Cerebrospinal Fluid Research

Poster presentation

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Analysis of twenty-four "failures" of Bactiseal™ antimicrobial shunts reported to FDA

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Background

Shunt infection rates vary considerably depending on patient's age, comorbidities, available follow up facilities and definition of shunt infection, but the rates are generally considered to be unacceptable. Prophylactic antibiotics cannot be shown to make a significant impact, and an antimicrobial shunt has been developed. Approximately 60,000 of the Bactiseal™ shunts (Codman & Shurtleff Inc) have been used worldwide over about 5 yrs. Complications, including infection, are expected to be reported to the Company for notification to FDA. When such a report of infection is received, the clinical data and removed shunt are sent to BRIG UK for investigation. The results of analysis of these reports are presented.

Materials and methods

Infections occurring in Bactiseal shunts were reported on a proforma containing clinical information and sent along with removed shunt components and any supporting material to BRIG, QMC, UK. The shunt components were examined externally and each component (ventricular catheter, valve chamber, peritoneal catheter) aseptically sampled for microscopy and culture. Isolates were tested for MIC to clindamycin and rifampicin (R+C). Clinical data were scrutinized and further information sought from the reporting institution where necessary.

Results

Twenty-four infections were reported (though it is accepted that under-reporting occurred). One was excluded due to lack of data and shunt material. On investigation, 9 were found not to be infected. Of the remaining 14 infections, 2 were due to gram-negative bacilli. In 5 cases, pre-operative CSF infection was present, all due to R+C resistant *Staphylococcus epidermidis*. One case was presumed ventriculitis but showed no growth before or after shunt removal. Two cases had further invasive shunt surgery after the 2-month Bactiseal™ protection period. Two cases were due to R+C – resistant *S epidermidis* contracted at Bactiseal™ shunt insertion and the remaining 2 cases were caused by R+C- susceptible *Staphylococcus aureus* and should have been prevented.

Conclusion

Of the 24 "infections" reported, nine were not infected, only four being contracted during shunt insertion, and these should have been prevented. Audit of shunt infection must include a clear definition as well as "forensic" microbiological assessment to yield accurate data.