

## ORIGINAL ARTICLE

# Septic and Aseptic Complications of Corticosteroid Injections

An Assessment of 278 Cases Reviewed by Expert Commissions and Mediation Boards From 2005 to 2009

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## SUMMARY

**Background:** Local corticosteroid injections can have serious septic and aseptic complications.

**Methods:** From 2005 to 2009, medical expert committees and mediation boards reviewed 1528 cases of alleged treatment errors relating to injections.

**Results:** 278 cases were identified in which complications arose after local glucocorticosteroid injections. The injections were intra-articular, paravertebral, intramuscular, and at other sites. In 39.6% of cases, treatment errors or patient information errors of the following types were found: aseptic technique was not maintained, injections were performed in the absence of an indication, time intervals between injections were too short, excessive doses were administered, infections were not diagnosed, erroneous injections were performed, patients were not informed of the risks, and there were errors of organization and documentation.

**Conclusions:** Injections of glucocorticosteroids must be performed in strict adherence to the manufacturer's instructions with respect to the composition of the solution to be injected, the quantity per injection, and the intervals between injections. Repeated injections with too little time between them raise the risk of infection. Physicians should pay more attention to this fact, particularly when deciding on the indication for paravertebral injections. Aseptic technique should be strictly maintained. The indication for the injection should be clearly documented. When glucocorticosteroids are injected into small joints and tendon spaces, the introduction of crystals into the subcutaneous tissue and adipose tissue should be avoided. The intramuscular administration of depot glucocorticosteroids should be avoided. Patients should be informed of the risk of infection and/or tissue atrophy, as well as of alternative forms of treatment.

### ► Cite this as:

Holland C, Jaeger L, Smentkowski U, Weber B, Otto C: Septic and aseptic complications of corticosteroid injections: an assessment of 278 cases reviewed by expert commissions and mediation boards from 2005 to 2009. *Dtsch Arztebl Int* 2012; 109(24): 425–30. DOI: 10.3238/arztebl.2012.0425

Parenterally administered corticosteroids are used both for systemic treatment (by the intravenous or intramuscular route) and for local treatment (by infiltration or intra-articular injection). They are typically obtainable either in aqueous solution or in crystalloid suspension. These types of preparation are said to confer a longer-lasting effect (a “depot effect”).

Ever since the historical beginnings of local treatment by injection, complications have been recognized, including, for example, joint empyema (1, e1) and abscess formation. Sepsis is a not uncommon sequela of such complications; even death is a possible result. The local administration of steroids in the spine can be complicated by weakness of variable severity, ranging all the way to paraplegia.

Aseptic soft-tissue damage or infection that arises in association with, or in the aftermath of, corticosteroid injections can vary in severity from a small, slightly discolored indentation in the skin over an area of soft-tissue attenuation to extensive necrosis of multiple layers of soft tissue.

In this article, we discuss corticosteroid-related infection and aseptic tissue atrophy but omit any discussion of bony necrosis after intramuscular or intra-articular injection (2, 3, e2, e3). Other types of complication that are beyond the scope of this article include tendon rupture after corticosteroid infiltration (4, e4; a complication that has been recognized for many years), systemic side effects (5), very rare cases of secondary adrenal insufficiency (6), and injection-related Tachon syndrome (7).

## Methods

The expert commissions and mediation boards of the medical associations of all states in the Federal Republic of Germany (hereinafter called the “expert panels”) evaluated a total of 36 575 medicolegal cases from 2005 to 2009 (Table 1). 1528 cases involved complications of injections, of which 278 were found to have been local injections of corticosteroids. In these 278 cases, there were 223 instances of infection and 55 of aseptic tissue damage.

The expert panels enter their findings into a nationwide database called MERS (Medical Error Reporting System) using criteria that are uniform across Germany. Even though the selective data contained in MERS cannot be extrapolated to yield an estimate of the total number of

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**TABLE 1**

**Cases of infection or tissue atrophy after local corticosteroid injection that were reviewed by the expert committees for medical malpractice claims and mediation boards across Germany from 2005 to 2009, as documented in MERS**

Time period: 1 January 2005 to 31 December 2009	Number of cases	Percentage	Number of cases in which a treatment error was found <sup>2</sup>	Treatment error yield (as a percentage of column 2)	Findings of lack of informed consent <sup>3</sup> (as a percentage of column 2)
Total number of cases <sup>1</sup>	36 575	100.0	10 375	28.4	251 (0.7)
Cases involving injections	1528	100.0	317	20.7	43 (2.8)
Cases with local corticosteroid injection	278	18.2	101	36.3	9 (3.2)
Infection as a complication:	223	14.6	73	32.7	5 (1.8)
– intra-articular	94	6.2	32	34.0	2 (2.1)
– paravertebral	43	2.8	10	23.3	1 (2.3)
– intramuscular	29	1.9	10	34.5	2 (6.9)
– other locations	57	3.7	21	36.8	–
Tissue atrophy as a complication:	55	3.6	28	50.9	4 (7.3)
– intramuscular, as a depot, mainly for allergy	28	1.8	20	71.4	1 (3.6)
– epicondylopathy	15	1.0	4	26.6	1 (6.7)
– trochanteric bursitis	4	0.3	–	–	2 (50.0)
– small joints	3	0.2	2	66.7	–
– other sites	5	0.3	2	40.0	–

<sup>1</sup>cases = medicolegal evaluations of the expert panels; <sup>2</sup>treatment errors relating to injection that were found to have occurred; <sup>3</sup>proper treatment according to the manufacturer's information, but failure to inform the patient of the risks of injection before the procedure; MERS, Medical Error Reporting System

injection-related adverse events that occur in Germany every year, they are certainly a good source of information on the cortisone injection-related complications and avoidable treatment errors.

In addition, we searched the literature for articles containing the terms “cortisone,” “injection,” and “infection” and looked for reports of the frequency of complications. This search also revealed further information about the efficacy of certain therapeutic procedures.

**Alleged treatment errors**

The expert panels evaluated patients’ allegations of treatment errors of the following types:

- inadequate diagnostic evaluation prior to injection
- faulty injection (in particular, inadequate aseptic technique)
- use of the wrong medication
- overtreatment
- failure to inform the patient of potential complications and non-invasive therapeutic alternatives
- delayed recognition of infection after injection.

**Case illustrations**

**Case 1: multiple abscesses after paravertebral injections**

A 74-year-old woman was treated in a neurosurgical group practice for “back pain radiating to the posterior aspect of the legs and cramps in the feet.” Nothing further about the patient’s history was documented. A computed tomogram (CT) of the lumbar spine that had been obtained nine years earlier was interpreted as showing “marked changes in the spinal joints.”

The patient was treated with a total of three “sacral blocks” in the space of four days. Five weeks later, because of “recurrent lumbar spinal pain,” she underwent four further paravertebral injections in the space of eight days. These injections were designated as “L3–S1 blocks.”

Only one physical examination was documented in the entire course of her treatment: “Lumbar spine stiff in fixed posture, no weakness, reflexes symmetric, sensation OK.”

All injections included both a local anesthetic and a corticosteroid. The physicians were later unable to say precisely what quantity was injected (probably a total of 240 mg of triamcinolone) or whether a fresh needle was used to inject the second side in each treatment. Patient information was documented by a standardized form.

Two days after the last injection, the patient was admitted to the hospital via the emergency room and remained hospitalized for four weeks. She underwent three operations for the treatment of abscesses in the paraspinal musculature, in a psoas muscle, and inside the spinal canal. The causative organism was identified as *Staphylococcus aureus*. The patient was paraparetic; her weakness resolved slowly during the period of inpatient rehabilitation that followed.

The main treatment error was judged to have been that too much corticosteroid was injected at too short intervals, elevating the risk of infection. A reprimand was issued because of the absence of documentation of the patient’s history and the failure to mention alternative treatments that clearly would have been feasible options in this case.

**Case 2: extensive necrosis after intragluteal injection for back pain**

An obese 49-year-old woman who was said to be suffering from a “chronic, recurrent spinal syndrome” received multiple intragluteal injections of 4 mg of dexamethasone dihydrogen phosphate, 4 mg of dexamethasone, and diclofenac. About six weeks after the last injection of one of these substances, she required surgery for the removal of 500 g of necrotic skin and subcutaneous fat from the buttock. An infection that arose at the resection site necessitated multiple further hospitalizations.

The expert panel determined that there were two treatment errors: injection into adipose tissue, rather than into the deeper-lying musculature (*prima facie* evidence, see *Box*), and the repeated parenteral application of the substances, instead of a switch to oral administration.

**Findings**

The distribution of complications (infections and aseptic tissue damage) by site of application, in both absolute numbers and percentages, is shown in *Table 1*.

Roughly half of the 55 cases of tissue atrophy after corticosteroid injections involved intramuscular depot injections, mainly for the treatment of allergy. Treatment errors were especially common in this situation.

The type and dose of the corticosteroid used could not always be ascertained from the medical record, as they were sometimes not documented. As far as can be determined, the most commonly used corticosteroid was triamcinolone.

The expert panels’ explanations for the individual treatment errors that they judged to have occurred, as documented in the MERS database, are shown for the infectious cases in *Table 2* and for the cases of aseptic tissue damage in *Table 3*. The most common errors were:

- delayed recognition of infection (24 cases)
- lack of indication (19 cases)
- faulty aseptic technique (18 cases)
- too superficial gluteal injection (14 cases)
- injection at too short intervals (14 cases).

Patients were found to have been inadequately informed of the risks of treatment in 20 cases; in nine of these cases, the treatment was judged to have been properly conducted in other respects. Whenever legally valid informed consent is lacking, the physician is liable for all adverse effects of the injection on the patient’s health.

**Discussion**

The injection of corticosteroids into inflamed joints is a method of treatment that has been used with good effect for decades (e5–e7). Unfortunately, it can also be complicated by intra-articular infection, sometimes leading to severe sepsis. Another complication that has been known and feared for decades is abscess formation after intramuscular injection; necrotizing fasciitis is a severe variant of this problem (8, e8). The reported frequencies of joint infection after intra-articular injection range from 1 in 3000 to 1 in 100 000 (9, e2, e6, e9–e12). Faulty aseptic technique at the time of injection is thought to be the main cause. Expert panels generally consider infection to be no more than the random expression of a small risk inherent

**TABLE 2**

**Treatment errors that were determined to have occurred in cases of infection after corticosteroid injection**

Time period: 1.1.2005 – 31.12.2009	Errors found
Treatment errors in corticosteroid injection leading to infection	73
Individual types of error that were found (may be multiple*):	
Missed infection	24
Faulty aseptic technique	18
Lack of indication	13
Injections in too rapid succession	9
Impermissible drug combination	5
Injection of excessive dose of drug	4
Faulty injection	3
Lack of documentation	2
Inadequate organization	2
Faulty documentation	2
Failure to inform patient of risks	12
– with proper treatment in other respects	5

\* up to 2 errors per physician

to the procedure if it is found to have occurred despite proper aseptic precautions. In such cases, infection is thought to be due to pathogenic organisms that were present in deeper-lying parts of the skin not accessible to aseptic disinfection (9, e1, e13).

It has likewise been known for at least 50 years that locally injected corticosteroids can damage the skin (10–12, e14–e18). Moreover, corticosteroid-related soft-tissue damage has been reported in the eye (e19), the hairy scalp (e20), the mandible, and the sole of the foot (e21). Soft-tissue damage can also be a complication of injections into tendon spaces (12) and of injections that were intended to be intra-articular (e22).

Most of these individual case reports involved mild, primarily cosmetic complications. Some involved more extensive ones taking the form of embolia cutis medicamentosa (e23) or even very extensive and severe tissue necrosis in Nicolau syndrome (13, e24–e28).

The locally injected drug is usually a combination of a local anesthetic with a corticosteroid; intramuscular injections are usually of a corticosteroid alone, or else of a corticosteroid combined with an analgesic (by intragluteal injection, as described in Case 2, above). Intra-articular corticosteroid injections are usually performed without any other admixed drugs, or else after local anesthetization of the needle trajectory. Sometimes the corticosteroid is given in combination with a so-called cartilage-production promoter.

The most common applications of corticosteroids other than in the joints (which we will designate as “injections into the soft tissues”) are infiltrations of

**TABLE 3**

**Treatment errors that were determined to have occurred in cases of tissue atrophy after corticosteroid injection**

Time period: 1.1.2005 – 31.12.2009	Errors found
<b>Treatment errors in local corticosteroid injection leading to tissue atrophy</b>	<b>n = 28</b>
Individual types of error that were found (may be multiple*):	
Gluteal injection too superficial	14
Lack of indication	6
Injections in too rapid succession	5
Injection of excessive dose	4
Faulty injection	1
Organizational error (injection on demand without medical evaluation)	1
Lack of documentation	1
Failure to inform patient of risks	8
– with proper treatment in other respects	4

\* up to 2 errors per physician

- muscle, tendon, and ligament origins and attachments
- synovial tissue and tendon spaces
- the carpal tunnel
- mucosa-lined pouches (bursae), particularly subacromial bursae (in rotator-cuff defects—which are more common from age 50 years onward—subacromial infiltration inevitably becomes intraarticular injection) and trochanteric bursae.

Such injections are always performed to treat a presumed state of inflammation that is diagnosed on the basis of the patient’s symptoms and physical findings. Examples include humeral epicondylopathy, de Quervain’s tendovaginitis, and achilodynia involving the synovial tissue.

Paravertebral infiltrations and injections are very common as well. They are generally performed in the vicinity of nerve roots. Facet infiltration is also a type of nerve-root infiltration, as it is intended to block the posterior branch that emerges directly from the spinal nerve (14, 15, e29–e31). Injections performed without image guidance are often soft-tissue infiltrations rather than nerve-root infiltrations. Infection after paravertebral injections is a less widely known complication than infections at other sites, even though it can have very severe consequences.

Superficial atrophy of skin and adipose tissue, with central discoloration of the skin, is attributed to a combination of the following factors:

- an inhibitory effect on fibroblasts that lowers protein synthesis;
- blockage of lymphatic pathways;
- displacement of tissue fluid.

In about half of all cases (as far as can be determined from an overview of case reports), the affected area returns to normal over a few months to years. The duration of this process seems to be a function of the cortisone dose.

It has been pointed out time and again—and rightly so!—that all patients should be informed in advance of this potential complication.

Nicolau syndrome is a rare entity that has been observed as a complication of the types of treatments that we have been discussing. It is caused by acute arterial thrombosis or spasm upon the intravascular injection of an insoluble drug, leading to ischemic soft-tissue damage in the distribution of the vessel in question. Severe pain and livid discoloration of the skin usually arise right after the injection. Nicolau syndrome can cause small central or more extensive necrosis, nerve damage, compartment syndrome, and gangrene. Corticosteroid injections without any other precipitating cause account for only a small minority of the reported cases. Superficial infiltration can cause more extensive damage (embolia cutis medicamentosa).

**Overview**

A thorough discussion of the pharmacological properties of the various types of glucocorticosteroid would be beyond the scope of this article. For more information on the half-life, crystal size, parenteral effects, and threshold doses of each type of corticosteroid, as well as the recommended temporal intervals between repeated injections at a single site, the reader is referred to the specialized literature (16) and to manufacturer-supplied information.

Overtreatment is certainly a problem in German medicine in general, particularly with respect to invasive treatments (17, e48). Many such treatments have turned out not to meet the high expectations originally placed on them when their effects were later subjected to careful study, e.g., in Cochrane Reviews (18–22, e32–e36). Clearly, some patients are being endangered where there is no justification for doing so.

The diagnosis of “facet syndrome,” for example, is often assigned in cases of nonspecific, chronic back pain, an entity whose proper treatment certainly does not involve serial injections (17, 23, e22, e46). As stated in the statistical report of the German Institute for Hospital Reimbursement (*Institut für das Entgeltsystem im Krankenhaus*) for the year 2010, “[...] interventional treatments for pain are carried out about ten times more often in Germany than in other countries, even though their lasting efficacy has not been demonstrated and despite the considerable danger of long-term patient dependency.”

Infection after corticosteroid injections is relatively common; there would be far fewer severe complications and complications overall if injections were performed only when strictly indicated.

The following conclusions can be drawn from the material provided by the expert panels:

Intra-articular corticosteroid injections should come into consideration only when there is a diagnosis of an “inflammatory state in a joint,” i.e., activated arthrosis with

## BOX

**Prima facie evidence**

According to German law, the burden of proof in cases of alleged treatment error is on the complainant. The complainant bears a lesser burden of proof if the events in the case have followed a typical course, and particularly if causality is supported by *prima facie* evidence. This type of evidence also plays an important role in medical malpractice law. It is defined as follows: If, after all the individual circumstances and special features of the case at hand have been duly considered, the course of events is determined in the light of experience to have been a typical one for the fact that was to be established, then this fact can be considered to be established (BGHZ 143, 268, 281).

Thus, for example, it is known that corticosteroid injections in too rapid succession can promote the development of infection and/or frequently lead to local aseptic tissue damage. Such events are so common that tissue damage after injections performed in rapid succession is considered to have been caused by these injections, without the need for any further evidence.

This conclusion is even more certain with respect to gluteal injections at an inadequate depth (as in Case 2), which often cause a typical pattern of necrosis in the skin and subcutaneous fat of the buttock (indentation as a result of soft tissue atrophy).

A common objection to the use of *prima facie* evidence in medical malpractice cases is that each patient's case has individual features that are not characteristic of patients in general. Experience shows, however, that typical courses of events do, in fact, exist and are encountered at high frequency.

It is important to realize that the concept of *prima facie* evidence does not simply remove the burden of proof from the patient and place it on the physician instead. Rather, the physician can bring a valid argument against *prima facie* evidence by asserting and proving facts that establish a substantial probability that the events in the case actually took a different, atypical course.

In Case 2, for example, the physician might be able to assert and prove that the needle used for injection actually was not too short. If the physician succeeds in establishing this, then the *prima facie* evidence has been refuted.

swelling and effusion. The quantity and formulation of the drug should be chosen in relation to the size of the joint, and the manufacturer's instructions should be strictly followed. Moreover, repeated injections should be performed only after an adequate interval, and the total quantity injected in one year should not exceed the allowable limit.

The relevant guidelines (AWMF Guideline Registry 029/006: Intraartikuläre Punktion und Injektionen [Intra-Articular Punctures and Injections] [24, e37–e39]) state that aseptic technique should be used. This implies, among other things, that the physician must invariably have an assistant when performing joint punctures and injections or paravertebral infiltrations (e40). Furthermore, expert panels generally cannot assess the methods that physicians claim to have employed to ensure asepsis, because the panels are not judicial bodies and cannot examine witnesses. Thus, panels must proceed from the assumption that the injection was performed in adherence to the specifications for standard aseptic technique, without any violation. Statements to the contrary by the complainant cannot be used as the basis for the panel's judgment. In any case, there should be standardized specifications for aseptic technique and instructions for treatment personnel in any institution or practice where such treatments are performed.

Missed infections (e41, e42) were judged several times to have been treatment errors (Table 2). On the slightest suspicion of infection after an injection, the appropriate diagnostic tests should be ordered at once (laboratory tests, ultrasonography, magnetic resonance imaging) and the patient should be followed up at short intervals, or, if

necessary, hospitalized. Joint fluid obtained by puncture should be sent for bacteriological testing on the slightest suspicion of an intra-articular infection.

The indication for treatment should always be documented in the medical record in such a way that it can be critically evaluated by others. Corticosteroids should be used for facet injections only when a prior test injection of local anesthetic has led to clear improvement. As the manufacturers' instructions point out, repeated injections at short intervals should be strenuously avoided.

The intramuscular injection of depot corticosteroids is held to be contraindicated because of the risk of characteristic adverse effects due to suppression of the hypothalamic-pituitary-adrenocortical axis. This mode of corticosteroid administration was designated as obsolete many years ago (e43–e47). Even though the "Red List" in Germany still permits the intramuscular administration of depot corticosteroids for certain indications (according to information from a small number of manufacturers), the physician can nonetheless be held liable for any complications that arise, as it is the long-established judgment of general medical opinion that such treatments should not be performed.

In all cases of extensive tissue necrosis, particularly in the buttocks, it can be assumed that the injection failed to reach the musculature because the needle used for it was too short. According to the juridical principles of *prima facie* evidence (Box), this can substantiate the determination that a treatment error has occurred.

Superficial tissue atrophy is likewise caused, in most cases, by crystal deposition outside the intended target of

injection, and less commonly by partial backward flow of the injected fluid. If the corticosteroid is mixed with local anesthetic and the injection is begun as soon as the needle perforates the skin in order to diminish the pain of the procedure, partial deposition of crystals in subcutaneous tissue is inevitable. It is, therefore, safer to infiltrate the needle trajectory with pure local anesthetic first, and only then to inject the corticosteroid.

All injections carry a risk of side effects of the injected drug as well as other risks related to the injection *per se* (infection, vascular injury, nerve injury). To assure patient safety, the indication for the injection should always be critically assessed, and the patient should be fully informed about all risks and therapeutic alternatives (e.g., oral corticosteroid administration instead of depot injection) (25).

Physicians should decline to perform any injection that is not medically indicated, even if the patient requests it. Whenever a proper indication is lacking, the physician can be held liable for any complications that arise.

**KEY MESSAGES**

- Perform intra-articular injections only for arthritis with signs of aseptic inflammation
- Double-check indications, document informed consent
- Adjust the corticosteroid dose and formulation to the joint that is to be treated
- Do not space injections too closely in time
- Use strict aseptic technique, in conformity with guidelines
- On the slightest suspicion of infection, take action at once
- Avoid injections into subcutaneous tissue and fat
- No depot injections

**Conflict of interest statement**

Mr. Smentkowski has received lecture honoraria and reimbursement of travel expenses from Bayer AG. Prof. Holland, Mr. Jaeger, Dr. Weber, and Dr. Otto declare that they have no conflict of interest.

Manuscript received on 1 September 2011, revised version accepted on 2 February 2012.

Translated from the original German by Ethan Taub, M.D.

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[www.aerzteblatt-international.de/ref2412](http://www.aerzteblatt-international.de/ref2412)

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