

Clinical experience in the treatment and prevention of vascular graft infection: the use of antimicrobial properties of silver compounds in vascular surgery

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The prevention and treatment of infection in conventional vascular surgery, or after endovascular procedures.

An infectious process complicating conventional implant surgery can occur early in the postoperative period or much later⁽¹⁾ (several years later). Can it be said that the same assertion is true in the field of endovascular procedures results? The answer is undoubtedly the same though less forcefully so, due to a lower number of observations collected for procedures involving the abdominal and peripheral aortic trunks⁽¹⁾.

The rate of occurrence varies, depending on the series, but can be estimated at between 0.5 and 3.5 % especially in the case of prosthetic replacements and is more frequent in the case of superficial or extra anatomic bypasses^(2,3). On the other hand, it occurs extremely rarely in the case of endovascular surgery^(4,5) (metallic stenting) but recently an infection rate has been found of 0.3 % out of 1,807 patients with a severe prognosis in relation to the use of closure devices for femoral puncture points⁽⁶⁾. One must however take into account the overall statistics, which show a 6.8 % incidence of sepsis following punctures for angiography and percutaneous therapeutic procedures. The level of infectious complications following endoprosthetic implants for abdominal aortic aneurysms also remains extremely low.

The principal bacteriological organisms responsible are the staphylococci (*Aureus*, *Epidermidis*) and gram-negative organisms *Pseudomonas* rather than some other anecdotal organisms. Staphylococcal infection alone of the methicillin resistance type (MRSA) appears to be responsible for 50 % of the mortality and amputations in one audit⁽⁷⁾ undertaken in the UK and involving 75 cases of clear-cut complex infections and infected vascular grafts (Grade II and III according to Szylagyi).

The severity of this complication makes it the most dangerous of all in the field of vascular surgery and in particular, in reconstructive aortic surgery, where its treatment can give rise to a mortality rate of 35 to 40 %. At the sub-inguinal level, the risk of amputation is prohibitive and can spoil 50 % of attempts at limb salvage. One must not however underestimate the unfavourable prognosis for the treatment of infections after endovascular procedures.

Predisposing risk factors are far from being

uncommon in the vascular patient cohort : diabetes, the possible presence of cutaneous ischaemic lesions, renal failure, the characteristic affinity of the non-organic prosthesis/organism, which is even more marked in haemodialysed patients, in the case of repeated invasive exploratory angiography, in primary surgery carried out as an emergency (for example a ruptured abdominal aortic aneurysm - AAA).

The widely known severity, given the prognosis of an infectious complication, goes hand in hand with the persistent uncertainty regarding traditional treatment options and their outcome.

Likewise, should we not consider in terms of prevention, the value of specific methods at the time of first revascularisation attempt? (routine antibiotic cover and its type, implants of certain antimicrobial prostheses or others sensitised as a result of a specific peroperative soaking).

The confirmation of the diagnosis:

This can take between a few days and decades after conventional vascular surgery and possibly, though very rarely, reported over the same time interval for an endovascular procedure.

The infection presents often with mistaken aspects suggestive of a general infectious syndrome from the past history: an inguinal fistula, a feared characteristic, a lymphocoele collection, an isolated haemorrhage, a dehiscence or false anastomotic aneurysm in the femoro-popliteal or leg region. With regard to extra anatomic revascularisation, seromas with an infected appearance with segmentational or overall peri-prosthetic detachment are worthy of note (bacterial biofilm supported by coagulase negative staphylococci) .

Confirmation and extension assessment:

This requires bacteriological assessment by means of direct sampling or punctures controlled by

ultrasound imagery, characteristic observations seen on tomodensitometry or MRI and doubts aroused by scintigraphy using labelled leucocytes. In terms of the assessment, there can be a tendency to try and arrange things in a too theoretical manner – the complication according to its degree of severity in grade I (no invasion in the direction of the subcutaneous tissue), in grade II (infectious extension to the subcutaneous tissue, but no theoretical involvement of the revascularisation pathway) and grade III (clear cut involvement of the graft).

Therapeutic strategies:

As we have already mentioned, these are divided between:

1 - The conservative approach with few indications (including local treatment – dressing and the debridement of lesions followed by prolonged irrigation with antiseptic solutions and/or targeted antibiotics – followed by myoplasty or a covering epiploplasty); on purely focal lesions and unlikely to harbour extensive infection. It is associated with a low mortality (5 to 8 %) and with an infectious recurrence rate of about 15 to 20 %.

2 - A palliative option combining a segmental ablation of the primary revascularisation material and an attempt at an extra anatomic revascularisation. This therapeutic solution does not appear to find favour within the vascular community as none have suggested it.

3 - Radical treatment calling for a total ablation of the material (generally prosthetic) combined with a complete attempt at revascularisation. The latter brings together two possibilities:

Either the ablation of aortic or aorto-femoral material, purely and simply leading to an extra anatomic revascularisation (axillo-femoral bypass, or from the thoracic aorta in the direction of the distally peripheral and supposedly healthy regions for example and preferably in two successive surgical interventions). This method has numerous supporters with results involving 60 patients (50 of whom had prosthetic infections), treated by the Portland/USA team⁽¹⁸⁾ with a favourable perioperative overall mortality of 13 %, a survival percentage rate of 67 % and 47 % at 2 years and 5 years as well as 93 % and 82 % limb salvage over the same time scale. Other authors consider that the risk of a secondary rupture of the aortic stump is not negligible however (between 8 and 10 %) and the coefficient of reinfection is between 15 and 20 %.

Or as a single intervention, the ablation of the infected material combined with an *in-situ* revascularisation with various techniques using:

- Occasionally an autogenic material⁽⁹⁾ and this will usually be at the aortic level, using the superficial femoral veins than the remaining arterial sectors of the patient. This technique of using the deep veins was reported by Clagget⁽¹⁰⁾ since then other authors around the world appear to have achieved satisfactory results even for some of them in cases of infection due to pseudomonas. However, an approximate mortality of 25 % was found in the most significant series whilst the neighbouring amputation percentage of 20 % is far from being negligible.

- Sometimes a cryopreserved arterial homograft rather than a fresh one will follow the removal of the infected material both at the aortic level as well as peripherally. The return to favour of this technique (initially conceived in the 1950s for first-line revascularisations, but abandoned at the onset of the 1960s following degradation) dates from the end of the 1980s with the improvement in conservation methods and under the impetus of the Parisian team of E.Kieffer⁽¹¹⁾ (Pages 165-176). In an initial series of 109 operations between 1988 and 1996, the postoperative mortality was 25 %. At the present time, a review of the literature reveals similar figures and appears to be in favour by some interim homograft implantation teams in the aortic position without considering whether the risks support a re-explantation in survivors for the insertion of a conventional neoprosthesis. One should also stress the immunological factors responsible for failures with this type of replacement by homograft⁽¹¹⁾. One can however support the method of cryopreservation of arterial or venous homografts of many limb salvages in the presence of thrombosed or infected peripheral bypasses.

- Sometimes the replacement *in-situ* is undertaken using a new prosthesis. From the start of the 1980s, the possibility of using a prosthetic material pre-treated during its manufacture has been proposed, or more commonly directly by soaking preoperatively in an antibiotic solution^(12,13). In the second instance, it is Rifampicin which appears to be the most often cited and used both in the most recent experimental

Studies of the French team, which is the most involved in this therapeutic approach⁽¹³⁾ as in clinical practice where however certain recommendations raise doubts as to its use. Its fixation to prostheses, which are currently the most commonly implanted and impregnated with collagen or gelatine⁽¹⁴⁾ appears to be satisfactory, both as a result of its penetration as well as due to its resistance in the blood stream, and also by its efficacious action on staphylococcal and

gram-negative flora. Caution is nevertheless called for in affirming its efficacy vis a vis MRSA infection⁽¹⁵⁾. Indeed, we should mention the clinical series undertaken by the Leicester team who, also using pre-soaking with rifampicin, with outcomes judged to be satisfactory, nevertheless had a poor prognosis for infections caused by MRSA strains⁽¹⁶⁾.

Discussion:

There are thus different therapeutic options in the presence of an infectious complication following a restorative aortic and/or peripheral vascular intervention in relation to the lower limbs^(8,17,18). Some may be more obvious than others; for example, if the infectious extension appears to be truly circumscribed then in this case, a local adapted treatment will enable a low risk situation to be controlled.

On the other hand, in the presence of threatening infected lesions from the life-threatening standpoint and/or for the survival of a limb, the discussion revolves inescapably around the choice between one of the radical treatment solutions previously presented. The indication for extra anatomic diversion followed by explantation in the absence of *in-situ* recovery undeniably finds favour amongst many teams in spite of a combined depressing mortality/morbidity coefficient. This technique does not close the door to cases with a moderate risk and within a reasonable timescale to an *in-situ* neo-implant with an extra corporeal closure of the bypass.

Conclusions:

The occurrence of an infectious complication no doubt represents the most severe immediate or secondary complication of conventional vascular surgery or of a strictly endovascular procedure. However, its incidence currently appears to be a lot more significant in terms of conventional surgery, though the extension of the field of endovascular interventional surgery might change this disparity. It appears essential to specify without delay the infectious characteristics (anatomical extension and bacteriological identification as precisely as possible) and the danger they represent for the survival of a limb, even of the patient himself and within the context of other risk factors. The most desirable therapeutic approach with regard to authenticated prosthetic infection, remains the most complete explantation possible as well as confinement to bed with the maximum dressing of neighbouring tissue and insofar as is possible, an epiploplasty can be

added if there is *in-situ* revascularisation and of whatever nature: (autogenic, neo-prosthetic or by means of a homograft) or extra anatomic diversion. The choice of indication is usually dependent on the experience of the teams and one should know nevertheless whether or not there are revascularisation techniques, which might be considered as being genuinely superior. It is believed that the differences might be due to the potential for prosthetic resection and the surroundings of the adjacent lesion. It is with this key condition in mind that we can propose the *in-situ* use of new prostheses to advantage, with an effective antibacterial spectrum and avoid the risks of reinfection in the long term without moreover ignoring in the majority of cases the need for systematic antibiotic cover in the mid-term.

The context of the prevention of infection during conventional vascular surgery or therapeutic endovascular interventions all appear just as important and when associated general or local factors are found pre or peroperatively it seems logical in terms of the choice of revascularisation material to initially focus on the new prosthetic implants with a potential antimicrobial spectrum of activity. There is no doubt that with regard to pure endovascular therapeutic interventions, plans might include an antibacterial load, the action of which may be significant, especially in the context of restenosis phenomena with an inflammatory potential. Moreover, standard prophylactic measures (the changing of gloves, of guides and sleeves, punctures avoiding haematomas etc...) are observed by surgeons especially during protracted or complex procedures. Antibiotic prophylaxis in this field is still debated by numerous authors.

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Antimicrobial properties of silver⁽¹⁾

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About 4000 years BC metallic silver was already being used for the production of jewellery and later also of coins. The antimicrobial activity of silver was recognised when it was noted that water in silver containers remained drinkable for longer than when stored in other containers. Thus, Aristotle is said to have advised Alexander the Great to use silver containers to preserve water on his military campaigns. Towards the end of the 19th century Ravelin and the botanist von Nägeli conducted systematic research into the antimicrobial properties of silver. Von Nägeli discovered that silver in very small concentrations inhibited the germination of *Aspergillus niger*, for example, and he described this phenomenon as the “oligodynamic” effect of silver. Eventually the Leipzig obstetrician Credé introduced his prophylactic method involving the administration of a 1% solution of silver nitrate to prevent neonatal gonococcal conjunctivitis. In 1968 silver sulphadiazine was used by Fox to prevent infection in burns patients, and since about 1980 silver has been used to prevent foreign-body infections, for example, in intravascular catheters, urological catheters, vascular grafts and other medical devices.

Pure metallic silver, which releases no ions, does not display antimicrobial activity. Silver compounds that are used in medicine include, for example, silver nitrate (toughened silver nitrate), silver acetate, silver citrate, silver picrate as well as silver sulphadiazine. Colloidal silver or “silver protein”, which is promoted by many manufacturers as a cure for a great many diseases, is of dubious benefit.

The active component in silver compounds is the cation Ag^+ , which displays antimicrobial activity against bacteria, fungi, and some viruses and also against protozoa. Depending on the pathogen, Ag^+ may display bacteriostatic and/or bactericidal activity. It possesses no activity against bacterial spores and mycobacteria. *In vitro* and *in vivo* the activity of the silver salts is adversely affected by ions such as phosphate, chloride, and sulphide as well as by proteins; increases in temperature and pH exert a positive influence.

The cation Ag^+ is able to bind to electron donor groups containing sulphur, oxygen and phosphorus and thus, for example, by reacting with the thiol

groups of enzymes, inhibits these in their activity. Silver nitrate causes harm to the cell by inhibiting cell division, by damaging the membrane and cytoplasm, and by inhibiting transport processes. Binding to DNA bases is a further important mechanism in the activity of Ag^+ .

Bacterial spores and mycobacteria are known to be naturally resistant, and there are also reports of chromosomal acquired resistance with *E. coli* and of plasmid-encoded transferred resistance with *Pseudomonas*, *Citrobacter* and other bacterial species. The staphylococci that are important in foreign-body infections, e.g., vascular graft infections, are not known to display any natural resistance. In our own investigations into the efficacy of silver nitrate against some 400 staphylococcal isolates, no resistant strains were detected; the minimal inhibitory concentrations for silver nitrate were between 1 and 10 $\mu g/ml$.

In summary, silver possesses an extraordinarily diverse antimicrobial spectrum, coupled with comparatively low toxicity for humans. The use of silver to prevent foreign-body infections caused by implantation of medical devices, such as intravascular catheters, vascular grafts etc., warrants further investigation.

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Preventing infection with medical devices⁽¹⁾

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A wide range of factors now influences the development of a new medical device, specifically in terms of the antimicrobial concept involved.

Approaches over the past 20 years have generally been based on combining an active antibiotic chemotherapeutic agent with the medical device. The goal here is to achieve efficient release of the effector both over time and in terms of dose. Other approaches are designed to prevent the adhesion of microorganisms to the device and to develop appropriate coatings to prevent the formation of biofilms. As illustrated by the currently published literature, the problem of biofilms will pose a special challenge in future to the developer of antibiotic concepts.

Recently, the use and release of systemically administered antibiotics and of active antimicrobial (locally or topically administered) chemotherapeutic agents (polyhexanide, iodine derivatives, etc.) has often been a prominent aspect of such efforts. However, toxic effects and the development of resistance have cast doubt on many concepts. Immobilisation of the antibiotic effector on the surface of the medical device usually results in inactivation. It has thus become popular to use (additional) coatings that form a reservoir for the bioactive effector to ensure its (more or less defined) release.

Why have systems based on the activity of silver proved successful in local infection prophylaxis and therapy?

The answer lies in the efficiency of silver ions and in their toxicological profile:

The minimal inhibitory concentration (MIC) starts at around 50 ppb Ag ions. Toxic effects have been reported only at high concentrations or following long-term exposure.

The resulting usable dose window is very large.

Silver ions act on a very broad bacterial spectrum, without resistance development.

Among other aspects, the low toxicity is due to minimal tissue penetration (and absorption) – an advantage for wound dressings. This also results in

the absence of dramatic systemic effects with silver ions released from medical devices.

Silver has a long history of use for therapy and prophylaxis.

In the context of implant integration and wound healing, the mechanisms underlying the interaction of silver ions are more clearly understood today and have been described at the level of molecular and cell biology

The regulatory and licensing framework encourages rational development.

As an element, silver is compatible with established sterilisation methods, such as radiation or gas blanketing with ethylene oxide (other chemotherapeutic agents with antibiotic activity frequently do not survive the sterilisation process).

Silver is stable over the shelf-life periods usual for medical devices.

Because silver is photosensitive, its use in ionic form is generally associated with cosmetic shortcomings (discoloration).

Silver ions display an interaction with many partners (e.g., sulfhydryl groups of cysteine).

In the context of infection prophylaxis and as a therapeutic adjunct, silver is particularly suitable for use in wound dressings. In fact, all the major manufacturers have silver-containing wound care products on the market or in development. However, the silver content differs quite markedly; the user is faced with an immense dose range from 5 ppm (ActisorbTM, activated charcoal compresses with silver) up to approx. 100,000 ppm (ActicoatTM) with nanocrystalline silver, which is also considered to be particularly bio-active because of its high surface activity.

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MRSA today – fate or fault? ⁽¹⁾

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Ever since antibiotics were first deployed in the treatment of infectious diseases, successive forms of resistance have emerged that increasingly limit the therapeutic options available in infections caused by multi-resistant pathogens. Methicillin was the first penicillinase-resistant antibiotic: it was introduced on to the market in the late 1950s to counter the increasing resistance of *Staphylococcus aureus* to penicillins. However, by 1961, soon after the introduction of methicillin, the first methicillin-resistant *S. aureus* (MRSA) had already been described. Because oxacillin is currently the representative substance in this group, having supplanted methicillin, the term oxacillin-resistant *S. aureus* (ORSA) is also commonly encountered; nevertheless, not least for historical reasons, MRSA should be regarded as the preferred terminology. One notable feature with MRSA is the marked parallel resistance to other antibiotic classes. The highest resistance rate is found with the quinolones, due to chromosomal mutations. This multi-resistance can be explained in particular by the clonal spread of a small number of highly resistant epidemic strains. With the isolation of the first glycopeptide-resistant *S. aureus* (GRSA) as an infectious pathogen in the USA in June 2002, it again became clear that, if resistance is to be eliminated, major importance must be assigned to the development of new, effective antibiotics, coupled with critical and restrictive use of antibiotics as indicated.

In Germany, but also throughout Europe and worldwide, MRSA infections are an increasing problem, not only in the hospital setting. The marked heterogeneity of MRSA prevalence in different countries, especially in Europe, appears remarkable. In particular, this discrepancy is attributable to varying strict strategies for control and prevention and to the differing assessments of restrictive antibiotic use in the individual countries. Reliable detection of MRSA in the course of microbiological diagnosis, and the establishment of consistent and systematic practices for public health management are of pivotal importance if the spread of MRSA is to be controlled.

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Mycotic aneurysm caused by *Brucella suis*⁽¹⁾

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Objective:

Our aim is to present an exceptional case of mycotic aneurysm caused by *Brucella suis*, which was treated by resection and *in-situ* replacement with a prosthetic graft.

Patients and method:

A 78-year-old patient was admitted to our hospital after suffering from left-sided lumbosciatic pain for two months, which caused functional incompetence of both lower limbs. He was afebrile and had no organ enlargement. The only history of interest was brucellosis (14 years ago), atrial fibrillation, arterial hypertension and acute MI. Examination by MRI, CT, arteriography and scintigraphy with labelled leucocytes revealed spondylolisthesis in L1-L2 and saccular aneurysm of the abdominal aorta in the posterior wall. Semi-urgent surgery was performed, involving aortic resection, disc cleaning, spinal stabilisation with iliac crest graft and *in-situ* aortic replacement by end-to-end polyester silver-coated graft (InterGard Silver, InterVascular, La Ciotat, France) combined with omentoplasty. All blood cultures and cultures of surgical specimens (thrombus and aortic wall) proved negative for acid alcohol-fast bacteria. Specific antibiotic treatment was carried out for three months.

Results:

After 12 months he was in good health and there were no complications.

Conclusion:

The existence of a mycotic aneurysm caused by *Brucella* is exceptional, even in endemic regions, which makes it very difficult to diagnose. Treatment involving resection of the aneurysm followed by *in-situ* prosthetic replacement and omentoplasty provides good results and is an alternative to extra-anatomical surgery.

Septic aneurysm of visceral aorta⁽¹⁾

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Introduction:

Septic aortic aneurysms are uncommon, difficult to treat and associated with high levels of morbidity and mortality. When their location is infra-renal, treatment includes resection and usually extrafocal surgery. However, in cases located in the para-visceral aorta, the only possibility is *in-situ* reconstruction, which can entail an increased risk of possible graft-related complications.

Patients and methods:

35-year-old patient with no history of i.v. drug addiction, admitted to our internal medicine department with fever of unknown origin. The presence of an aortic aneurysm was suspected on the basis of an abdominal ultrasound. CT confirmed the presence of an aneurysm of the visceral abdominal aorta, extending from the coeliac trunk to the renal arteries, which essentially involved the posterior aortic wall. In view of the associated picture of sepsis, this was classified as a septic aneurysm of the visceral aorta.

Results:

Surgery comprised midline and left subcostal laparotomy to check visceral vessels within the peritoneal cavity and, by detachment of the left parietocolic gutter, to check the aorta from the crura of the diaphragm to the renal arteries. Resection of the posterior and lateral surfaces of the visceral aorta was performed, leaving an anterior pad. The wall was reconstructed with a silver-coated polyester graft (InterGard Silver, InterVascular, La Ciotat, France). Postoperative progress was complication-free and, after six months, the patient remained afebrile with no gas or any other worrying signs on CT examination.

Discussion:

1) *In-situ* reconstruction necessitated by the presence of visceral branches. 2) Aggressive approach with optimal exposure of the area.

(1) Sociedad Española de Angiología y Cirugía Vascular 2001
Poster Communication, Ovadoid - Spain

(1) Sociedad Española de Angiología y Cirugía Vascular 2001
Poster Communication, Ovadoid - Spain

Ruptured mycotic aortic aneurysm in a 15-year-old girl⁽¹⁾

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Introduction:

Abdominal aortic aneurysms are exceptional in childhood and are usually diagnosed by their complications: mainly rupture, as in the case presented here.

Case study:

15-year-old female, with no general history, operated on two days before in another centre for abdominal pain and fever of one week's duration; a blank appendectomy was performed. She was referred with persistent pain, abdominal distension and serious haemodynamic deterioration. Physical examination: conscious, BP 70/40; abdomen tight, with pain spontaneously and on palpation; Blumberg's sign positive, haematocrit 20%, haemoglobin 6.7 g/dl. Abdominal CT: saccular aneurysmal dilatation of infra-renal aorta, with retroperitoneal extravasation and abundant free intraperitoneal fluid. Urgent surgery with aortic approach by midline laparotomy; an irregular mass was found which involved the distal aorta and the origin of both iliac arteries and complete loss of structure. The aortic bifurcation was totally resected and reconstructed by end-to-end aortic/bi-iliac graft interposition with a silver-coated polyester graft (InterGard Silver, InterVascular, La Ciotat, France).

Results:

There were no postoperative complications, except a coagulation disturbance secondary to multiple transfusion. Blood cultures negative. Culture of vessel wall negative. Serology positive for Salmonella. Pathology: chronic inflammatory infiltrate and interstitial fibrosis. Wall fragments showed necrosis and abscess formation. One year later the patient is asymptomatic with no evidence of lesions elsewhere.

Conclusions:

Aortic aneurysms in childhood are very rare and their morbidity/mortality very high, usually related to diagnostic delays. The lack of experience with this situation means that every case should be treated on an individual basis.

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Vascular graft infections in the diabetic vascular patient - results of *in-situ* reconstruction with the Silver-impregnated polyester graft⁽¹⁾

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Objective:

To determine whether the diabetic patient occupies a special place in the total population of patients undergoing *in-situ* reconstruction with the silver-impregnated Polyester graft.

Introduction:

Infection of a vascular graft is a rare but serious complication in vascular surgery. The mortality rate is high. Anastomotic ruptures, sepsis and massive haemorrhage are the predominant features. Accepted techniques are *in-situ* reconstruction with autologous material or extra-anatomical reconstruction with synthetic material.

Based on findings from therapeutic trials, good experiences have been reported with a triclosan-bonded Polyester graft. Recently a Silver-impregnated Polyester graft (InterGard Silver) that has a broad antimicrobial spectrum which includes methicillin-resistant *Staphylococcus aureus* (MRSA) has been released.

Method:

Since 7/1999, a nationwide multicentre questionnaire-based survey in Germany has been monitoring cases in which vascular grafts with proven infection in an *in-situ* position have been exchanged for a Silver-impregnated graft (n = 102). A separate analysis was performed for those cases where diabetes mellitus was present (n = 21).

Results:

In 9 patients with diabetes mellitus the implanted vascular graft material was explanted completely. In this group there was one instance of re-infection with subsequent death due to persistent infection in the graft bed. Three further patients died without re-infection. In 12 patients the vascular graft material was explanted only partially. In this group there were 6 cases of re-infection, and three of these patients died. Two further patients died without any evidence of re-infection. Where the graft material was explanted completely in diabetic patients, the infection eradication rate was 89%. Where the graft material was explanted only partially, the re-infection rate was 50%. This result is comparable with the data from non-diabetic patients (complete explantation n = 62, re-infection rate 9.6%; partial explantation n = 19, re-infection rate 42%).

Conclusion:

The strategy of *in-situ* reconstruction with the silver-impregnated graft also appears to be effective in diabetic patients. However, complete explantation of the primary implanted graft material is also a requirement in this category of patients.

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