EVALUATION OF MEASURES TO DECREASE INTRA-OPERATIVE BACTERIAL CONTAMINATION IN ORTHOPAEDIC IMPLANT SURGERY

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Introduction

Infection is one of the most common complications in surgery. In particular deep periprosthetic infections in orthopaedic surgery constitute a disaster for both patient and doctor. Conservative estimates of infection rates average 1-2% for hip implants and 2-4% for knee implants.\textsuperscript{1-7} The number of joint replacements is expected to double in the next twenty years and if the infection rate is not reduced, also the incidence of infection will double, yielding increased morbidity, hospital stay and costs for the healthcare system.\textsuperscript{8}

Deep prosthetic infections can be subdivided into: (i) early (within three months after surgery); (ii) delayed (within one-and-a-half to two years after surgery); and (iii) late infections. Both early and delayed infections can be caused during surgery by direct contact with the wound, airborne colonisation or cross-infection on the ward. Late infection is mostly caused by bloodborne contamination; for example during insertion of a urinary catheter, infection of an intravenous canula, or skin or dental sepsis.\textsuperscript{9} However, haematogenous infection only plays a minor role in orthopaedic surgery, with an incidence of 0.3-7%.\textsuperscript{10,11}

This study focused on early and delayed infections caused by intra-operative contamination. It has been suggested that the main sources of contamination are the patient’s skin and airborne particles from theatre personnel.\textsuperscript{12-15} Whyte et al. found that the source of contamination was the patient’s skin in 2% of cases and theatre personnel in 98% of cases. In the latter, 30% of contaminants reach the wound directly via the air and 70% reach the wound via hands of the surgical personnel or the instruments used.\textsuperscript{16}

In general, the policy to reduce intra-operative contamination is based on a behavioural and systemic approach. In a behavioural approach, preventive measures focus on reducing the number of airborne particles in the operating room through disciplinary measures. Simple and cheap measures include limiting the number of personnel in the operating room and restricting the movements of personnel in the operating room to a minimum, as it has been shown that increased activity enhances the dispersion of bacteria.\textsuperscript{17}

A systemic approach consists of improving the airflow system. The introduction of laminar airflow systems has greatly reduced infection in orthopaedic implant surgery. Laminar flow, as opposed to turbulent flow, allows airborne particles to pass the operating area and prevent them from landing in the wound area. For example, in a downflow laminar system, the unidirectional air enters the operating room in the ceiling above the operating area through filters.
Adjustments to existing operating rooms is presently estimated to cost about € 540,000 for two new airflow systems. This should be compared with the costs of treating a septic joint (estimated to be $50,000 to $62,100). It should be emphasized that such a comparison only includes direct medical costs.

The aim of this study was to evaluate whether behavioural and systemic measures decrease intra-operative contamination as monitored during 207 total hip or knee replacements. The influence of these measures on subsequent prolonged wound discharge, superficial surgical site infection and deep periprosthetic infection was also investigated during an 18-month follow-up of the patients involved.

Materials and methods

Interventions

During the two-and-a-half year evaluation period, interventions were carried out on two occasions in order to decrease bacterial contamination in the operating room. Both interventions are described in Table I. The first intervention was implemented in March 2003 and was a behavioural intervention. From that time on, instrumentation and other sterile equipment were only unpacked and used in the area of laminar flow (the so-called ‘plenum’).

The second intervention was introduced in August 2003 and consisted of some major behavioural changes as well as a systemic change. The behavioural changes were new guidelines for patient work up, use of body coverage, and restricting activity in the operating room. In the second intervention, the old conventional airflow system was replaced with a new laminar system, yielding a major increase in airflow from 2700 m$^3$ to 8100 m$^3$ per hour by the introduction of large quantities of recirculating air (5400 m$^3$ per hour). The air inflow speed was increased from 10 to 20 cm per second. Consequently, airflow was diluted rather than mixed, increasing the total number of air changes in the entire operating theatre from 22 to 60 per hour. Better laminar flow was achieved due to the use of new glass panels extending from the ceiling which, in combination with the increase in airflow, resulted in 240 air changes per hour at the operating table. Besides this, the plenum size was increased from 3 m$^2$ to 10.2 m$^2$, and the filter and bottom ceiling layer were replaced.
Table I. Behavioural interventions undertaken in the operating room.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Correct use of plenum</td>
<td>Limiting needless activity</td>
</tr>
<tr>
<td>- Instrumentation unpacking only in plenum</td>
<td>- Number of people in operating room kept to minimum</td>
</tr>
<tr>
<td>- Instrumentation unpacking just before surgery</td>
<td>- Opening of doors kept to minimum</td>
</tr>
<tr>
<td>- Instrumentation never leaves plenum, else considered unsterile</td>
<td>- Use only smallest door to washing room</td>
</tr>
<tr>
<td>- Head of patient always out of plenum</td>
<td>- Movement of people kept to minimum</td>
</tr>
<tr>
<td>Work up in preparation room, not in operating room</td>
<td>- No changing of personnel during an operation</td>
</tr>
<tr>
<td>- Anaesthetic work up</td>
<td>- All communication with world outside via intercom</td>
</tr>
<tr>
<td>- Shaving</td>
<td>- Only conversation if needed for surgery</td>
</tr>
<tr>
<td>- Putting on blood bands and blankets</td>
<td>Proper wearing of body coverage</td>
</tr>
<tr>
<td>- Positioning patient with leg support</td>
<td>- No hair visible</td>
</tr>
<tr>
<td>Proper wearing of body coverage</td>
<td>- No nose visible</td>
</tr>
<tr>
<td>- Beard mask and safety glasses for persons working in plenum</td>
<td>- Renew mouth mask after every operation</td>
</tr>
<tr>
<td>- Change clothes each time after leaving the operating complex</td>
<td>- Change clothes each time after leaving the operating complex</td>
</tr>
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</table>

Selection of operations

Between July 2001 and January 2004, intra-operative bacterial cultures were taken during 207 random operations involving placement of primary knee or hip prostheses. Before the first intervention, from July 2001 to March 2003, cultures were taken during 70 operations that were performed under original, control conditions (control group). Sixty-seven operations were monitored after the first intervention (group 1). The second intervention was initiated in August 2003 and 70 operations were evaluated from August 2003 to January 2004 (group 2). All operations involved a total hip or knee arthroplasty in patients with osteoarthritis or rheumatoid arthritis, and took place in the University Medical Centre Groningen, Groningen, The Netherlands. All patients received antimicrobial prophylaxis (cefazoline, 1000 mg intravenously) twenty minutes before the operation and postoperative anticoagulation (nadroparine, 0.3 mL subcutaneously combined with acenocoumarol orally). Patient characteristics were not significantly different between the three groups.

Culture technique

Intra-operatively, samples were taken at different stages during the operation, two from the instruments used, two from the instruments not used and two from removed bone. In the hip procedure, the first sample (culture 1) represents the swab of the smallest acetabular broach before it was used for reaming. The second sample (culture 2) represents the swab of an unused
acetabular broach after the reaming procedure. In the knee procedure, cultures 1 and 2 represent swabs of the adjustable femur sizer before and after sawing the femur. Furthermore, in the hip procedure, the third sample (culture 3) represents the swab of the smallest femoral broach before it was used for reaming. The fourth sample (culture 4) represents the swab of an unused femoral broach after the reaming procedure. In the knee procedure, cultures 3 and 4 represent swabs of the adjustable tibia saw before and after sawing the tibia.

Removed bone was sampled for contamination as well. Culture I represents the acetabular bone in case of the hip joint and the femoral bone in case of the knee joint; culture II represents the femoral bone in case of the hip joint and tibia bone in case of the knee joint. Cultures 1, 2 and I were taken during the early phase of the operation and cultures 3, 4 and II during the late phase.

During all procedures, a clean swab was quickly (10 s) taken out of its transport medium (Transwab Charcoal medium, Medical Wire & Equipment Co, Bath, United Kingdom) into the operating room after which it was immediately put back into the medium in order to make sure no contamination occurred during transport and culturing of the samples (control swab).

Cotton swabs (cultures 1-4 and the control swab) were transported in the Transwab Charcoal medium. Removed bone material (cultures I-II) was put into sterile cups filled with a growth medium, Tryptone Soya Broth (TSB, Oxoid, United Kingdom).

Within 2 to 4 h after sampling, the cotton swabs (1-4) were smeared over blood agar and incubated, together with the cups containing cultures I and II, for 7 days at 37°C, both aerobically and anaerobically. After 7 days, the content of the cups was also smeared over blood agar and again incubated for 5 days. Instrumentation or bone material was considered contaminated, when bacterial growth was observed, regardless of the amount of growth.

Follow up

In order to investigate whether infectious complications occurred post-operatively in relation with the interventions taken, all patients were followed up for 18 months. Previous studies in our hospital pointed out that nearly all periprosthetic infections became manifest within 18 months after surgery. First, patients were monitored during their stay at the orthopaedic ward to see whether prolonged wound discharge or superficial surgical site infection occurred. Wound discharge was recorded postoperatively by a specialized nurse from the local hospital infection committee, monitoring both the wound and the drain site, taking the
fifth day after surgery as the cut-off point. The diagnosis of a superficial wound infection was made by the orthopaedic surgeon based on the definition of the Surgical Infection Study Group. This definition relies solely on clinical observations in the absence of microbiological confirmation. Deep periprosthetic infection was, eventually, defined by an increase of infection parameters caused by the prosthesis site, as judged by the orthopaedic surgeon.

Statistical analysis

The Pearson’s Chi-square test for categorical data was used to test differences between the experimental groups and the control group, when all cells of the contingency table contained at least five people. Otherwise the Fisher’s exact test was used. Statistical calculations were performed using SPSS software version 12.0 (SPSS Inc., Chicago, IL, USA).

Results

Intra-operative bacterial contamination before and after the interventions

In the control group, contamination of one or more of the samples was seen in 23/70 (32.9%) cases. Group 1 showed contamination in 34.3% of the cases (23 out of 67) and group 2 showed contamination in 6/70 cases, equalling 8.6%.

In order to follow the contamination percentage in time, the total number of 207 patients was divided in 9 groups of about 20 patients, consecutively operated upon in time. Figure 1 shows that the contamination percentage in the control period and in the period after the first intervention ranges between 30 and 40%. It was only after the second intervention in August 2003 that the contamination percentage decreased to 15%. After that it further reduced to 5% in the end of 2003. In the first few months of 2004, the contamination percentage amounted 7%.
Early and late intra-operative bacterial contamination during surgery

During all included procedures, four swabs of the instruments used were cultured (1-4), as well as two portions of bone chips (I-II). The control swab did not show bacterial growth at all times. The implantation of a hip or knee prosthesis can be divided in two parts: first, the preparation of the acetabulum (hip) or femur (knee) and secondly the preparation of femur (hip) or tibia (knee). The samples 1, 2 and I were taken during the early phase of the operating procedure and the samples 3, 4 and II during the late phase. In Table II the early samples are compared with the late samples. In all three groups more samples taken in the late phase showed bacterial growth as compared to those taken in the early phase. These differences only reached statistical significance in group 1 (p=0.022). In the total group of 207 procedures, growth was found in 40/207 samples taken in the early phase and in 23/207 samples taken in the late phase (p=0.020).
Table II. Number of intra-operatively acquired swabs and bone chip portions that showed contamination in the early and late phases of the operating procedure. Numbers and percentages are given for each group. P values indicate the significance of the difference between early and late samples (* indicates p<0.05).

<table>
<thead>
<tr>
<th>Sample</th>
<th>Control group (N = 70)</th>
<th>Group 1 (N = 67)</th>
<th>Group 2 (N = 70)</th>
<th>Total (N = 207)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Instrument swab 1</td>
<td>16/70 22.9%</td>
<td>20/67 29.9%</td>
<td>4/70 5.7%</td>
<td>40/207 19.3%</td>
</tr>
<tr>
<td>Instrument swab 2 Bone chips portion I</td>
<td>11/70 15.7%</td>
<td>9/67 13.4%</td>
<td>3/70 4.3%</td>
<td>23/207 11.1%</td>
</tr>
<tr>
<td>Late Instrument swab 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument swab 4 Bone chips portion II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td>0.284</td>
<td>0.022 *</td>
<td>1.000</td>
<td>0.020 *</td>
</tr>
</tbody>
</table>

Follow up

During the control period, prolonged wound discharge was found in 16/70 (22.9%) cases, of which 8 were diagnosed with a superficial wound infection (11.4%). After a follow up of 18 months, deep periprosthetic infection became manifest in 5 of these cases (7.1%), all of which needed revision surgery.

After the first intervention, wound discharge was found in 21/67 (31.3%) cases, of which 10 had a significant superficial wound infection (14.9%). In the end, after an 18 month follow up, three of these patients suffered a deep periprosthetic infection (4.5%), two of which underwent revision surgery. The third patient was inoperable because of underlying disease and only received intravenous antibiotic therapy.

After the second intervention, wound discharge was found in only 7/70 (10%) patients, of which one suffered a superficial wound infection (1.4%). This superficial infection later on appeared to be a deep periprosthetic infection, needing revision surgery.

Figure 2 graphically summarizes the parameters contamination, prolonged wound discharge, superficial surgical site infection and deep periprosthetic infection over the different groups. Surprisingly, contamination, prolonged wound discharge and superficial surgical site infection all increased after the first intervention. Only the incidence of deep periprosthetic infection decreased. These changes, however, were not statistically significant. The second intervention established significant decreases in contamination (p=0.001), prolonged wound discharge (p=0.002) and superficial surgical site infection (p=0.004). The decrease in deep periprosthetic infection was not statistically significant (p=0.359).
**Figure 2.** Bacterial contamination, prolonged wound discharge, superficial surgical site infection and deep periprosthetic infection in each of the three periods. Periprosthetic infection was diagnosed during 18 months of follow-up. All data are presented as percentages with respect to the size of the control group and groups 1 and 2.

**Discussion**

This study found that a combination of systemic and behavioural changes in an operating room significantly decreased the incidence of intra-operative bacterial contamination, and subsequently decreased the incidence of prolonged wound discharge and superficial surgical site infection. After one year of follow up there was also a decrease in deep periprosthetic infection; however, this difference did not reach statistical significance because of the small numbers of patients involved. Most of the individual parameters combined in the interventions have been shown to reduce contamination in the operating room, but their combined effects have not been determined previously. However, combination of all these parameters evidently creates the most effective weapon against infection. In 1972, Charnley recognised that intra-operative contamination was a major threat to the success of total joint replacements, but others stated that its role as a cause of deep infection was highly overemphasised. The major decrease in intra-operative contamination after the second intervention, followed by the decrease in prolonged wound discharge, superficial surgical site infection and subsequent deep periprosthetic infection, suggests that intra-operative contamination does influence postoperative infection.

The first intervention in March 2003, the better use of the plenum, did not yield any significant decrease in the outcome parameters, perhaps because the plenum was too small. In
orthopaedic implant surgery, many baskets of instruments are present in the operating room. Although the baskets were unpacked within the plenum, they were still standing near the edge of it, and hence close to the turbulent zone. Clearly, unpacking of the baskets just before surgery caused a considerable amount of bacterial shedding that could not be handled adequately by the conventional airflow system before the operation commenced.

The decrease in intra-operative contamination after the second intervention in August 2003 occurred in two steps (Figure 1). The first decrease was from 33% to 15%, and the second decrease from 15% to 5%. Air sampling demonstrated that the air flow system, as part of this intervention, worked properly; subsequently, the infection committee of the authors’ hospital enforced the desired behavioural changes more strictly in September. This indicates that the second intervention actually consisted of two parts: a systems part in August 2003 and a behavioural part in October 2003. This correlates with the two steps in the decrease of intra-operative contamination.

One might expect that the longer the duration of an operation, the more bacteria are present in the operating area and thus able to gain access to the wound. In 2004, Clarke et al. stated, after investigating 40 total hip procedures with both polymerase chain reaction and normal culture, that the contamination percentage at the end of surgery was significantly higher than at the start of surgery, with both cultures from early and late stages taken from the posterior joint capsule. This is in contrast to the present results, which showed more contamination during the early phase of a procedure than during the late phase. However, samples from the present study were taken at six different times during surgery and originated from six different sites. It is hypothesized that just prior to an operating procedure, considerable movement is taking place in the operating area in terms of final preparations, covering the patient and entry of the surgeon. After this high initial movement, movement is limited as much as possible during the entire procedure. Consequently, it is not surprising that the initial samples in this study showed a higher contamination rate than the samples taken during the late phase.

In summary, radical alterations in behaviour and airflow system in an operating room can decrease intra-operative contamination. To maintain low bacterial counts, both the airflow system and behaviour have to be monitored consistently. Both the manufacturer of the airflow system and the hospital’s infection control officer (e.g. a consultant microbiologist) should advice on the microbiological performance of the airflow system, and therefore have responsibility for the monitoring. An infection committee should monitor the behavioural
changes and report frequently to the people working in the operating room. Both positive and negative feedback help to maintain the reduction in bacterial dispersal. Finally, it is important to emphasize that all personnel working in the operating room, including surgeons, operating room assistants, anaesthesiologists and cleaning personnel, must follow hygiene protocols very strictly.
References
