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ADHERENCE TO PROTOCOL RECOMMENDATIONS FOR CHILDREN WITH WILMS TUMOUR IN TWO CONSECUTIVE STUDIES IN THE UK AND IRELAND – DOES VARIATION MATTER?

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Background and Aims

Wilms tumour (WT) has excellent event-free and overall survival rates. However, those with advanced disease have more variation in adherence to the treatment protocol. We examined the extent of variation and its possible effects on survival

Methods

Retrospective analysis of all children with unilateral WT treated with pre-operative chemotherapy in the SIOPWT2001 (2002–11) and IMPORT (2012–18) studies in the UK and Ireland. Pre- and post-operative treatments (including radiotherapy) were classified as: per protocol (PP); deviation (PDEV) – variation for specified clinical reasons; violation (PVIOL) – not treated within protocol-defined parameters. Survival analysis was conducted by Kaplan–Meier, to calculate 2 and 5 year OS and EFS.

Results

1130 children with WT were registered by 20 centres. 1044 (92%) had unilateral WT treated with pre-operative chemotherapy. All had centrally reviewed pathology. Case Report Forms allowing categorisation of the whole treatment pathway were available for 752 patients. Survival rates for both studies were identical, with 5-year OS 92% and 5-year EFS 86%. For patients with localised disease (Stage I–III) 5-year EFS was 88% for PP (n=402) and PDEV (n=123) and 84% for PVIOL (n=72), corresponding 5-year OS was 96%, 95% and 93%, respectively. For patients with metastatic disease (Stage IV), 5-year EFS was 80% for PP (n=45) and PDEV (n=50) and 83% for PVIOL (n=54), corresponding 5-year OS was 89%, 78% and 90%, respectively. None of these

differences were statistically significant. In SIOPWT2001 33% of PVIOL patients could be categorised as over-treated and 56% as under-treated. In IMPORT, 47% were over-treated and 45% were under-treated.

Conclusions

Variation in adherence to protocol recommendations is more common in Stage IV disease. Whilst variation does not affect 5-year EFS or OS, it comprises both over- and under-treatment, which may affect risks of late effects.

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