

Chapter 20

General Approach to Evaluating Beneficial and Adverse Effects of CAM Use in Kidney Diseases

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ABSTRACT

This chapter will address the issue of how to evaluate benefits and nephrotoxicity of complementary and alternative medicine (CAM) in chronic kidney disease, dialysis therapy, kidney transplantation, and urolithiasis. Serum creatinine, proteinuria and estimated glomerular filtration rate are standard parameters to assess kidney function. Serum creatinine is used in evaluating acute kidney injury, which is the most common nephropathy from using herbal medicine. Assessment of electrolyte imbalance and urolithiasis is included in this chapter. The modified Naranjo algorithm has been proposed as a way to evaluate renal adverse effects of herbal medicine due to a lack of disease-specific causality assessments in herbal use. Measurement of humanistic outcomes is mentioned in this chapter. The SF-36 is commonly used in evaluating quality of life in CAM users and patients with kidney diseases. The MYMOP2 is to assess individual's symptoms in CAM use and might be used in this population.

INTRODUCTION

Efficacy and safety of CAM on the kidneys are required to be investigated by clinical trials. This chapter will explain the principle of evaluating the benefits and adverse effects of CAM use in patients with kidney diseases, relating to conditions that include chronic kidney disease (CKD), dialysis therapy, kidney transplantation, and urolithiasis. Benefits from CAM will be measured via clinical outcomes, such as slowing the progression of CKD, preventing allograft rejection, improving CKD complications, and providing kidney stone relief. The progression of CKD is measured using an estimated glomerular

DOI: 10.4018/978-1-5225-7122-3.ch020

filtration rate (eGFR). Benefits from CAM are not only seen in clinical outcomes, but also humanistic ones. Humanistic outcomes are defined as an individual's perspective on symptom relief, health-related quality of life, and health satisfaction (Skena, 2000). These outcomes have been measured in conventional medicine since the 20th century. Current evidence reports that conventional medicine is likely to improve the quality of life in patients with CKD (Travers et al., 2013). Patient-Reported Outcomes Measures (PROMs) are the current tool to measure humanistic outcomes (Refolo et al., 2012).

This chapter will explain how to assess potential renal adverse events associated with herbal and dietary supplements (HDS), whilst nephropathy of CAM will be addressed in Chapter 7. Common nephropathy related to herbal medicine and dietary supplements are acute kidney injuries (AKI), electrolyte imbalances, and urolithiasis. AKI is an abrupt reduction in kidney function measured by a rapid decline in glomerular filtration rate occurring over a period of minutes or days that results in the dysregulation of extracellular volume, waste products and electrolytes. The clinical spectrum of AKI can be attributed to any process that interferes with the renal structure or its function such as hypovolaemia, toxic drug induced renal tubular injury, acute glomerular renal diseases, acute interstitial nephritis or obstructive nephropathy (causing urinary blockage). Measurement of nephropathy will be explained in this chapter.

AKI has a significant impact on developing CKD and end-stage kidney disease. There are different definitions of AKI based on Risk, Injury, Failure, Loss of kidney function, and End stage kidney disease (RIFLE) classification (Bellomo et al., 2004), and the Acute Kidney Injury Network (AKIN) classification (Lopes et al., 2013). Each classification has its own advantages and disadvantages. The AKIN classification will be explained in this chapter as it is widely accepted and used. There are no specific tools to assess a likelihood of renal adverse effects related to herbal medicines. The World Health Organisation's Uppsala Monitoring Center causality assessment and the Naranjo algorithm have been globally used for assessing adverse drug reactions (Edwards et al., 2000). However, the Naranjo algorithm may not be appropriate to assess adverse effects of herbal medicines as one category in this algorithm requires evidence to confirm their negative effect. This is often lacking in herbal medicines and dietary supplements (Naranjo et al., 1981). The modified Naranjo algorithm and the World Health Organisation's Uppsala Monitoring Center causality assessment have been proposed to evaluate causal relationships of adverse events involving herbal and dietary supplements (Ide et al., 2015).

BENEFITS OF CAM

Beneficial effects of CAM in kidney diseases are assessed by the use of both clinical and humanistic outcomes. This section will focus on methods of evaluating the benefits of CAM in clinical studies, so this information could guide practitioners and researchers how to conduct studies in this field.

Clinical Outcomes

Chronic kidney disease is defined as a kidney disease with either persisting abnormalities of renal function (longer than 3 months) or structure. Thus, a patient with CKD may present with albuminuria, abnormal urinary sediments, electrolyte abnormalities, a history of kidney transplantation, or abnormal structure on imaging for at least 3 months (Kidney Disease: Improving Global Outcome (KDIGO) CKD Work Group, 2012b). There are four common outcomes that are expected from using CAM. First of all, an ultimate goal of therapy for CKD is a slower progression of CKD measured by eGFR. Estimated

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