

Exposure to metallic gold in patients with contact allergy to gold sodium thiosulfate

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Gold allergy is common, with approximately 10% of patients patch tested because of eczematous disease being positive to gold sodium thiosulfate (GSTS). However, clinical relevance seems to be rare. The aim of this prospective double-blind study was to demonstrate the effects of exposure to metallic gold, in this case earrings, in gold-positive patients. 60 female patients with pierced earlobes test-positive to GSTS were included in the study. The patients were randomized into 2 groups, 30 patients receiving earrings with a surface layer consisting of 24-carat gold and 30 patients earrings with a surface layer of titanium nitride, virtually indistinguishable from gold. The patients wore the earrings for 8 weeks. During the study, any dermatitis on the earlobes, as well as on other body sites, was registered. The skin reactions observed were weak but, in total, 17 of the 60 patients had a skin reaction (local or remote) during the study, 12 of whom had received gold earrings and 5 titanium ($p < 0.05$). 11 patients had a reaction on the earlobes, 7 of whom had received gold earrings and 4 titanium (NS). With these facts it is hard to exclude that exposure to gold jewelry can be clinically relevant in persons hypersensitive to gold.

Key words: gold sodium thiosulfate; contact allergy; gold; clinical relevance; ear piercing; allergic contact dermatitis; earlobe dermatitis; titanium. © Munksgaard, 2000.

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Gold added to the standard series as gold sodium thiosulfate (GSTS) yields a contact allergy rate of approximately 10 % in consecutive patients tested because of eczematous disease (1). The correlation between a positive patch test to gold and clinical symptoms is usually considered low. In previous studies, the clinical relevance of gold allergy has been assessed retrospectively from the patient history (2–7). The present prospective controlled study on the effect of exposure to metallic gold was designed to evaluate the clinical relevance of GSTS allergy. Many women have pierced earlobes and wear earrings daily. In addition, we have earlier shown that the earlobes constitute an eczema site overrepresented in patients positive to GSTS (3). This particular area was therefore chosen as the provocation site.

Materials and Methods

60 female patients were included in the provocation study. The patients were randomly selected from patients investigated during the last 3 years with patch tests, because of eczematous disease or

dental/oral problems, and found to be positive to GSTS. The patients had been tested with a standard series including GSTS 0.5% and 2.0%, in some cases also with 5.0% w/w, in pet. Further inclusion criteria: all patients ≥ 18 years of age and with bilaterally pierced earlobes. Patients with dermatitis on the earlobes or under treatment with systemic corticosteroids or other immunomodulatory drugs were excluded. Simultaneous contact allergy to other allergens did not imply exclusion. Before the study, the patients answered a questionnaire in which they were asked about gold exposure from dental gold as well as systemic treatment with gold salts, and whether they used to get symptoms from skin contact with gold objects or other metals. They were also asked about previous or present atopic dermatitis, asthma or hay fever.

The patients were patch tested with GSTS (Chemotechnique Diagnostics, Malmö, Sweden) dissolved in water using 8 steps, 5.0 to 0.0016% with a dilution factor of $\sqrt{10}$. In 44 cases, however, the higher concentrations were excluded since previous patch testing with GSTS had caused intense or persisting reactions. The application units were



Fig. 1. Earlobe with the type of earring used in the study.

Finn Chambers[®] (Epitest, Tuusula, Finland, 15 μ l on each patch unit) on Scanpor[®] (Norgesplaster, Vennesla, Norway). The patients were also tested with titanium 50% (metallic powder) and titanium nitride 5.0% in petrolatum. In some cases the patches were applied on the back, while others for practical reasons were tested on the outer upper arm. The patches were removed after 2 days and the test was read on day (D) 3 and D 10.

The stud earrings were manufactured and delivered by Blomdahl Medical AB, Halmstad, Sweden, and there were 2 types, $\frac{1}{2}$ of each: type I with a core of titanium covered with 0.3 μ m titanium nitride, giving the jewelry a surface practically indistinguishable from gold; type II with a core of titanium, first covered with 0.3 μ m titanium nitride and then covered with 0.2 μ m 24 carat gold (Fig. 1).

According to the manufacturer, the nickel content in the titanium and the titanium nitride used in the earrings was $<0.05\%$. The gold layer consisted of 99.99% pure gold, nickel not being measurable. The earrings were delivered in pairs, the 2 earrings in each pair being of the same type.

The patients were randomized into 2 groups and after the test reading at D 3 each patient received a pair of earrings of type I or type II. The study was double blind; the 2 types of earrings looked very similar and neither the patient nor the investigator knew which type of earrings the patient had received. The patients were instructed to use the earrings daily for 8 weeks but were allowed to take them off during the night. The patients were seen after 10 days and then every 2nd week throughout the study. At every visit, the earlobes were inspected for eczematous signs and the patients were asked about subjective local symptoms like itching,

and about development or exacerbation of dermatitis at other body sites.

48 consecutive gold-positive women with pierced earlobes, not taking part in this provocation study, patch tested during December 1998–October 1999, were interviewed about skin symptoms from gold jewelry.

Statistical analysis

Fisher's exact test was used in all comparisons.

Results

The patch tests with GSTS were positive on D3 or D10 in 50 of the 60 study patients. The patch tests with titanium and titanium nitride were negative in all 60 patients.

The skin reactions noted during the study are shown in Fig. 2. Most reactions were quite weak but, in total, 17 of the 60 patients had a skin reaction during the study. In 11 cases, this was a dermatitis on the earlobes, and in 6 cases there was a development or exacerbation of dermatitis at other body sites. 12 of the 17 patients had received gold earrings and 5 titanium; this difference was statistically significant ($p < 0.05$). After excluding reactions of duration shorter than 1 week, 9 patients with reactions remained, 8 of whom had received gold earrings and 1 titanium ($p < 0.05$). Looking

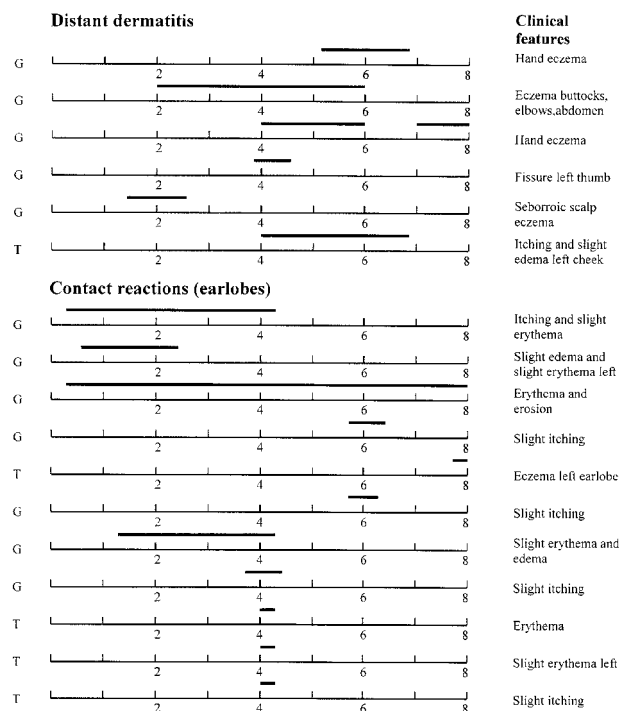


Fig. 2. Clinical reactions during the 8-week observation period of exposure to metallic gold (G) and titanium (T).

Table 1. Frequency of nickel allergy (Ni+) among the patients who had a skin reaction and those who did not

Reactors	Ni+ (<i>n</i> =7)	Total (<i>n</i> =17)	
gold	5	12	41.7%
titanium	2	5	40.0%
non-reactors	Ni+ (<i>n</i> =23)	total (<i>n</i> =43)	
gold	10	18	55.6%
titanium	13	25	52.0%

exclusively at the earlobe dermatitis 11 cases remain, 7 of whom had received gold and 4 titanium (NS). Exclusion of reactions shorter than 1 week

leaves 4 reactions, of whom all had received gold ($p=0.056$).

15 patients (25.0%) gave a history of intolerance to red gold earrings before the study. 6 of these patients were randomized to gold earrings, of whom 4 had a skin reaction, while only 1 of the 9 patients randomized to titanium reacted ($p=0.09$).

Of the 48 consecutive gold-positive women interviewed about skin symptoms from gold jewelry 10 (20.8%) gave a history of dermatitis from red gold earrings.

50% of the patients were allergic to nickel according to previous patch testing. There was no

Table 2. Published cases of allergic contact dermatitis from gold jewelry confirmed by patch testing

Pat No.	Sex/Age	Region	Patch test	Notes	Reference
1	F 23	finger	P: GSTS 1%	exp (3 w)	(23)
2	F 20	ears, finger	P: GSTM 0.5%, GM		(24)
3	M 29	multiple	P: GTC, GSTM N: GM	exp (2–4 d)	(25)
4	F 23	finger	P: GTC 1%, GSTM 0.5% N: GM	rash	(26)
5	F 24	ears, finger, wrist	P: GTC 2%, 0.2% N: GM	con (6 w)	(21)
6	F 27	ears, finger, wrist	P: GSTM, GTC 0.5% N: GM	flare-up after patch tests	(27)
7	F 28	finger, hands	P: GSTS 2.5–0.04%, GM		(28)
8	F 62	finger	P: GTC 1% N: GSTS 1%, GM	rash	(29)
9	F 34	finger, hands	P: G(I)chloride 1% N: GSTS 1%, GTC 1%, GM		(29)
10	F 45	finger, hands	P: G(I)chloride 1%, GSTS 1%, GTC 1%, GM	rash	(29)
11	F 29	ears, finger, wrist	P: GTC 0.5%	con (6 m)	(30)
12	M 64	wrist	P: GTC 0.5%		(31)
13	F 30	ears	P: GTC 0.5%	con (3 w)	(31)
14	F 20	ears, finger	P: GTC 1% N: control	con (6 w)	(32)
15	F 29	finger	P: GTC 2, 1% N: GM, 8 controls		(33)
16	F 36	ears, arm	P: GSTS 0.5–1% N: G(I)III)salts, GM	con (2 w)	(34)
17	F 36	ears, finger	P: GSTM 1%	con (3 w)	(35)
18	F 46	ears	P: GSTM 1%	con (directly)	(35)
19	F 34	multiple	P: GSTS 0.5% N: PDCA 0.002%		(36)
20	F 40	ears	P: GSTS 0.5%, PDCA 0.002%	con (2–3 m)	(36)
21	F 21	ears	P: GSTM 1%	con (1 m)	(37)
22	F 20	ears	P: GSTM 1%	con (1 m)	(37)
23	F 32	ears	P: GSTM 1%	con (directly)	(37)
24	F 24	ears	P: GSTM 2% (?)	con (3 w)	(38)
25	F 34	ears, neck, finger	P: GSTS 0.05%, PDCA 0.002%	con	(39)
26	F 40	ears, finger	P: GSTS 0.05%, PDCA 0.002%	con (1 m)	(39)
27	F 52	multiple	P: GSTS 0.5%, PDCA 0.002%	rash after chrysotherapy	(40)
28	F 38	ears	P: GSTM 2.5, 1%	con (directly)	(41)
29	F 44	ears, neck	P: GSTS N: GM	exp (4–5 d)	(42)
30	F 21	ears	P: GSTS 0.5%		(43)
31	F 22	finger, neck	P: GSTS 0.5%		(44)
32	F 20	ears	P: GSTM 1%, GTC 0.2%, GSTM 0.1% i.c. test	con (1 m) rash after i.c. test	(45)
33	F 27	ears	P: GSTS 0.5%	con (6 w)	(46)
34	F 34	ears	P: GSTS 0.5% N: GSTM; PDCA, Gold sodium chloride, GM		(47)
35	F 34	ears, neck, finger, wrist	P: GSTS 0.5% N: PDCA 0.002%		(48)
36	F 20	ears	P: GSTS 5–0.05%, PDCA 0.01%	con (2 m)	(49)

P=positive, N=negative; GSTS=gold sodium thiosulfate, GSTM=Gold sodium thiomalate, PDCA=potassium dicyanoaurate, GTC=gold trichloride; GM=metallic gold; con=apparent connection between earlobe piercing including insertion of gold ring and clinical hypersensitivity to metallic gold (time for induction in days (d), weeks (w) or months (m)), exp=time between exposure to metallic gold and contact dermatitis.

difference between the number of patients allergic to nickel among the patients who got a skin reaction and those who did not (Table 1).

22 patients (36.6%) answered that they had dental gold and 2 patients did not know whether they had or not. There was no correlation between the patients with dental gold and those who got a skin reaction, and no correlation between type of reaction (remote/local) and dental gold.

3 of the 12 patients (25.0%) who had a dermatitis from gold earrings had a history of present or previous atopic dermatitis. The equivalent figure among those who did not react was 3/18 patients (16.7%); the difference is not significant.

Finally, there was no statistical correlation between the degree of patch test reactivity and the clinical reactivity to metallic gold.

Discussion

When GSTS was added to the patch test standard series in our test laboratory it turned out to be the 2nd most common allergen in patients tested because of eczematous disease (1). A high frequency of gold allergy has thereafter been confirmed by others (2, 8, 9). In general, it is difficult to demonstrate clinical relevance after positive GSTS tests and the majority of the patients are able to wear gold jewelry without any obvious skin problems. On the other hand, dermatitis elicited from gold jewelry has been described and documented several times in the literature (Table 2). From these case reports it is, however, impossible to assess the actual frequency of contact dermatitis from gold.

To estimate the general clinical relevance of gold allergy, prospective experimental studies are needed. Another method is studies based on questionnaires. Such studies have been made, and in some the questions were answered by the patients before the patch test results were known (2–4), in other studies afterwards (5–7). The value of the patient's answer probably decreases if she is aware of the test results, since she probably has a tendency to overestimate to make her symptoms match the allergy just discovered. If the questions are given before the test, the patients might underestimate since gold is considered a safe metal. It is also important to have a control group with gold-negative patients. When the questionnaire is answered before the results of the patch tests are known, a control group is automatically obtained. Only if the frequency of patients who experience symptoms from gold contact is higher in the gold-positive group compared to the gold-negative one can the allergy be considered relevant. In the questionnaire study from Malmö (3) we found no difference be-

tween the groups in this respect (16.7% for the gold-positive compared to 15.9% for the gold-negative). On the other hand, Sabroe et al. (2) made a similar study and the corresponding figures in that study were 53.8% for the gold-positive group compared to 12.6% for the gold-negative group.

It is also important which questions are put to the patients. Usually, the patients are asked whether they ever had symptoms from gold contact, which means that it has not been taken into consideration whether the relevance is current or past. Furthermore, there has been no possibility to check carat and other metals in the gold alloy which has induced a contact dermatitis.

To consider a contact allergy clinically relevant, exposure to the sensitizer and a dermatitis that is understandable with regard to the exposure have to be demonstrated (10). Most people are exposed to metallic gold through jewelry and/or dental gold but it is not known how the patients are sensitized.

Sensitization by metals starts with a corrosion process and the formation of soluble metal ions (11). Brown et al. (12) found that metallic gold is soluble in a wide range of aqueous amino acid solutions and might thus be slowly soluble in sweat. They also found measurable amounts of gold in skin samples from ring fingers. In earlobe contact dermatitis due to gold, scanning electron microscopy and x-ray microanalysis have shown small dense fragments containing gold (13). On the other hand, simple salt solutions ("artificial sweat") appear insufficient to ionize metallic gold (11, 14).

A higher frequency of contact allergy to gold has been demonstrated among patients with pierced earlobes compared to those without, suggesting that pierced ears are a risk factor for gold sensitization (2, 15). It has also been shown that the earlobes constitute an eczema site overrepresented in patients positive to GSTS (3).

Although the previous patch test was positive in all cases included in the study, in the present study the patch test was negative in 10 cases. This can be explained by the fact that in all these cases the 5% patch was excluded, and in 2 cases also the 1.6% patch, because of previously intense reactions. Also, these patients were tested this 2nd time on the arm, while the original test had been applied on the back (16). Furthermore, water seems to be less efficient as a vehicle when testing with GSTS (1). Studies on NiSO_4 have shown that patch test reactivity changes over time and that patients with positive patch tests can even have negative test reactions when retested (17).

During the last decade around 1000 patients have tested positively to gold at our department.

For many hypersensitive patients, no clinical relevance has been found; i.e., they have, for example, been able to wear gold jewelry such as earrings and rings without getting skin problems. Many hypersensitive patients have been provoked with their own gold jewelry and in those reacting the reaction has usually come after days or weeks of exposure, in contrast to the corresponding situation with provocation with nickel jewelry in nickel-hypersensitive patients, which results in contact dermatitis within a few days. Because of this background, a study design with 60 gold-hypersensitive patients exposed during 2 months was considered necessary to enable a statistically significant overrepresentation of local and distant skin reactions in those wearing gold earrings. To distinguish between allergenicity and irritancy as the cause of the overrepresentation, a control group with patients without gold allergy was necessary. Such a group was not enrolled for management reasons and mainly because of the significance of the interpretations available without a control group. As the titanium and gold earrings were exactly the same except for the additional gold surface, this means that any overrepresentation of reactions in those patients exposed to the gold earrings would be due to the release of gold ions. The induction of an irritant contact dermatitis due to gold release from gold earrings would have been even more surprising than the elicitation of an allergic contact dermatitis. In the study protocol we also decided to register distant skin reactions as such can be induced by systemic provocation of gold-positive patients (18), and also elicited by cutaneous absorption of a contact allergen (19, 20). Expectedly, local and distant skin reactions were registered in a small number of patients. Nevertheless, this prospective double-blind study showed a statistically significant overrepresentation of skin reactions in the group wearing gold earrings; a significant overrepresentation remaining when excluding transient reactions shorter than 1 week. When looking at earlobe dermatitis and distant reactions separately, there were numerically more, but not statistically significant, patients reacting in the group wearing gold earrings. Excluding the transient earlobe reactions, the *p*-value almost reached significance. Surprisingly, the patients who experienced a flare-up at other body sites did not have a simultaneous dermatitis on the earlobes, which might have been expected. Currently, we do not have any explanation for this discrepancy.

As previously mentioned, the reactions noted in the present study were weak and a possible explanation for this could be that we, to exclude influence from other metals, used 24-carat gold. Brown et al. (12) showed that the higher the copper con-

tent in the alloy, the more gold dissolves, which means that lower carat gold will probably give rise to more intense skin reactions in patients with contact dermatitis from gold. The fact that the earrings were new could also be significant since it may take some time for the corrosion process to start. In spite of the quite long study period it is also possible that even 2 months was too short (21). In most cases, the symptoms on the earlobes disappeared during the study despite the fact that the patients continued wearing the earrings. A possible explanation for this could be that the ions dissolved from the gold metal were so few that they were under the threshold of eliciting dermatitis in the gold-positive women. During some periods, e.g. because of increased sweating or special weather conditions, an increased amount of ions may be dissolved provoking the dermatitis. Furthermore, the patients were allowed, if they wanted, to take the earrings off during night. Another explanation for the disappearance of the dermatitis could be that, when the symptoms appeared, the patients stopped wearing the earrings when sleeping.

As previously mentioned, $1/2$ the patients were allergic to nickel sulfate. This figure is quite high but it has to be remembered that the patient material is highly selected because of the inclusion criterion of pierced earlobes (22). As mentioned above, the nickel content was extremely low in the materials used in the study. Furthermore, the frequency of patients allergic to nickel was not significantly different among the patients who reacted compared to those who did not, which ascertains that nickel allergy did not influence the result. Theoretically, irritancy from gold metal is a possible explanation for the contact dermatitis induced in the study. However, in the group that had received gold earrings there was no difference in the frequency of patients with a history of present or previous atopic dermatitis among those who reacted and those who did not.

It might be objected that patients interested in participating in our study were those with a clear history of gold hypersensitivity or those without any skin problems from gold contact. We studied this possible bias by interviewing a group of women with gold allergy and pierced earlobes but not taking part in the provocation study. Here, however, there was a similar rate of gold hypersensitivity by history.

In conclusion, this prospective randomized and controlled study showed a numerical, though statistically non-significant, overrepresentation of local skin reactions in gold-positive patients wearing gold earrings compared to those wearing titanium. However, together with the distant reactions, there

was a statistically significant overrepresentation of skin reactions in the patients wearing gold earrings. Furthermore, an overrepresentation was noted in the group of patients with a history of gold sensitivity. With these facts, it is hard to exclude that exposure to gold jewelry can be clinically relevant in persons hypersensitive to gold.

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