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# Five Years Experience with Recombinant Human Growth Hormone Treatment of Children with Chronic Renal Failure

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## Five Years Experience with Recombinant Human Growth Hormone Treatment of Children with Chronic Renal Failure

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### ABSTRACT

11 males, aged 2.5-16.3 years ( $6.8 \pm 4.1$ ) with growth retardation (Standard Deviation Score - SDS  $> -2.00$ ) consequent to chronic renal failure (CRF) received recombinant human growth hormone (rhGH) for 18 to 60 mo ( $40.9 \pm 15.4$ ). Growth velocity (GV) increased from  $5.4 \pm 2.2$  for the year prior to rhGH to  $8.9 \pm 1.6$  ( $p=0.00001$ ),  $7.4 \pm 1.7$  ( $p<0.03$ ),  $7.6 \pm 1.6$  ( $p<0.006$ ),  $6.5 \pm 1.0$  ( $p<0.05$ ) and  $7.5 \pm 1.3$  ( $p=NS$ ) cm/yr following 12, 24, 36, 48 and 60 mo respectively of treatment. The mean SDS for height decreased from  $-3.21$  at baseline to  $-0.85$  at 60 mo ( $p=0.0004$ ); 7 of 8 pts treated for  $>36$  mo had a SDS more positive than  $-2.00$ ; 3 reached the 50th percentile on the growth curve. In 2 patients the dosage was doubled to achieve the increase in GV; in one patient it took 5 yrs to reach a SDS more positive than  $-2.00$ . A significant increase in weight gain and mid-arm muscle circumference over baseline values were indicative of the anabolic effect of rhGH. The mean increase in bone age was similar to the increase in chronologic age; the delta bone age - delta height age was not significant indicating no loss of growth potential following rhGH. Although 3 patients required the initiation of dialysis following rhGH treatment, the mean calculated creatinine clearance did not decrease significantly. No significant adverse effects were noted. These data indicate that long-term rhGH treatment is effective in improving the GV of

children with CRF and facilitating catch-up growth without loss of growth potential.

### INTRODUCTION

Based upon studies in the uremic rat model demonstrating that supraphysiologic doses of heterologous growth hormone (GH) could improve the growth velocity of growth retarded rats /1/, a phase I study was initiated in late 1986 to determine the safety and efficacy of recombinant human growth hormone (rhGH) in growth retarded children with chronic renal failure (CRF).

The initial reports of this phase I study demonstrated a salutary affect on 5 patients following 6 /2/ and 12 /3/ months of rhGH treatment. Subsequent reports which extended the number of patients treated to 9 /4/ and 11 /5/ and the interval of treatment from 12 to 36 months /4/ and 48 months /5/ demonstrated continued improvement in growth velocity with rhGH treatment. This report will detail the course of the 11 children with CRF and growth retardation who received rhGH treatment for periods of up to 5 years.

### PATIENTS AND METHODS

#### Patients

11 males aged 2.5 to 16.3 years were entered into the study. The entrance criteria were as follows:

1. CRF with a creatinine clearance ( $C_{CR}$ ) between 5 and 75 ml/min/1.73m<sup>2</sup> as calculated by the method of Schwartz *et al.* /6/;

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