DEVELOPMENT OF THE MEDIBEACON TRANSDERMAL GFR MEASUREMENT SYSTEM

Martin P. Debreczeny, MediBeacon Inc.
mdebreczeny@medibeacon.com
Richard B. Dorshow, MediBeacon Inc.
Kate Bechtel, Triple Ring Technologies

Key Words: transdermal fluorescence, fluorescence tracer agent, kidney function, glomerular filtration rate, medical device

Current methods of kidney function monitoring, based on plasma creatinine concentration, suffer from poor accuracy, lack of sensitivity, and potentially long delay times (24-72 hrs) before detecting acute kidney injury. A kidney function monitor is being developed by MediBeacon, based on transdermally measured fluorescence clearance of the novel fluorescent tracer agent, MB-102. After vascular injection, the agent equilibrates into the extracellular spaces of the body and is cleared exclusively by the kidneys, without being metabolized. Plasma pharmacokinetic (PK) analysis of MB-102 compared to the known GFR agent, iohexol, across subjects with a wide range of chronic kidney disease states, has demonstrated the close equivalence (R^2=0.99) of the GFR derived by the two methods. Transdermal monitoring is accomplished using blue (peak □~450 nm) LED excitation to induce green (peak □~560 nm) fluorescence of MB-102. In a pilot study, the full day fluorescent decay kinetics of MB-102 were shown to be directly related to body-size normalized GFR (tGFR). Achieving accurate GFR assessment from shorter time segments is a primary goal, in order to provide near real-time monitoring of kidney function, for example in hospital intensive care units (ICU). The primary interferents to the tGFR measurement are hemoglobin, melanin, and tissue autofluorescence. The focus of the talk will be on the development of several generations of instruments designed to address these challenges, and their performance during clinical studies to date. Business and regulatory challenges faced along the path toward commercialization of this combination device and agent, will also be briefly described.

Figure 1 – MediBeacon Transdermal GFR Monitor and Agent