postural (orthostatic) hypotensive reaction, which may be relieved by administration of fluids or by assuming a sitting position.

Severe extrapyramidal symptoms, confusion, agitation, and hallucinations may occasionally occur in elderly patients treated with haloperidol, and may be manifested by slurred speech and difficulty in walking or talking. These reactions are not necessarily related to the presence of extrapyramidal symptoms and may be more often related to delirium, dementia, or drug fever. The symptoms may be alleviated by the use of anticholinergic drugs. However, when anticholinergic agents are used concurrently with haloperidol, the potential for additive anticholinergic effects may be increased.

Tardive Dyskinesia

Tardive dyskinesia is a potentially irreversible, involuntary, discontinuous movement disorder that typically begins weeks to months after antipsychotic treatment is initiated. The longer the duration of antipsychotic treatment and the higher the daily dose, the greater the risk of developing tardive dyskinesia. Tardive dyskinesia may begin at any time during antipsychotic treatment, although it is more likely to occur in elderly patients. Although it is reversible if the antipsychotic drug is discontinued, tardive dyskinesia may persist indefinitely in some cases.

Tardive dyskinesia is characterized by repetitive, purposeless, and involuntary movements of the mouth, tongue, face, trunk, or limbs. The movements may vary in severity and frequency and may wax and wane over time. Tardive dyskinesia may be associated with other extrapyramidal symptoms, such as akathisia or pseudoparkinsonism.

The risk of developing tardive dyskinesia is greater in patients who have been treated with antipsychotic drugs for an extended period of time. The risk is also higher in patients who have received higher doses of antipsychotic drugs. The risk is lower in patients who have been treated with antipsychotic drugs for a short period of time.

The management of tardive dyskinesia is often challenging. In some cases, the symptoms may improve or resolve if the antipsychotic drug is discontinued. In other cases, the symptoms may persist even if the antipsychotic drug is discontinued. In some cases, the symptoms may stabilize or improve if the antipsychotic drug is continued at a reduced dose. In other cases, the symptoms may worsen if the antipsychotic drug is discontinued.

In some cases, the symptoms may be managed with anticholinergic drugs, such as benztropine or diphenhydramine, or with a combination of anticholinergic drugs and a benzodiazepine, such as lorazepam or alprazolam. In some cases, the symptoms may be managed with a combination of anticholinergic drugs and a dopamine antagonist, such as aripiprazole or risperidone.

In the treatment of tardive dyskinesia, it is important to consider the balance between the benefits of the antipsychotic drug and the risks of the anticholinergic agent and the dopamine antagonist. The benefits of the antipsychotic drug may be outweighed by the risks of the anticholinergic agent and the dopamine antagonist, or the opposite may be true. The decision to use an anticholinergic agent or a dopamine antagonist should be individualized and should be based on the patient's symptoms and the potential risks and benefits of the treatment.

In some cases, the symptoms may be managed with a combination of anticholinergic drugs and a dopamine agonist, such as bromocriptine or cabergoline. In some cases, the symptoms may be managed with a combination of anticholinergic drugs and a dopamine antagonist, such as aripiprazole or risperidone.

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No mutagenic potential of haloperidol was found in the Ames Salmonella microsomal activation assay. Negative or inconclusive positive findings have been obtained in vitro in mammalian cells. However, these tests do not predict potential on chromosome structure and number. The available cytogenetic evidence is considered too inconclusive to be conclusive at this time.

Carcinogenicity studies of haloperidol did not indicate any carcinogenic potential. However, the change in longevity from young subjects. The studies did not identify differences in responses between young and elderly patients. However, the prevalence of idiopathic Parkinson disease appears to be higher in elderly patients. Also, the pharmacokinetics of haloperidol in geriatric patients generally varies from the younger population. These differences may result in lower plasma concentrations when given in the same dosages as for younger patients.

Additional Adverse Reactions Reported in Double-Blind, Placebo- or Active Comparator-Controlled Clinical Trials with Injectable or Oral Haloperidol

Additional adverse reactions that are listed below were reported by haloperidol-treated patients in clinical trials. They include reports from placebo-controlled clinical trials with the injectable or oral formulation, or at ≤1% incidence in double-blind, parallel, placebo-controlled clinical trials with haloperidol decanoate.

Cardiac Events: Tachycardia

Eyes: Ocular irritation

Hyperkinesia

Incontinence

Skin and Subcutaneous Tissue Disorders: Acne

Skin Disorders: Rash

Skin and Appendage Disorders: Pruritus

Skin and Appendage Disorders: Pityriasis rosea

Skin and Appendage Disorders: Pruritus ani

Skin and Appendage Disorders: Ichthyosis

Skin and Appendage Disorders: Erythema multiforme

Skin and Appendage Disorders: Angiokeratoma

Skin and Appendage Disorders: Erythema nodosum

Skin and Appendage Disorders: Cutaneous amyloidosis

Skin and Appendage Disorders: Hypertrichosis

Skin and Appendage Disorders: Hair loss

Skin and Appendage Disorders: Eczema

Skin and Appendage Disorders: Impetigo

Skin and Appendage Disorders: Petechiae

Skin and Appendage Disorders: Sarcoidosis

Skin and Appendage Disorders: Paronychia

Skin and Appendage Disorders: Raynaud phenomenon

Skin and Appendage Disorders: Steatodermia

Skin and Appendage Disorders: Alopecia areata

Skin and Appendage Disorders: Acrodermatitis enteropathica

Skin and Appendage Disorders: Keratosis pilaris

Skin and Appendage Disorders: Hyperhidrosis

Skin and Appendage Disorders: Dermatitis

Skin and Appendage Disorders: Folliculitis

Skin and Appendage Disorders: Pruritus vulvae

Skin and Appendage Disorders: Tinea pedis

Skin and Appendage Disorders: Psoriasis

Skin and Appendage Disorders: Leukoderma

Skin and Appendage Disorders: Vitiligo

Skin and Appendage Disorders: Hair loss

Skin and Appendage Disorders: Tinea corporis

Skin and Appendage Disorders: Tinea cruris

Skin and Appendage Disorders: Tinea capitis

Skin and Appendage Disorders: Tinea versicolor

Skin and Appendage Disorders: Tinea unguium

Skin and Appendage Disorders: Tinea nigra

Skin and Appendage Disorders: Lichen planus

Skin and Appendage Disorders: Lichen simplex chronicus

Skin and Appendage Disorders: Lichen ruber

Skin and Appendage Disorders: Lichen scleratus

Skin and Appendage Disorders: Lichen striatus

Skin and Appendage Disorders: Lichen planus

Skin and Appendage Disorders: Lichen planopilaris

Skin and Appendage Disorders: Lichen aureus

Skin and Appendage Disorders: Pityriasis rosea

Skin and Appendage Disorders: Pityriasis rubra pilaris

Skin and Appendage Disorders: Pityriasis lichenoides
disease including that due to haloperidol, therefore, there is no assurance that these differences are attributable to haloperidol.

Adverse Reactions in Treatment-Emergent Conditions

Adverse reactions in treatment-emergent conditions are reported when the reaction occurred for the first time or worsened for the first time since baseline, regardless of attribution to the study medication. Treatment-emergent conditions are the sum of those adverse reactions reported since baseline that were not reported at baseline or in the placebo group at baseline.

Investigations: Electrocardiogram (ECG) prolonged QT interval, weight decreased, weight increased.

Metabolic and Nutritional Disorders: Hypoglycemia.

Musculoskeletal and Connective Tissue Disorders: Rheumatism.

Nervous System Disorders: Somnolence, confusion, headache, dystonia, akathisia, paresthesia.

Psychiatric Disorders: Agitation, confusion, depression, disorientation, dyskinesias, hyperkinesias, akathisia, akinesia.

Reproductive System and Breeding Disorders: Priapism, impotence.

Respiratory, Throat, and Mediastinal Disorders: Laryngitis, bronchitis, exacerbation, bronchospasm, dyspnea.

Drug Reaction: Sepsis.

Overdose:

If excessive, the symptoms of overdose would include exaggeration of known pharmacologic effects and adverse reactions, the most prominent of which would be: 1) Torsades de pointes, 2) hypotension, or 3) sedation.

The patient would appear comatose with cyanosis, hypotension, hyperthermia, tachypnea, bradycardia, and incontinence. The patient would present with refractory hyperkinesia which might be an exaggeration of known pharmacologic effects and adverse reactions, the most prominent of which would be: 1) Torsades de pointes, 2) hypotension, or 3) sedation.

The patient would appear comatose with cyanosis, hypotension, hyperthermia, tachypnea, bradycardia, and incontinence. The patient would present with muscular weakness or rigidity and a generalized or localized tremor or rigidity which could be severe enough to produce a shock-like state. The patient would present with muscular weakness or rigidity and a generalized or localized tremor or rigidity which could be severe enough to produce a shock-like state. The patient would present with muscular weakness or rigidity and a generalized or localized tremor or rigidity which could be severe enough to produce a shock-like state. The patient would present with muscular weakness or rigidity and a generalized or localized tremor or rigidity which could be severe enough to produce a shock-like state.