Hospital Practice

A SCORING METHOD (ASEPSIS) FOR POSTOPERATIVE WOUND INFECTIONS FOR USE IN CLINICAL TRIALS OF ANTIBIOTIC PROPHYLAXIS

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Summary To compare antibiotic regimens for their effectiveness in preventing or treating wound sepsis, well-defined criteria for outcome are needed. A method of assessing wound healing has been devised that defines carefully the characteristics to be considered and how they are to be awarded points. Objective criteria are also included in the assessment. Points are given for the need for Additional treatment, the presence of Serous discharge, Erythema, Purulent exudate, and Separation of the deep tissues, the Isolation of bacteria, and the duration of inpatient Stay (ASEPSIS).

INTRODUCTION

POSTOPERATIVE wound sepsis is a serious cause of morbidity and occasional mortality[1] and antibiotics are prescribed as often for prophylaxis as for treatment of infection.[2] Where there has been no break in aseptic technique or entry into the respiratory or gastrointestinal tract, the frequency of wound infection after general surgery can be less than 2%.[3] With cardiac surgery, antibiotics are generally given prophylactically because of the additional risks arising from the length of the operation, the number of staff required, possible contamination of blood during recirculation,[4] and depressed function of most components of the immune system.[5] With valvular surgery, there is also a fear of early prosthetic valve endocarditis, which carries a 77% mortality;[6] furthermore, the only placebo-controlled trial of antibiotic prophylaxis had to be abandoned after pneumococcal endocarditis occurred in 2 placebo-treated patients.[7]

Sutherland et al judged antibiotic prophylaxis in coronary artery surgery to be unnecessary because a placebo-controlled trial of 904 patients showed a low frequency of sternal wound infection in the control group (1·8%).[8] However, a more recent study comparing cephradine with placebo had to be stopped after only 38 patients because of a high overall wound infection rate in the control group (12 of 22 patients affected compared with 1 of 16 in the treated group, $p = 0 \cdot 002$) and a death attributable to wound infection.[9] All British cardiac units now give antibiotics prophylactically for coronary surgery[10] and future clinical trials are unlikely to have a placebo group. For successful comparison of antibiotic regimens well-defined criteria for outcome are needed.[11] Wound sepsis is usually defined as the breakdown of a wound in the presence of pus and infecting organism. However, lesser degrees of infection are also clinically important and, unless they can be quantified, it may not be possible to demonstrate a significant difference within a reasonable number of cases. Furthermore, a trial may not be double-blind because the regimens being compared differ in their mode of administration, schedule, or appearance of the drug. It is important to have an objective and reproducible method of assessment that takes account of these factors and is applicable to all forms of surgery. We have devised a method of wound scoring which we believe meets these requirements.

METHOD

In October, 1984, a prospective randomised clinical trial was started to compare a new antibiotic, teicoplanin, given as two intravenous injections 24 h apart, with the regimen currently most popular in British cardiac surgical units,[10] an aminoglycoside and flucloxacillin, given three or four times a day for 3–5 days, by intravenous and then oral routes. Such differences in administration precluded a double-blind study. Patients undergoing any type of cardiac surgery done with cardiopulmonary bypass were included. The expected differences are small and cohort analysis after every 50 patients was planned to a total of 500 cases, with the trial being stopped if a clearly significant result was obtained earlier. During the pilot study the following wound scoring method was devised for use in the trial.

On 5 of the first 7 days all sternal and leg incisions were examined methodically by a single observer (A. P. R. W.) for deep wound separation, serous or purulent exudate, and erythema extending 5 mm or more from the line of the incision. The proportion of the wound, as measured to the nearest 10% of its length, showing each of these features, was assigned a numerical score as set out in table I. Although assessment of these four features may be prone to subjective bias, the other characteristics are objective and their presence is determined independently by individuals not involved in the study or aware of the antibiotic regimen. These other characteristics can contribute to the total score beyond the first 7 postoperative days. In our trial, they were assigned points for up to 2 months, which was when the patients were reviewed (table II).

The total score indicates the severity of wound infection and can be used in two ways for the analysis of data. The first, easier, method is by grouping the scores into five descriptive classes (table II) and using the numbers of each class of infection for the comparison by Fisher's exact test or by the χ^2 test (if there are more than five in each class). However, some information may be lost by the arbitrary grouping. The other method is to compare the raw data by a Mann Whitney U test. With large numbers of patients, a Student's *t* test may be used since corrections for the skew distribution become very small.

TABLE I—POINTS SCALE FOR THE DAILY WOUND INSPECTION

Wound characteristic	Proportion of wound affected (%)					
	0	<20	20–39	40–59	60–79	>80
Serous exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

TABLE II—THE WOUND SCORE: ASEPSIS

Criterion	Points
Additional treatment:	
Antibiotics	10
Drainage of pus under local anaesthesia	5
Debridement of wound (general anaesthesia)	10
*Serous discharge**	daily 0–5
*Erythema**	daily 0–5
*Purulent exudate**	daily 0–10
*Separation of deep tissues**	daily 0–10
Isolation of bacteria	10
Stay as inpatient prolonged over 14 days	5

*Given score only on 5 of first 7 postoperative days.
Category of infection: total score 0–10 = satisfactory healing; 11–20 = disturbance of healing; 21–30 = minor wound infection; 31–40 = moderate wound infection; >40 = severe wound infection.

Postoperative fever was not included for the wound score because most patients are pyrexial for 2–3 days after cardiopulmonary bypass.[12] There is uncertainty about the clinical significance of pyrexia occurring subsequently; the fever may be due to chest or urinary tract infection rather than wound sepsis.[12,13]

We did not give scores at weekends but this did not alter the comparison of the scores since operations were performed throughout the week on patients randomly allocated to each prophylaxis group.

RESULTS

The wounds of 250 patients were assessed in the first year of the trial. 210 (84%) showed satisfactory healing, 20 (8%) had disturbance of healing, and 11 (4·4%), 3 (1·2%), and 6 (2·4%) had minor, moderate, or severe wound infection. Typical examples of the use of the score are given below.

Patient 1.—4 days after a coronary artery bypass graft operation, a 66-year-old man had erythema and serous discharge on the lower 10% of the sternal wound and erythema of 40% of the leg wound in the thigh. The condition of the sternal wound changed little over the next 3 days but erythema spread to involve 60% of the leg wound and serous exudate (20%) was noted on the 7th postoperative day. The five daily scores were thus 0, 2, 2, 1 (no erythema), 2 for the sternal wound and 0, 3, 4, 4, 6 for the leg wound, making totals of 7 and 17, respectively. *Enterobacter* and *Klebsiella spp* were isolated from both sternal and leg wounds (10 points each wound) and the inpatient stay was prolonged (5 points each wound) but no further treatment was required. The total sternal wound score was 22 (minor) whilst the total for the leg wound was 32 (moderate).

Patient 2.—A 65-year-old man underwent aortic valve replacement without complication until the 5th postoperative day, when a serous discharge was noted from the lower 20% of the sternal wound. Serous exudate, erythema, and pus were noted on 20%, 10%, and 5% of the wound, respectively, on the next day and on 10%, 20%, and 5% of the wound on the seventh day. The daily scores were thus 0, 0, 2, 5, 5, giving a total of 12 points. A coagulase-negative staphylococcus was isolated from the exudate (10 points) and the patient was treated subsequently with oral flucloxacillin (10 points) because of a clinical impression of cellulitis. The final wound score was 32 points, which represented a moderate infection.

DISCUSSION

Definitions of major and minor wound infections in cardiac surgery[14-18] vary in the criteria used. Moreover, the criteria often consist of mixtures of subjective or non-quantifiable observations, making comparisons between trials impossible. Wells, Newsom, and Rowlands[19] improved on this by grading wounds 1 for normal healing, 2 when they were inflamed and had some exudate, and 3 when they were breaking down and had purulent exudate. In our 250 patients the frequency of grade 3 wounds according to Wells and colleagues agreed closely with scores of more than 40 (severe wound infection) by our ASEPSIS method. However, those classed as grade 2 were distributed among all four of our remaining classes. Also, they included lesions with a transient serous discharge from a small part of the wound but not erythematous wounds that were not discharging on our designated observation days (1, 3, 7, and 10 days postoperatively). Isolation of a "presumptive pathogen" was required for Wells and colleagues' definition of wound infection but coagulase-negative staphylococci were not counted. In our experience, erythematous discharging wounds yielding coagulase-negative staphylococci may be clinically indistinguishable from those yielding *Staphylococcus aureus* and they should not be disregarded.[20]

TABLE III—DEFINITION OF INFECTION OF THE STERNAL WOUND FOLLOWING CARDIAC SURGERY IN 33 PUBLISHED PAPERS*

Criterion	Number of studies in which criterion: Required	Contributory	Stated separately	Not stated
Purulent exudate	14	10	1	8
Erythema	5	5	1	22
Serous exudate	0	6	1	26
Wound dehiscence	0	8	3	22
Sternal osteomyelitis	0	1	5	27
Bacterial growth	22	9	2	0
Prolonged inpatient stay	0	1	10	22
Reoperation	3	6	12	12
Antibiotic therapy	0	2	15	16
Fever	5	4	5	19
"Clinical impression"	8	1	0	24

*List of papers used to compile this table available from A. P. R. W.

Therefore, in ASEPSIS, the isolation of an organism gives weight to the score but is only one of many features considered. Other indices of the clinical importance in a wound infection, such as length of hospital stay and the need for additional surgical or antibiotic treatment, have helped to make our score less vulnerable to observer bias but have often not been considered in the evaluation of wound infection (table III).

When the frequency of the endpoint event is expected to be low, a significant difference can be missed if the trial is not large enough—the beta error.[21] For instance, in a trial with 110 patients in each treatment group, 5 cases of wound infection in one group and 12 in the other would not be a statistically significant result ($0 \cdot 1 < p < 0 \cdot 2$).[17] To ensure only a 10% chance of missing a significant difference (alpha = 0·05), more than 700 patients would have to be randomised. More sensitive methods of detecting the endpoint—in this case minor degrees of abnormal healing—would improve the power of the trial provided the statistical analysis demonstrates a consistent pattern of major and minor infections between treatment groups.

Our wound scoring system (ASEPSIS) attempts to take into account these points. The final classification of the wound relies upon a large number of small, easily made assessments. This should improve the consistency with which infected wounds are graded and facilitate some comparison between reports from different units and at different times. Although devised for use in cardiac surgery, application in other types of surgery should be possible.

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Occasional Survey

FAMILIES IN WHICH TWO OR MORE COT DEATHS HAVE OCCURRED

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Summary A survey of twelve families with 2 or more cot deaths showed that in two families the deaths were completely unexplained; in three the babies had a probably familial developmental disorder; in two the care of the infants was seriously at fault and could have contributed to death; and in five filicide was probable. 3 of the mothers in the last group were psychologically ill. Detailed pathological and psychosocial investigations are needed in dealing with these deaths and in planning the care of future children.

INTRODUCTION

TWO or three times a year we are contacted by doctors caring for a family in which there has been more than 1 cot death. Usually there is insufficient pathological and clinical information for a diagnosis to be made. We tend to take the most obvious active line—that of recommending apnoea monitors and extra general care for subsequent children. This is not satisfactory. Since 1963, I have come across twelve families in the Sheffield area which have had 2 or more cot deaths, and these families have probably been investigated in more detail anatomically and socially than any others that have been reported. We may be able to learn something by considering these families.

CASE-REPORTS

Family 1.—The first child died at the age of 2 months with an upper respiratory tract infection and an early pneumonitis from which haemolytic streptococcus was grown, but this was considered insufficient to cause death. The second child died 2 years later at the age of 3 months. He had an upper respiratory tract infection, an acute tracheobronchitis, and an acute mastoiditis, but again of insufficient degree to explain death. We were unaware of the second pregnancy in this socially very deprived family. Both the children were registered as cot deaths but earlier and more vigorous general medical care may have influenced the outcome—they belong to our classification group 'B',[1] which includes deaths associated with acute infection in deprived environmental circumstances. It is doubtful whether this family could have coped with any type of home monitoring.

Family 2.—The first baby presented at 8 weeks. Necropsy revealed a mild upper respiratory tract infection and many petechiae in the thymus and lungs. The second cot death occurred in the next child 2 years later at the age of 7 weeks. Again there was a mild infection of the respiratory tract, streptococci were grown, and there were many petechiae. The mother later revealed that she had put her hand over the baby's nose and mouth to stop it crying and she remarked, "It went to sleep but didn't wake up this time". The same had occurred with the previous child. This mother said that she loved children but could not cope with any child that cried continuously. We eventually discovered that she had been under probation in another part of the country for having done the same thing when, as a teenager, she was baby-sitting.

Family 3.—The first death occurred at 3 months, 2 days after a triple vaccine injection. The necropsy findings were almost completely negative. The second death of another son 6 years later at the age of 3 months was quite unrelated to an inoculation, and the necropsy revealed a tracheobronchitis. The home circumstances were good. Both of these deaths were completely unexplained.

Family 4.—The first death occurred at 3 months. The child had achondroplasia and a mild hydrocephalus, and had a small foramen magnum. In retrospect, death, though completely unexpected, was probably related to medullary compression because of the small foramen magnum. The next child, who died 2 years later at exactly the same age, had no clinical achondroplasia but had gross oligonephronia. Other organs from both these children revealed many minimal dysplasias, thus this family probably had some unrecognised multiple organ dysplasia syndrome.

Family 5.—This was a family with 2 previous unexpected deaths, both at the age of 1 month. In the first child pneumonia had been diagnosed elsewhere, and in the other I had identified a considerable amount of bronchopulmonary dysplasia, but the child had not appeared abnormal at birth. The third child died unexpectedly at age 12 days with much hyaline membrane in the lung and a considerable amount of cerebral dysplasia. This child had been born at term and had shown no respiratory distress in the newborn period. This family seemed to have some form of pulmonary dysplasia.

Family 6.—Perhaps this family should not be included in this paper but both babies presented and were registered as unexpected home deaths. The first child died unexpectedly at the age of 2 months and very little was found other than a mild infection at necropsy—death was put down as "cot death". Little over a year later the next child died at 2½ months and a remark by the mother that "He had not lately been holding his head so well" made us look at the skeletal muscle fibres which revealed Werdnig Hoffman disease. Examination of the earlier child's skeletal muscle (collected routinely but put aside for research study) also showed Werdnig

A. WILSON AND OTHERS: REFERENCES—*continued*

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