

Are urinary biomarkers from clinical studies biomarkers of disease or biomarkers of medicine?

Abstract

Unlike blood which is stable because of homeostasis mechanisms, urine accumulates all kinds of changes, some of which will become biomarkers. More and more biomarker researchers will realize urine can be better biomarker source. But most researchers underestimate how dynamic urine is. The changes caused by medications usually neglected when clinical biomarker experiments were designed. Since certain medication is strongly associated with certain disease, the candidate urinary biomarkers proposed from these studies may be from the difference in medication instead of from different pathophysiological conditions. Here I propose a new area, pharmuromics, which studies the effects of medicine on urine. It is part of the foundation for urine biomarker discovery.

Keywords: pharmuromics, urine, medicine, biomarker

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Biomarker is change associated with disease. But blood tends to be stable because of the homeostasis mechanisms of the body. Urine can be a better biomarker source because it accumulates all kinds of changes unwanted for the body.¹ Some of the changes are caused by disease. These changes can be biomarkers. But changes can also be caused by medicine too. Different diuretics,² different anticoagulants³ were found to make different changes in urine proteome. It is very likely that other medications may cause changes in urine too.

When clinical biomarker studies were designed, sex, age, disease stages, complications were usually taken into consideration. But different medicines taken by the patients were usually not. If this difference can be balanced off later in the study, it may not be a problem at all. But what if the disease is strongly associated with a particular medication, and healthy control is strongly associated with no medication, the result of the study may reveal the difference of the medicine instead of the disease. And the effects of disease and medicine can never be separated in the study. Normally and ethically, we can never stop medicine for the patients; we can never give the healthy volunteers medicines they do not need, just for the sake of biomarker study. So the patients-medicine, healthy-no medicine associations exist in all of clinical biomarker studies. It is devastating for the field. Clinical biomarker studies are not cheap. We now have to reevaluate the candidate biomarkers proposed from most of early biomarker studies. We have to rule out the effect of the medicine. This becomes so urgent; it becomes part of the foundation of urinary biomarker study. This is why I cannot wait to propose the pharmuromics (pharm-uro-mics) which studies the effect of medicine on urine. The other parts can probably be named physiouromics, pathouromics which are the effect of a physiological or pathological process on urine.

Even with the effect of medicine, urine biomarker era should not be far away. We can always use animal models to start the discovery study and then to validate in clinical samples.⁴ The confounding factors are almost all balanced off between disease and control. Medicines are not used at all in animal model just like in control. Simplicity itself is a beauty.

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Conflict of interest

The author declares no conflict of interest.

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