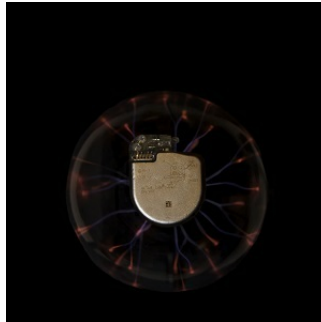

Do defibrillators deliver in dialysis?



Patients who have to undergo dialysis are known to have a higher mortality rate. This is mainly attributed to sudden cardiac death (SCD), which in turn is attributable to arrhythmic triggers including electrolyte and fluid shifts, myocardial ischaemia, and dialysis-induced haemodynamic stress superimposed on a vulnerable cardiac substrate of left ventricular hypertrophy, fibrosis, and autonomic dysregulation.

It has already been established that the risk of SCD is higher in patients undergoing dialysis, compared to those with congestive heart failure. However, dialysis patients have usually been excluded from clinical trials of implantable defibrillators (ICDs) because of competing risks that could potentially lessen the benefit of the device. Also, studies that have previously evaluated the role of ICDs in patients undergoing dialysis have usually found no improvement in survival and high complication rates. Overall, there is very little data available on the utility of primary prevention ICDs in the dialysis patient population. That is why the ICD2 trial (A Prospective Randomized Controlled Trial to Evaluate the Prevention of Sudden Cardiac Death Using Implantable Cardioverter Defibrillators in Dialysis Patients) was conducted to provide greater insight into this yet to be completely understood patient population.

This is the first trial of its kind, of ICDs in patients undergoing dialysis. Study patients were randomly assigned to receive a transvenous ICD or no device therapy and followed for a median of 6.8 years. A total of 188 patients were included in the trial over a 10-year period, after which the trial was terminated. Results showed a cumulative death rate of >50% in both groups, but the incidence of SCD was 9.7% in the ICD group and 7.9% in the control group. Also, the complication rates were higher in the ICD group and were primarily dominated by infection and lead failure. These results clearly indicate the need to reevaluate our understanding of SCD and the role of ICDs in patients undergoing dialysis.

There could be several different explanations with respect to the failure of ICDs to reduce SCD risk in these patients. It might be possible that the patient population included in the trial had a low risk of SCD. Based on clinical evidence, patients undergoing dialysis have a 25% to 30% risk of SCD, with yearly incidences of 5 to 7%. But in this trial, the proportion of deaths due to SCD in the control group was only 8.8% with a cumulative SCD risk of <2% per year. Also, the fact that patients were from a single European country could also have played a role because intercountry differences can also have an impact on risks and results. Finally, other factors such as age, prevalence of comorbid diseases, underlying renal disease, and racial/genetic status, also contribute to survival along with differences in weekly dialysis duration, vascular access type, and management of comorbidities. Also, the fact that 30% peritoneal dialysis patients were included could impact the results because these patients have a relatively lower risk of SCD. We should also not dismiss the possibility that the estimate of the proportion of deaths attributable to arrhythmia could be incorrect, or that these patients may have had SCD but the device may have failed to terminate VT/VF or failed to capture myocardium during fatal bradyarrhythmias.

Overall, the results of the trial show a 27.5% complication rate and a higher than expected rate of lead dislocation, lead malfunction, and a requirement for device explantation because of infection. But the ICD2 trial demonstrates no SCD benefit in patients undergoing dialysis. It is entirely possible that SCD in patients undergoing dialysis could be due to other factors. It is necessary to better understand this issue and further assess whether these patients are likely to benefit from ICD. As far as these findings are concerned, this patient group showed high complication rates and no significant improvement in survival, regardless of implant indication.

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