

LATE BREAKING NEWS

from the **National Wilms Tumor Study**



Health After Treatment for Wilms Tumor

by Daniel Green, MD

The available data demonstrate that survivors of Wilms tumor in general have fewer late effects from their prior treatment than most other adult survivors of childhood cancer. Those late effects which do occur are rarely disabling or life-threatening. Most recent survivors of Wilms tumor may look forward to many years of adult life with few, if any, treatment related limitations on their activities or potential.

The treatment of children with cancer has become increasingly successful. Approximately 80% of all patients and 90% of those with Wilms tumor survive for 5 years. Successful treatment of children with Wilms tumor, with the exception of those children who have tumors in both kidneys at their initial diagnosis, involves removal of the involved kidney (nephrectomy). Depending upon the presence or absence of tumor spread beyond the kidney,

radiation treatment may be given to part or all of the abdomen. If the tumor has spread into the liver, lungs, bones or other sites, radiation treatment may be given to those sites. All children with Wilms tumor receive treatment using drugs (chemotherapy). About one-half are treated with only two drugs: vincristine and actinomycin D. Most of the remaining children are treated with these two drugs and an additional drug, doxorubicin.

The National Wilms Tumor Study Group has tracked the health of the participants in its studies since their inception in 1969. However the published evaluations have been limited to very specific conditions, including kidney function, heart function, growth and new cancers. A recent publication from the Childhood Cancer Survivor Study (CCSS) which has evaluated a cohort of approximately 14,000 five or more year survivors of various childhood

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cancers, including Wilms tumor, indicated that almost one-third of the participants reported at least one severe or life-threatening condition and that by 30 years after diagnosis, approximately 40% reported a severe, disabling or life-threatening condition or death.

Approximately 20% of the adult survivors of Wilms tumor in the CCSS reported a severe, disabling or life-threatening condition or death by 30 years after diagnosis.

The available data demonstrate that survivors of Wilms tumor in general have fewer late effects from their prior treatment than most other adult survivors of childhood cancer.

Commonly reported conditions in survivors of Wilms tumor included legally blind or loss of an eye (associated with absence of iris as in WAGR syndrome) (1.6%), hypertension, not on medication (6.1%), hypertension, on medication (3.4%), pulmonary fibrosis, not on oxygen (2.4%), surgery for intestinal obstruction (6.6%),

recurrent bladder/kidney infection (11.9%), decreased sense of touch or feeling in hands, fingers, arms, or legs or prolonged pain or abnormal sensation in arms, legs, or back (8.8%), and ovarian failure (4.8%)¹.

A study of 1362 long-term survivors, including 189 with Wilms tumor, evaluated at the Emma Children's Hospital in Amsterdam, the Netherlands demonstrated that survivors of Wilms tumor had the highest frequency of no adverse events (29%). Fifty percent had a medium adverse events burden (one or more moderate or one severe condition)². ■

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LATE EFFECTS CLINICS

Dr. Green's article gives us an excellent occasion to remind participants about the availability and purpose of late effects clinics. We wrote about these clinics in the 2007 newsletter. Since then we have received many inquiries from families and participants looking for knowledgeable medical care. We believe we should again emphasize the importance of these facilities which provide access to such care.

These clinics are designed to provide specialized care to survivors of childhood cancer. Each clinic is different; some see adult survivors and some do not. To find a clinic in your area you can go to the website of the Children's Oncology Group: www.childrensoncologygroup.org. Please click "Late Effects Directory of Services" to access this resource. We have also found an excellent explanation of these clinics on the website of the Candlelighters Childhood Cancer Foundation: www.candlelighters.org/treatmentfollowupcare.stm. We encourage you to visit these websites. If you do not have access to the internet, please call us and we will assist you.

Please know that our office continues to be a resource for you. If you or your physician would like to consult a physician associated with our study, please send us an email at nwtsg@fhcrc.org or call the NWTS Project Manager Pat Norkool at 206-667-4843. ■

The National Wilms Tumor Study

A 40 Year Perspective

by Giulio J. D'Angio, MD

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INTRODUCTION

The nephroblastoma, a malignant neoplasm of the kidney, is seen mostly in children. It was first accurately categorized as a mixed tumor by the German surgeon, Max Wilms in 1899.¹ This was a major contribution to the understanding of the nature of the growth, and it has since been universally known as Wilms' tumor (WT) in acknowledgement of his work. It is one of the most common solid (i.e., not leukemic or lymphomatous) malignant neoplasms of childhood.

The 5 year overall survival for children with cancer was less than 20% in 1950. It's now 75-80%.

The first clinical advances were made by pioneering surgeons.² They developed safe surgical procedures and anesthesia, and better pre- and post-operative care, so that

the operative mortality dropped from 25% to near zero. This encouraged attempts at surgical removal, and the survival rate slowly rose in the early 1900's from zero to about 25%. Routine post-operative radiation therapy (RT) was added and was credited with the almost 50% survival rate in the mid century reported by the Boston Children's Hospital group.²

The next major advance came with the discovery of two anti-cancer drugs that were effective against the WT: dactinomycin (AMD) and vincristine (VCR).³ Outcomes rose to the 70-80% range when chemotherapy was added routinely to surgery and RT. Moreover, it led to a major step forward in cancer care. That was the welding of the multimodal cancer team; that is, the surgeon, radiation therapist and chemotherapist working in concert for every child with a malignant tumor.³ Multi-modal teamwork within the ambits of cooperative clinical trials has been the core ingredient responsible for the notable progress made in pediatric oncology in the last 50+ years.^{2,3} The 5 year overall survival for children with cancer was less than 20% in 1950. It now is 75-80%.³

Not every WT patient is the same. Some arrive with localized disease; in others, the cancer has already spread to other organs.^{4,5} As successful therapy evolved in the 1950's and 1960's, it became obvious that treatments of differing intensity were indicated for these subsets. For example, was routine RT really needed for children with totally excised WTs? At the same time, it was becoming clear that what had been termed "variants" of WT were perhaps entirely different from WT, and not variants at all. Bolande et al.⁶ described the mesoblastic nephroma, an essentially benign tumor that was curable in most children when totally excised. Two other distinct entities were added in 1978 with both histopathologic and clinical features that are different from Wilms tumor.

One of these is the rhabdoid tumor of the kidney (RTK).⁹ It is a rare, highly aggressive tumor that is more commonly encountered in very young children. It often spreads to the brain, a rare site of secondary deposits for Wilms tumor. The second different malignant renal neoplasm is what has come to be called the clear cell sarcoma of the kidney (CCSK). This lesion, unlike Wilms tumor, tends to metastasize to the bony skeleton, as emphasized in the nomenclature used in the report by Marsden et al., but the brain and lung are also frequent targets.^{9,26}



METHODS

None of the then-extant American pediatric oncology cooperative clinical trial groups — let alone any single institution — collected enough WT patients each year to answer these pressing clinical and biologic questions. The annual incidence is about 8 per million children in North America under the age of 16; thus, only 400 or so new patients with WT were seen in all the USA and Canada every year during the 1960's.⁷ It was obvious every WT patient in N. America would need to be made available for comprehensive study. Only in that way could enough children be stratified into the appropriate sub-groups required to answer these and other outstanding issues. The separate cooperative groups therefore agreed in 1967 to pool their pediatric patient resources into the first inter-group clinical trial, the National Wilms Tumor Study (NWTS).⁸ A steering committee was brought together. It included not only pediatric surgeons, urologists, oncologists and radiation therapists but also a pathologist, Dr. J. Bruce Beckwith, and a statistician/epidemiologist, Dr. Norman E. Breslow. It was probably the first time that representatives of these two critically important disciplines were included in the decision-making committee of a clinical cooperative trial on a par with their clinical colleagues. Their voices thus were heard, and their judgment and guidance contributed greatly to the sound planning of all the multi-faceted research that ensued in subsequent decades.

One of the fundamental questions was whether the intergroup mechanism was feasible. Not only did it call for cooperation and coordination among the multiple medical disciplines involved but also among the multiple administrative centers of the individual centers and groups. It was by no means clear that such an organization could function smoothly, efficiently and effectively.

It is therefore of interest to turn to the prospectus of the NWTS.⁸ The objectives of the research were listed (and paraphrased here) as:

1. To establish the best treatments for Wilms tumor stratified according to extent of disease.
2. To study the nature and biology of the renal tumors of childhood.
3. To gather information regarding possible genetic correlates.
4. To determine whether the intergroup mechanism was feasible.

Added to these from the beginning was a plan to accumulate data on long-term survivors. This was so that the late untoward consequences of pediatric cancer therapies could be catalogued and studied, and an appropriately designed form was included in the trial documents for NWTS-3, launched in 1980.^{10,11,12}

RESULTS

The first patient was enrolled in August of 1969; since then, the NWTS has successfully fulfilled its mandates as detailed below. First, the intergroup model proved to be feasible and successful. It was subsequently employed to study other childhood cancers; e.g., soft tissue sarcomas.³ Moreover, the nature and biology of pediatric kidney tumors has been clarified.⁹ There are 2 two forms of Wilms tumor *per se*. These are the so-called favorable histology type, which has a better outlook, and the anaplastic form, which is more resistant to radio-chemotherapy. Here, the focus will be on Wilms tumor because it makes up about 85% of all the renal tumors of childhood.

The rare RTK and CCSK have their own patterns of clinical behavior and response to therapy. The 5 clinical trials, some employing a factorial design (Fig. 1), mounted in the last 4 decades have shown the following:

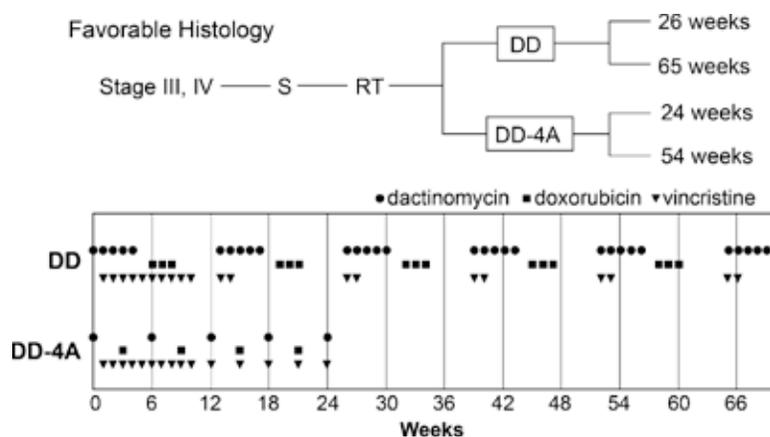


Fig. 1, Top panel—Treatment randomizations for patients with favorable histology tumors at an advanced stage (Stages III and IV) entered on National Wilms Tumor Study-4. S=surgical removal; RT=radiation therapy. See bottom panel for drugs in regimens DD and DD-4A. **Bottom panel**—The two regimens plotted to dramatize the number of clinic visits per treatment course and duration of treatment. Note that A and D were administered in 5 daily doses and 3 daily doses, respectively, not weekly as depicted. Duration of treatment for the standard course (DD) was 65 weeks that included 45 visits for A and D. The DD 4-A regimen adopted for NWTS-5 takes 24 weeks requiring only 9 visits for those 2 agents. All vincristine infusions entailed a single visit with or without concomitant A or D on the same day, as shown.

1. The combination of the 2 drugs, dactinomycin (AMD) plus vincristine (VCR), forms the building block of therapy.¹⁰
2. The addition of doxorubicin (DOX) to AMD + VCR in patients with more advanced disease provides better protection against relapse.^{11,12}
3. RT is not needed for children in whom the tumor is localized and is totally removed.^{11,12}
4. RT, when needed in multi-modal care, can be used effectively at much lower doses than those given in the past.^{12,13}
5. Chemotherapy can be given in single dose courses rather than multiple daily doses.^{13,14}
6. The total treatment time can be reduced from about 15 months to 24 weeks.^{13,14}
7. Certain histologic and molecular genetic configurations within the tumor cells are associated with a more ominous outlook.^{9,15}



DISCUSSION

These results are especially gratifying, remembering the rallying cry of pediatric oncology: “Cure is not enough”.¹⁶ A child of 3 cured of childhood cancer must not suffer at age 13 or 30 — or 60 for that matter — from the deleterious delayed consequences of the curative but toxic treatments employed.^{17,18} These late effects can include (A) failure to grow and develop normally, (B) delayed but incapacitating if not lethal treatment-induced changes in the lungs, liver, heart and other vital organs, (C) impaired fertility and mental acuity, (D) gestational difficulties, and (E) therapy-associated second malignant neoplasms.¹⁷⁻²¹ The NWTS has contributed to the long-term well-being of the cured child by reducing the amount, the intensity and the duration of the toxic treatments employed. This has had beneficial socio-economic consequences as well. The fourth NWTS was designed with these specific considerations in mind. The number of chemotherapy symbols, each entailing a clinic visit, and the number of courses by strata seen in Fig.1 must be viewed from the perspective of the parent—usually the mother—with other children at home. Baby sitters must be hired, or the siblings need to be taken to a cooperative relative or neighbor, or one of the parents must stay at home for the treatment days and thus miss those days’ work. Many other equally trying alternatives can readily be envisaged. There are also the daily out-of-pocket expenses for train or bus fares, or even more costly taxis, in getting the child to the treatment facility: If driving, bridge and highway tolls, gasoline costs, and parking fees must be met. Clinic visits only once a week rather than 5 days running, and for 24 weeks instead of 65 is a socio-economic and psychologic boon for the family. And for the hospital staff, too: less crowded waiting rooms, fewer drugs to be prepared and administered, more time with patients who need attention.

Study results showed that the shorter courses were not only less toxic but that they also saved more than a million dollars of therapy-related and out-of-pocket expenses a year, even for this rare tumor of childhood.¹⁴ Most important, the excellent survival rates were not compromised.

It is an interesting example of how the clinical trial mechanisms can be used for other types of research: in this case health care delivery. The NWTS has also investigated protocol design modeling, and in a novel use of stored data, validated a proposed modification in patient stratification criteria.^{22,23}

THE FUTURE

The NWTS as a clinical trial group no longer exists because the individual pediatric oncology research units were consolidated in 2001. However, the valuable and productive Late Effects Study (LES) still functions as such under the able surveillance of Dr N. E. Breslow. The need to collect information concerning the health status of long term survivors was recognized from the inception of the NWTS. That need was formalized in 1980 by the inclusion of appropriate data-gathering forms among the third NWTS documents.¹² More than 9000 patients are in long-term follow-up in the LES. It should therefore be possible to ascertain whether the modulations of therapy in the several NWTS trials have mitigated the delayed adversities of therapy; and if so, by how much.

One of the notable findings so far reported by the LES has to do with the renal failure that develops in some long-term survivors when adolescents or young adults. In them, the kidney dysfunction is linked to a defect in the Wilms tumor suppressor gene WT1. That deletion is associated with the development of severe genito-urinary malformations as well as Wilms tumor. These findings are important in themselves, but they also show the importance and need for decades-long follow-up of survivors.²⁵

The clinical work of the NWTs is being carried forward by the Renal Tumor Committee of the Children's Oncology Group, the single entity that was formed from the amalgamated pediatric groups. That committee, which includes several members of the defunct NWTs Trials Group, faces daunting tasks in study design. Small numbers of patients in sub-sets, and survival rates of better than 90% are major impediments to standard methods like concurrent control vs trial arm randomization. Given these stringencies, one might be tempted to use past clinical results as controls for the study of new strategies or drugs. Doing so can yield misleading conclusions. This is true even when dealing with only one change in the treatment of children suffering from a tightly circumscribed entity like WT. It concerns a single organ—the kidney—treated by the same group of cooperating institutions using the same basic modalities. This was shown in a thought-provoking analysis by Farewell *et al.* dealing with concurrent vs simulated control samples derived from past NWTs data files.²³

Further, should better relapse-free survival (RFS) or better over-all survival (OS) be the criterion on which to judge success? It may be possible to improve the short-term RFS rate by adding agents that are more toxic in the long run to those used in a relatively innocuous competing regimen. Should that be the focus even though the OS outcomes of the two methods are similar? Breslow has discussed these issues in a recent publication.²⁴ Even more fundamental is the realization that the standard Phase I→II→III method for testing new agents and advancing them to trial in WT patients is no longer feasible because of the constraints listed above. These are some of the challenging problems facing biostatisticians to-day.

CONCLUSION

The two-year survival rate for Wilms tumor over the last 100 years has been an ever-upward curve, starting at zero at the turn of the last century and approaching 100% as this one starts (Fig.2). That is gratifying, of course, but is only part of the story. The late untoward effects of some therapies remain a problem. There is still work to be done in (A) finding ways to validate the results of clinical studies under great stringencies, and (B) identifying non-toxic treatments, refining regimens and paring them down to the minimum needed for cure, because—indeed—**CURE IS NOT ENOUGH. ■**

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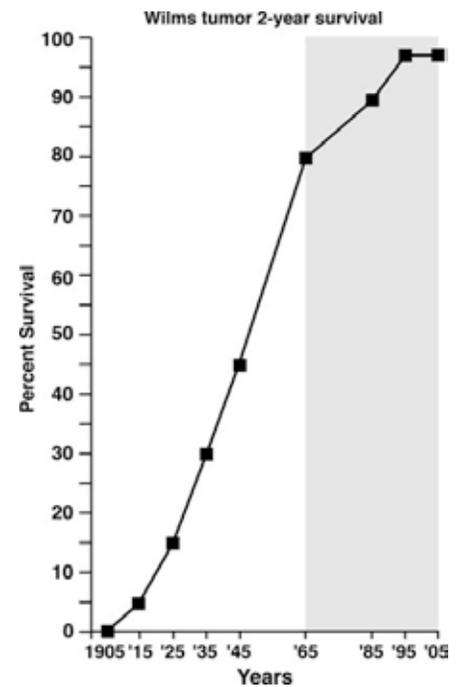


Fig. 2—Two year survival rates over a 100 year period, those up to 1965 derived from published data from the Boston Children's Hospital. Thereafter (the shaded area) from the NWTs

HOW HAVE ADULTS TREATED DECADES BEFORE FOR WILMS TUMOR HELPED IN THE BATTLE AGAINST THAT DISEASE?

The Staff of the NWTS Late Follow-up Study are sometimes asked whether information about treatment for patients diagnosed before the advent of the NWTS has been of any help. The answer is, "Yes". For example, in 2008 we were contacted by Rose Kania, whose daughter, Suzanne, was diagnosed and treated in 1957. Suzanne recently died following many years of late effects health problems related to her treatment, which included a much higher dose of radiation therapy than would be given today. We would like Rose to know that Suzanne and others treated before the advent of the NWTS did indeed contribute to progress in the treatment and survival of children diagnosed with Wilms tumor.



The very first NWTS clinical treatment protocol was designed to establish if radiation therapy (RT) could be omitted in the management of Wilms tumor with early stage disease. This question was asked because of the information physicians learned regarding the health status of long-term survivors, such as Suzanne. Similar questions were raised concerning the late effects of the various drugs employed before the advent of the NWTS. These agents included dactinomycin and vincristine. Young men and women so treated did not appear to develop any long-term secondary effects from these agents. The NWTS trials were therefore built on those 2 anti-cancer drugs. Each of the next four NWTS clinical trials protocols built upon information learned in previous studies and from information regarding long-term survivors treated before the establishment of the NWTS. Thus, information gathered from adults treated successfully 40 or 50 years ago helps to-day's children—and will continue to help those born tomorrow. We all owe the long-term survivors of early treatments immense gratitude. ■

Reappraisal of Sports Participation in Patients with a Solitary Kidney

by Michael Ritchey, MD

In our 2006 newsletter, we reviewed restrictions on sports participation in children with a solitary kidney following surgery. The American Academy of Pediatrics (AAP) has published recommendations regarding sports participation for children with a solitary kidney. [1] They state that children need individual assessment for contact, collision, and limited-contact sports. They do not recommend participation in boxing and suggest only a limited amount of body checking for hockey players 15 years and younger. Sports identified as high contact/collision potential include football, martial arts, rugby, rodeo, basketball and wrestling. Several recent publications have questioned the need to restrict participation in contact sports.

The vast majority of renal injuries in children and adults are due to motorized vehicular accidents and are not sports related.[2] Dirt bikes and all terrain vehicles now comprise a much greater proportion of pediatric renal trauma cases.[3] Grinsell et al found an incidence of serious sports related kidney injury of 0.4 per million per year from all sports.[4] The most common sports injuries were due to cycling, followed by skiing, soccer, football and horseback riding. Loss of a kidney due to trauma was far more common with skiing, cycling, horseback riding and soccer than football. Of interest, bicycling is considered a limited contact sport by the AAP. Sports related injuries in children with a solitary kidney are very rare, but this is likely due to the rarity of this condition.

In summary, data to support restricting participation in contact sports such as football for patients with a single normal kidney are rare. Patients should be educated regarding the risk of renal injury during participation in other activities, notably cycling. Although the risk of renal injury from sports is low, children with a solitary kidney who participate in contact sports should consider commercially available protective equipment. ■

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Breastfeeding Survey

Some of our participants who are now mothers received a breastfeeding survey in early 2006. We thank everyone who completed the survey and know that most of you are wondering what we did with the results. Shortly after we mailed the survey we received notice that our funding was being reduced. This resulted in laying off three valuable staff members and curtailing some of our activities. The breastfeeding survey had to be put on hold. We apologize for this long delay and hope that you will understand our situation.

Fortunately, we are now able to revive this project, which will be improved by the comments we received from respondents to the first survey. We received some valuable suggestions about how to make the form better and more efficient. Thanks for helping to produce a friendlier and more useful survey.

It is clear from comments from many respondents that this is an important subject. We certainly hope to be able to provide answers.

This year we will send out these new and improved surveys. A copy of the breastfeeding form and of the Pregnancy Questionnaire are both posted on our website if you would like to report your breastfeeding experience(s) or report a pregnancy you have not already reported to us. We greatly appreciate your contributions to the study and any information or advice we can share with your fellow participants. ■



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