Antisepsis and genital hygiene in scrotal surgery: liability claims in the event of treatment errors

Abstract

Systematic observance of infection control principles in surgery, whether conducted on an inpatient or outpatient basis, is an indispensable precondition for quality management. In Germany, the introduction of the Protection against Infection Act (IfSG) on 1 January 2001 represented a milestone for regulation of the framework conditions in outpatient surgery. Once again, infection control issues were the main focus of attention. Section 36(1) IfSG stipulates that infection control policies specify in-house procedures for infection prophylaxis in agreement with quality assurance measures. On 1 January 2004 this was further reinforced, inter alia, by means of a new tripartite contract based on Section 115b of Book 5 of the German Code of Social Law (SGB V). Since experience shows that incidents are more likely to result in liability claims the smaller the operation and the more unexpected the complications from a lay person’s perspective, surgery carried out on patients who spend the night before and after the operation outside the hospital or clinic is becoming a particularly liability-prone area.

In the event of a postoperative infection, often involving a protracted hospital stay and in some cases considerable permanent damage, the patient often cites an infection control error. This paper highlights by way of example some liability aspects whose observance as a matter of principle can reduce the liability risk for the physician.

Zusammenfassung

Die systematische Beachtung hygienischer Grundsätze ist in der Chirurgie, ob ambulant oder stationär, stets eine kardiale Voraussetzung des Qualitätsmanagements. Das Inkrafttreten der IfSG zum 01.01.2001 stellt einen Meilenstein zur Regulierung der Rahmenbedingungen beim ambulanten Operieren dar. Die Aufmerksamkeit wurde wieder,drücklich auf Hygienefragen gelenkt. § 36 IfSG (Abs.1) verpflichtet in Hygieneplänen innerbetriebliche Verfahrenweisen zur Infektionsprophylaxe mit der Vereinbarung von Qualitätssicherungsmassnahmen festzulegen. Zum 01.01.2004 wurden noch zusätzliche Akzente gesetzt u.a. durch den neuen dreiseitigen Vertrag nach § 115b SGB V. Da bei Zwischenfällen erfahrungsgemäß haftungsrechtliche Konsequenzen um so eher drohen, je kleiner der Eingriff und je unerwarteter die Komplikationen vom Laien eingeschätzt werden, entwickelt sich die Operation von Patienten, die die Nacht vor und nach dem Eingriff außerhalb des Krankenhauses oder einer Klinik verbringen, zu einem besonders haftungssträchtigen Gebiet.

Bei Auftreten einer postoperativen Infektion mit häufig langwierigem Krankheitsverlauf und unter Umständen erheblichem Dauerschaden schließt der betroffene Patient häufig auf einen Hygienefehler. Es werden Beispielhaft Haftungsgefahren aufgezeigt, deren grundsätzliche Beachtung zur Minderung des Haftungsrisikos für den Arzt beitragen kann.
Introduction

Systematic observance of infection control principles in surgery, whether conducted on an inpatient or outpatient basis, is an indispensable precondition for quality management. In Germany, the introduction of the Protection against Infection Act (IfSG) on 1 January 2001 represented a milestone for regulation of the framework conditions in outpatient surgery. Once again, infection control issues were the main focus of attention. Section 36(1) IfSG stipulates that infection control policies specify in-house procedures for infection prophylaxis in agreement with quality assurance measures. On 1 January 2004 this was further reinforced, inter alia, by means of a new 3-page contract based on Section 115b of Book 5 of the German Code of Social Law (SGB V). Since experience shows that incidents are more likely to result in liability claims the smaller the operation and the more unexpected the complications from a lay person’s perspective, surgery carried out on patients who spend the night before and after the operation outside the hospital or clinic is becoming a particularly liability-prone area. In the event of a postoperative infection, often involving a protracted hospital stay and in some cases considerable permanent damage, the patient often cites an infection control error. This paper highlights by way of example some liability aspects whose observance as a matter of principle can reduce the liability risk for the physician.

Case report

A 38-year-old patient underwent outpatient, bilateral vasectomy to suppress his procreative capacity. Following twofold scrotal skin disinfection with Octenisept® and bilateral local anesthesia of the scrotal attachment, a skin incision, of approx. 1 cm long, and resection of a short portion of each seminal duct were carried out. The respective stumps were tied, additionally folded over and sutured. The surgical wound was closed by means of single button sutures. According to the patient, who was able to follow the course of the procedure, it was only after a long search that it was possible to localize the right seminal duct. During the first postsurgical days, he developed painful swelling and hematomatic skin discoloration in this area. After 5 days by the latest, a clinically manifest, feverish wound infection was seen on the right side, involving the scrotal contents (ultrasonography showed: epididymitis, partially organized hematoma of the testis). After admission to hospital, abscess lancing was effected, and the patient was now given antibiotic treatment with ciprofloxacin 500 (2 x 1 tbl.). A few days later the infection had spread to the left scrotal contents. Here, too, abscess lancing had to be carried out – albeit against a background of a rapidly spreading infection in the space of a few hours. The patient was immediately transferred to a urology clinic CRP rise, pronounced leukocytosis, body temperature >38.5 °C, tachycardia, blood sugar 130 mg/dl. Due to phlegmonas in the region of the right inguinal area and necrotizing infection of the now massively swollen scrotum (Fournier’s gangrene) extensive wound revision was carried out for the seriously ill patient, with debridement of the entire bilateral soft tissue, resulting in an extensive penoscrotal skin defect and a loss of the right scrotal contents affected. The left testis could not be covered because of lack of scrotal skin and had to be implanted within the inguinal tissue. Bacteriological investigation revealed a mixed infection with Staphylococcus aureus, Enterococci and Bacteroides, without any specific resistance characteristics.

Discussion

The average rate of wound infections following vasectomy given in the literature is 3.5% [4]. The development of a genital gangrenous inflammation, first described as necrotizing fascitis by A. Fournier in 1883 (Lit. s. b. [7]) was repeatedly cited as the maximum form of infection following vasectomy [5]. In addition to concomitant diseases (comorbidity) acting as co-factors in triggering infection, such as diabetic metabolic disorders, alcoholism, poor genital hygiene may be seen in most cases. These factors contribute to the genesis and complications of infection. Lethality mediated by toxin-related, disseminated intravascular coagulopathy and septic multiorgan failure is more than 45%.

For infection prevention in scrotal surgery systematic observance of infection control principles is an indispensable precondition for quality management. Section 2(2) of the Infection Prevention Regulation (Infektionsverhütungsverordnung) [3] stipulates that before performing a procedure involving skin penetration the physician carrying such a procedure must disinfect the skin of the surgical area. Skin disinfection is intended as a means of killing, to the greatest extent possible, the microbes on the skin to prevent them from entering the wound, with the aim of assuring as aseptic as possible an operation wound. Skin disinfection mainly targets the patient’s own resident bacterial skin flora. Staphylococci are a particular problem. In view of the high colonization rates in the follicular-perifollicular scrotal skin area and their potential pathogenicity stringent requirements must be met when carrying out disinfection measures. These bacteria also colonize deeper skin layers. Inoculation of even a few colony-forming units can give rise to in some cases insidious, extremely dangerous, and in particular deeper and systematic infections. Staphylococci are among the most common pathogens implicated in postoperative wound infections and in soft tissues abscesses. In skin that is rich in sebaceous glands (e.g. perineum, intertriginous regions) the German Society of Hygiene and Microbiology (DGfM) stipulates that the skin area to be disinfected be kept permanently wetted with a suitable disinfectant for 10 minutes (continuous, direct
exposure). According to Para. 5 of the Infection Prevention Regulation only those disinfectants featured in the Disinfectants List and tested as per the Guidelines for Testing Chemical Disinfectants and deemed effective by the DGHM may be used. The main antiseptics used should preferably be products containing a high percentage of alcohols. Povidone-iodine compounds are a suitable option for patients undergoing surgery on an outpatient basis, because of the unpleasant irritant effects of alcohol-based products as experienced by patients who are not given a general anesthetic. The antiseptic should be applied with an impregnated swab to potentiate the effect mediated by the mechanical action. Anyone using agents and methods other than those listed, is acting in a negligent and illegal manner pursuant to Section 69(2) of Federal Epidemic Act (BSG) and to Section (6) of the Infection Control Regulation.

The disinfectant Octenisept® used in the present report for skin disinfection of the scrotal surgical area is intended, as stated on its label, for “aqueous mucosal and wound antiseptic.” No positive expert opinion has been issued to attest to this product’s efficacy for antisepsis of skin rich in sebaceous glands. Failure to comply with the disinfection regulations exposed the patient to an infection risk going beyond the limits of the inevitable. Postoperative wound infection calls for initiation of immediate antibacterial treatment at an early stage even if there is no confirmed evidence of staphylococci infection. In view of the risk of infection-mediated destruction of deeper vital structures (e.g. testes/epididymes) the antibiotic must be tailored to the bacteria posing a risk to the wound in the respective case! In the case of this “calculated” antibiotic therapy for wound infections of, in all probability, staphylococci etiology modern staphylococci antibiotics (not ciprofloxacin!) are used. In view of the enhanced therapeutic profile, immediate systemic combination treatment with at least two antibiotics with high anti-staphylococcal activity should take preference over monotherapy (with only one antibiotic), while making maximum use of the dosage spectrum. There is also the likelihood of a mixed flora, comprising enterococci, – the Enterococcus is a bacterium that is being increasingly implicated in complications, at least in postsurgical infections. The agents of choice are Inhibitor-protected penicillin plus gentamycin. Oxacillin-resistant staphylococci (MRSA) must be identified! In the case described, oral ciprofloxacin did not constitute adequate antibiotic early-stage treatment. Admittedly, purulent soft tissue infection cannot be managed with antibiotics alone. Rather, this area should be opened up on time, with if necessary resection of inflammation-destroyed tissue and placement of wound drainage at a sufficiently deep level to limit gangrene development [6]. Another case of similar infection following outpatient vasectomy which had to be reviewed in the context of liability law involved a perianal oozing fistula (= increased infection risk). This situation did not permit conductance of an aseptic procedure in its immediate vicinity. While the surgical area with heavy hair growth had been draped in a “sterile manner” with water-impermeable perforated adhesive film, the use of such self-adhesive film to protect against microbial import from the microbially colonized surrounding scrotal surgical area is not effective in the case of hairy skin and jeopardizes aseptic surgery. What was needed here was gentle removal of the genital hair at the operation site, including the suprapubic region, immediately before surgery in order to assure as far as possible the quality of scrotal skin disinfection, local draping and wound closure. Here we give preference to a meticulous shaving technique using a disposable razor (Dahlhausen) since it is difficult to manage a clipper machine here.

Preoperative hair removal was neglected in this present case; the reason for this omission was that “on the basis of numerous infection control investigations” it was well known “that shaving the operation site increased the infection rate and for that reason many surgical departments had dispensed with hair removal”. However, this is not at all true in the case of genital hair [1].

Not least in association with implanted suture material, especially where there is major tissue contusion and effusions, any shortcomings in skin disinfection can give rise to infection through imported, or persisting, microorganisms into the scrotal wound and operation site. Accordingly, the utmost care must be taken, particularly when working under unfavorable conditions, to ensure that postoperative wound infection is prevented not only by employing a particularly subtle surgical technique but also by taking stringent infection control measures.

Conclusion

An aseptic, gentle surgical technique is a prerequisite for reducing the risk of infection. This presupposes aseptic preparation of the operation site using a listed product. Proper disinfection of the skin in the intertriginous scrotal region, which has a high microbial load and is rich in sebaceous glands, must be immediately preceded by gentle hair removal for surgical/organizational reasons but also because otherwise it would not be possible from an anti-septic viewpoint to manage the high level of purulent cocci. Any other approaches are not adequate or suitable, and would pose a risk of wound and soft tissue infection, possibly necessitating surgical revision and a longer treatment period as well as posing a vital threat. From a legal viewpoint, the decisive criteria used when carrying out surgery must, on the one hand, be careful risk calculation and, on the other hand, a quality guarantee to the patient.
Curriculum Vitae

Univ. Prof. Dr. med. habil. Peter Brühl

Figure 1

Professor emeritus of Urology (Children Urology) at the Medicinal Faculty of the Bonn University and former Head of focal point Children Urology at the University Clinic Bonn.

It is almost impossible to introduce Professor Brühl shortly: so many functions, activities, more than 500 publications, co-operation for guidelines as well as many honours are demonstrating the life-long exceptional engagement but also the national and international credit Professor Brühl received.

Born in Göttingen he studied medicine in Bonn and Vienna. He started his career in the federal state of Saarland and changed to the Surgical University Clinic and the Policlinic for Urology in Bonn in 1966. Not only is he a specialist for urology but also for medical microbiology and infection epidemiology. He started out first with his state doctorate in clinical bacteriology but then became professor for Urology and Medicinal Microbiology first in the federal state of Saarland then in Bonn. There he received a call for professorship by urology (children urology) in 1984 and became emeritus in 1997 from where he moved into a definite “restless retirement”: he is committed to the university by a lecturer’s appointment (“urological infections” and “children urology”) until 2007 – besides many, many other activities.

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