CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

This study was a randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy and safety of oxymetholone 50 milligrams twice daily in end-stage renal disease patients on maintenance hemodialysis in terms of: (1) lean body mass alteration, (2) the adverse event rates, and (3) to investigate the relationship between change in lean body mass and insulin resistance. It was initiated from June 2006 to February 2007 at hemodialysis unit, The Kidney Foundation of Thailand at Kalayaniwattana building, Priest hospital. The participants were end-stage renal disease patients on maintenance hemodialysis who met the entry criteria. Forty-three eligible patients were randomly assigned equally into the control and study groups. The patients in the control group received placebo 1 tablet twice daily, while the patients in the study group received 1 tablet of oxymetholone 50 mg twice daily. All participants had taken on their assigned medications for 24 weeks. Efficacy and safety were evaluated by anthropometry data, DEXA scan measurement, laboratory data, and patient interviews. Data were analyzed using intention-to-treat analysis with a significant level of 0.05. Descriptive and inferential statistics were used to evaluate data. The conclusions of this study are shown as following:

1. Oxymetholone 50 mg twice daily had a superior effect on changes in body weight, body mass index, and lean body mass measured by DEXA scan, which were statistically significantly different compared to placebo.

2. Change in lean body mass significantly inversely correlated with change in insulin resistance, which inferred that increased lean body mass can result in reduced insulin resistance.

3. The number of patients experienced adverse events were significantly different between patients receiving oxymetholone and placebo. Most of the patients receiving oxymetholone had elevated liver enzymes and decreased HDL-C level compared to baseline, and appeared androgenic-related side effects, especially in female. However, these adverse events returned to normal after discontinuation.

Recommendations

Further studies are needed to evaluate other aspects included:

1. Assessing a quantitative patient's performance task, for example, gait speed, time required to climb a flight of stairs, and time required to stand repeatedly from a chair without assistance because it is expected to be more reliable than self-reported functioning and more predictive of major outcomes or more sensitive to changes over time.
2. Monitoring risk-benefit of long-term administration accompanied with survival rate.
3. Determining the durability of outcomes associated with intermittent therapy whether it can be effective to improve lean body mass.
4. Determining the effect of oxymetholone on regained lean mass and body weight whether they are maintained after discontinuation.
5. Determining effect of oxymetholone on behavioral, sexual functional, and spatial cognitive variables.
6. Achieving anabolic effects of oxymetholone without adversely affecting cardiovascular.
7. Comparing the different oral AAS to identify the highest potent AAS that should be use with less toxicity.
8. Determining the effect of oxymetholone on the immune response due to a previous study in a murine model showing that oxymetholone inhibited production of antibody, whereas, it induced the production of the inflammatory cytokines IL-1β and TNF-α.
9. Using human activity profile to confirm self-reported exercise by individual.