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SIDE-EFFECTS OF SYNOPEN

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It is often difficult to decide whether an antihistaminic is therapeutically effective and to compare its side effects with another drug. It is only easy to see very marked differences between two drugs while it is difficult to compare the common side effects such as sleepiness, drowsiness, vertigo, nausea and increased talkativeness. Therefore in the following account only subjective observations have been made. The patients have not been asked to fill up questionnaires, as their value in an investigation of this type is highly problematical.

In the Diaconessenhuis, antihistaminics are used for the following purposes:

- a. postoperative injections of antihistaminics as a substitute for morphine and the like in asthmatic patients;
- b. injections of antihistaminics in the treatment of acute allergic conditions;
- c. administration of a single antihistaminic tablet or sugar-coated tablet to prevent possible reactions during desensitization therapy;
- d. a course of treatment with antihistaminics—the dosage being adjusted to the symptoms of the patient—over the period during which the patient shows symptoms (hay fever, urticaria in the spring or autumn, dust rhinitis, etc.).

Treatment with synopen was given on these lines, only the spontaneous symptoms and complaints of the patient being observed or listened to; accordingly, the patients were never asked whether they had noticed anything, on the assumption that apparently symptoms not reported spontaneously are of so little importance to the patient, that they may be ignored.

Attention was paid to the following side-effects (both those occurring immediately and those which usually do not appear until 3-4 days later) :

- a. mild symptoms (varying markedly with the patient and the dosage employed) such as sleepiness, vertigo, insecurity, tremors, nervousness, talkativeness, excitement, sense of increased energy, palpitations and tachycardia, hypotension or hypertension, or disturbances of the gastro-intestinal tract (nausea, vomiting, colic pain, diarrhoea, heartburn), ocular symptoms;
- b. more severe symptoms (marked drowsiness and sleepiness, great excitement, convulsion, urinary symptoms, disturbances of libido, dryness of the mouth (impaired secretion of saliva, etc.), cardiovascular symptoms, rise in temperature, erythema, agranulocytosis, anaemia) ;
- c. allergic symptoms.

PERSONAL OBSERVATIONS

- A. Eleven patients were given 2 ml. of synopen by intramuscular injection. All of them then slept soundly for about 8-10 hours on end. This shows that treatment had a marked *sedative effect* in every case.

Blood sugar level over 24 hours: continued normal or showed a slight decrease (in 3 cases) ; (3 determinations).

Eosinophil count: continued unchanged during 48 hours (6 counts).

Leucocyte count: continued unchanged during 48 hours (6 counts).

Hb: continued unchanged during 48 hours (6 determinations).

Blood pressure: remained unchanged or showed a slight increase (150–175 after 1 hour, 170 after 2 hours and 175 after 4 hours in one case).

Urine: several examinations failed to reveal any changes in all cases. No impairment of urination.

- B. Eight patients were given 0.25 ml. of synopen every 3–6 hours for 7–8 days during an acute allergic reaction.

No side-effects were observed. It should be pointed out, however, that these were all hospitalized patients, so that drowsiness, increased talkativeness, fatigue, etc. were less apparent.

- C. To prevent untoward reactions, an antihistaminic is often administered half an hour prior to making an injection in desensitization therapy with pollen, succus Liquiritiae or ipecacuanha. This was done in forty patients (about 250 sugar-coated tablets). The consulting-hours for outpatients are in the morning or afternoon, so that possible symptoms during work will become apparent.

One woman could not tolerate any antihistaminic, as it induced prolonged sleepiness; nor could she tolerate synopen.

No other patients had symptoms of this type, reported them or asked for a different drug on account of the symptoms.

- D. During the hay fever season (8 weeks), 12 patients with hay fever and a number (6) with urticaria were handed synopen during a prolonged period, the patients being ordered to take the sugar-coated tablets (which have the drawback that one has to keep to the given dosage and cannot divide and even quarter them like ordinary tablets) in doses depending on the symptoms, varying from no tablets to one every twelve hours or every eight hours in 24 hours. Prior to treatment, and in one case during and after treatment, a complete morphological examination of the blood and urine was made, the patients were also questioned as to the appearance of symptoms of hay fever or urticaria and their general state of health (in this case,

possible gastro-intestinal disorders, etc. would have been stated).

No symptoms were reported in these 18 cases. Examination of the blood and urine failed to reveal any changes. The blood pressure remained unchanged.

CONCLUSION

The attractive idea of injecting an entire ampoules of synopen, as the rest will have to be thrown away, is rewarded with a day's sleep. No other reactions were observed. Administration of smaller doses at frequent intervals was well tolerated.

The sugar-coated tablets, which have the disadvantage of being indivisible, so that they can never be administered to children, were given as a single dose in desensitization therapy and as a drug over prolonged periods in patients with hay fever and urticaria.

The patients did not complain of marked sleepiness, excitability, etc.

On purpose, they were not questioned as to the possible presense of drowsiness, fatigue and talkativeness (which are very common symptoms), on the assumption that no value should be attached to these symptoms if they are not reported spontaneously.

But for the sedative effect in some cases, there were no other reactions.

Treatment of out-patients with sugar-coated tablets and of in-patients with injections is possible without any severe side-effects.

As a rule, a drug chosen from the various so-called "good" antihistaminics may be given to patients in so small a dosage, that side-effects will be almost negligible, though the desired therapeutic action is obtained.

As far as this is concerned, synopen may be classed with the "good" antihistaminics.

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