
CTS Collaborative Transplant Study

Newsletter 4:2000

December 1, 2000

The new **center-specific analysis** function is a resounding success. Most participating centers have already used this option which allows comparison of a center's own results with the overall CTS data. Except for the often-expressed desire to have exact survival statistics presented together with the survival curves, we received uniformly positive comments. The statistics issue has already been resolved. As of now, you can retrieve **statistical data including p values** from the website. This will enable you to use your own center's results for publication. The validity of certain findings that may become apparent in your own center's data can now easily be assessed.

In order to provide for more **flexibility**, the computer program has been modified in such a way that you can request the **time interval** for which your center's analysis should be performed. Should an important change have been introduced at your center (e.g. introduction of new treatment protocols, improved physical facilities, organizational changes), you may want to analyze your data from a certain year onward rather than for the entire 1985-1999 period. Simply **preselect the first and last year** of the chosen analysis period by entering the appropriate digits on the screen.

I would like to address two common problems that can be easily avoided. Be sure to select the correct center-specific access code for the **type of organ** that you would like to analyze. Since the codes are organ-specific, it is not possible to analyze heart transplant results using the kidney transplant key, or vice versa. Pancreas transplants can be analyzed using the kidney transplant key since pancreas grafts are usually done in combination with kidney grafts.

Another point is that **safeguarding the center-specific key(s)** is extremely important. Please understand that, for administrative reasons, we had to decide that **one person at each center** must be responsible for safeguarding the code. Because the code can be changed locally on the screen (e.g. for use of a more convenient password or for disallowing access if someone leaves the team), one person must be responsible for such changes and for keeping the latest valid code in a safe place.

Of course, whenever a change of the password is introduced, all those at the center who should have access to the analysis must be informed. When a code definitely gets lost, the only way to reactivate your access is by contacting the CTS webmaster. The procedure involved is quite time consuming. Therefore we appeal to you to keep a close eye on your access code.

For **PowerPoint users**, there now is an additional two-step download function. Please follow the instructions provided on the website.

We are planning a **complete update of all CTS analyses** for the March 2001 website release. Because we need a couple of weeks for generating the graphics, I would appreciate it if your **clinical follow up returns** could be mailed for arrival in our office by

February 10, 2001

at the latest in order to provide you with the most up-to-date results. Thank you for your understanding and cooperation!

The **Steroid Withdrawal Study** has been continued and we are now able to provide you with the **four-year analysis** results. To refresh your memory, these are patients who were clinically stable at the time of steroid tapering and who fulfilled the entry criteria of the CTS steroid project. All patients had been on steroids for a minimum of 6 months posttransplant.

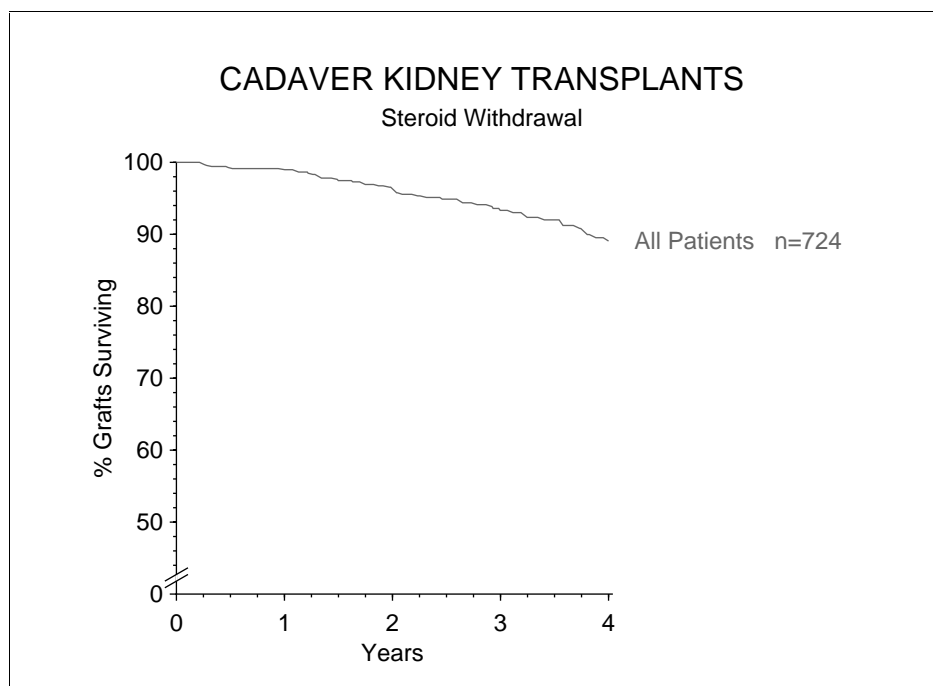


Figure 1

Figure 1 shows the survival rate of **724 cadaver kidney grafts**, calculated **from the time of steroid-tapering**. Four years after steroid withdrawal, **90%** of the patients continue to have **functioning grafts**. This high success rate exceeds our expectation. Converted to semi-log scale, the data show a 21.4 year half-life for these transplants, an excellent result by all standards (Figure 2).

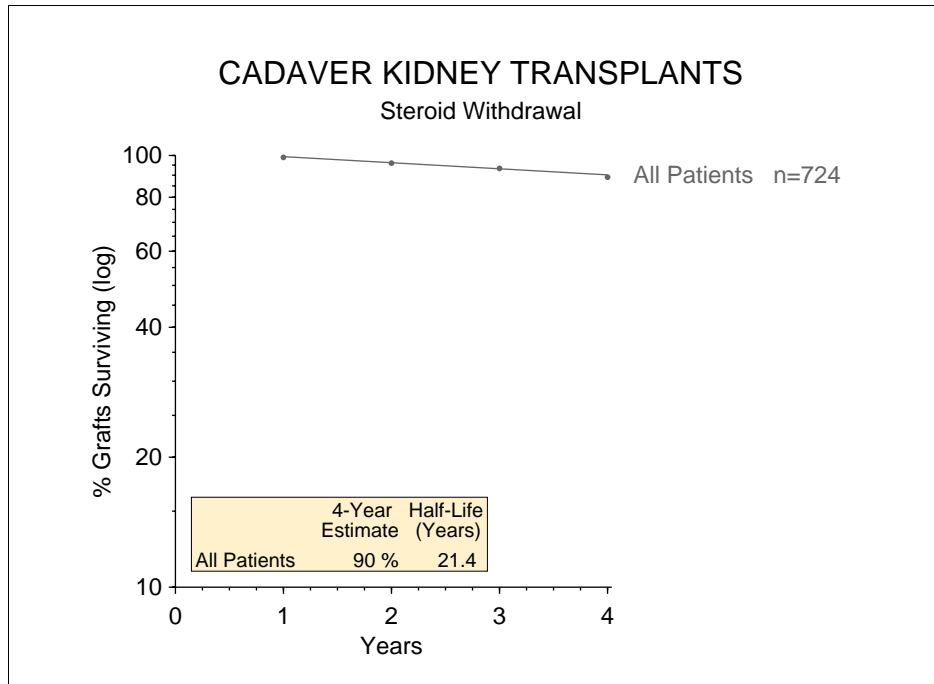


Figure 2

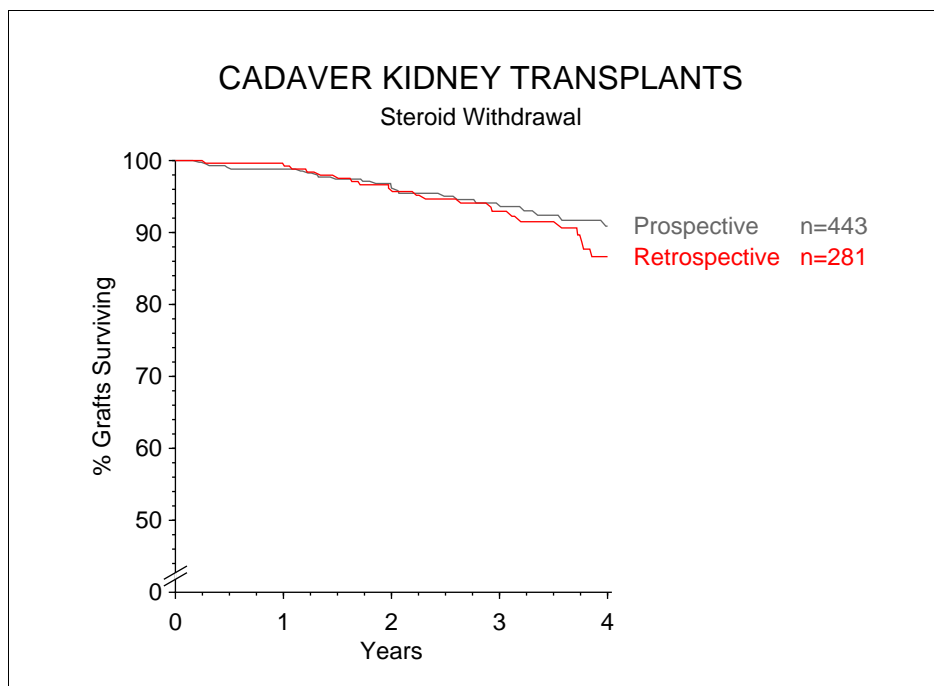


Figure 3

Because not all patients were registered “prospectively” for this special study, we performed a separate analysis for patients who met the stringent prospective criteria, comparing them with those whose enrollment forms reached us some time after steroid-tapering had been initiated. “Retrospectively” registered cases might have had an advantage because a possibility of exclusion existed. However, the analysis clearly shows that **no undue exclusion** process took place. The survival curves for the two groups are statistically not different. The decline observed during the last three months of observation in the “retrospective” group is statistically not relevant (Figure 3).

A parallel analysis of heart transplants shows a similar gratifying result. **364 heart recipients** enjoyed an **88% success** rate four years after entering the steroid-withdrawal study (Figure 4). This result is a mirror image of the kidney transplant result. The associated half-life computation shows a 20-year half-life time (Figure 5).

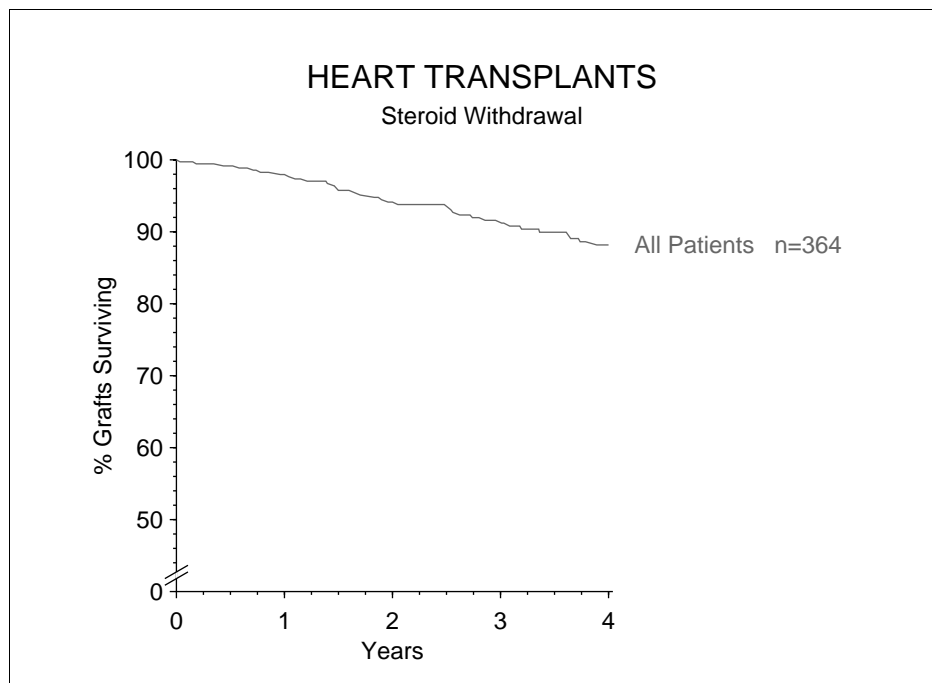


Figure 4

Altogether, these results show - in an impressive series of more than 1000 patients - that **steroid-withdrawal can be successfully done**, at least as evaluated after a **four-year follow up**. In addition to emphasis on long-term follow up, we are continuously **enrolling new patients**. The CTS retrospective data do not indicate that steroid-free patients exhibit increased failure rates after five or more years of follow up. However, since the critical point raised by the Canadian study was that graft function might deteriorate after five years or more, it is very important to **continue the study**. Even in the unlikely case that deleterious effects should appear during the fifth or sixth year, newly enrolled patients whose steroids are discontinued now could theoretically be put back on steroids well before adverse effects occur.

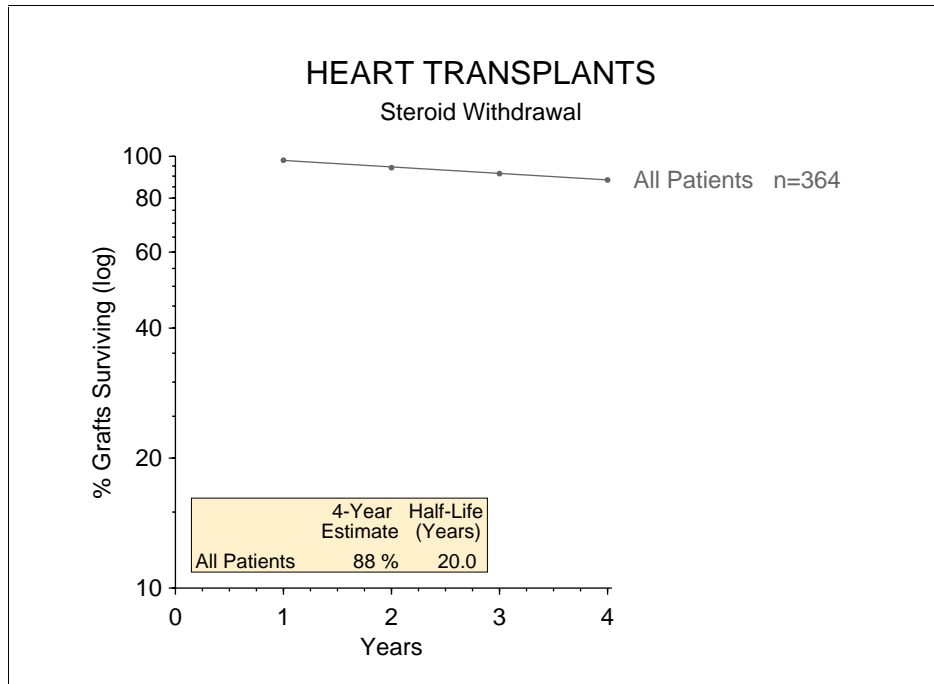


Figure 5

By **enrolling your patients** in the prospective steroid-withdrawal study you will opt for an immunosuppressive protocol that is most likely associated with a **benefit for your patients**, and you will contribute to **solidifying** the eventual message resulting from this large multicenter study. Enrollment forms are provided with this mailing.

The **“Cancer Confirmation Questionnaires”** have been returned by a good two-third of all centers. Your cooperation in returning your update together with the completed questionnaire **before the end of the year** will be highly appreciated. We will send reminders to the remaining centers in January. Thank you very much for your support.

Would you please be so kind and check that the **address** indicated for your center on the CTS **website is up-to-date**. Changes in staff, phone numbers or e-mail addresses sometimes make it impossible to contact centers via the web address. **Notification of changes** can be sent by e-mail to the webmaster or to me personally.

The CTS continues to be an impressive example of selfless international cooperation in the interest of transplantation science. Within a short time, the CTS website has become the **worldwide primary information source** for results on organ transplantation.

Thanks are due to each individual person who has contributed!

On this positive note, I would like to wish you a peaceful and quiet holiday season.

With all good wishes for the year 2001

Sincerely yours,

Gerhard Opelz