それぞれの施設やコホート内での尿検体を用いた研究が進んでいるだけではなく、全体研究であるレジストリーで収集された尿検体をすでに用いて validation が進行している。これも当初の目的であったバイオマーカー開発の基盤研究とレジストリーが融合していることを示し、目的がはたせているものと考える。

同時に、この成果を一般臨床に広く応用させるためには、低コスト・ハイスループットなマルチバイオマーカー測定系が必要となるため、この技術開発も合わせて行っていく予定である。今後も、糖尿病性腎症のより早期かつ特異的に診断し予後予測が可能なバイオマーカー開発の基盤研究を順次進めていく必要がある。

個別研究

①トランスクリプトーム解析

血液を用いた糖尿病病態診断の試み；2型糖尿病患者の肝臓では分泌タンパク SeP の産生が亢進しており、この過剰産生が全身のインスリン抵抗性と高血糖を生じさせている可能性がある。最近になって、サプリメントを通じてセレンを過剰に摂取すると糖尿病発症リスクが高まるとする疫学研究が報告され、セレンと糖尿病の関係についても注目されている。

本研究は、肝臓由来ホルモン「ヘパトカイン」が2型糖尿病の病態形成に寄与していること、ヘパトカインが2型糖尿病を代表とするインスリン抵抗性関連疾患の治療標的になりうることを示唆する。

SeP は autocrine, paracrine として肝細胞に作用し、AMPK のリン酸化を減弱させることで肝インスリン抵抗性を誘導する。SeP の AMPK リン酸化減弱作用は主に AMP 非依存性メカニズムを介すると思われるが、その詳細の解明にはさらなる検討を要する。現在、糖尿病腎症モデルをセレノプロテイン P ノックアウトマウスに導入し、表現型を解析中である。

②エクソゾーム解析

糖尿病によるポドサイトの障害に関して、どのような障害を受けて脱落に至るかは、ヒトでの検討はあまりなされていなかったが、障害を反映して発現の変化するタンパク質群が徐々に明らかになりつつある。ポドサイト障害の分子機序およびそれをとらえる尿中エクソゾーム蛋白のプロファイルの変化が糖尿病性腎症の病期にあわせ、病変の進行を検出しうるマーカーとして有用であると考えられる。

③メタボローム解析

尿サンプルの解析から糖尿病性腎症の各病期に特異的な複数のマーカー群を確認し、糖尿病性腎症の早期診断・予後推測・治療効果予測等を可能とするバイオマーカー検索に有用な手法と考えられる

分科会：糖尿病性腎症の新規治療法の開発

本分科会では、抗老化薬としてのレスベラトロール、CCR2 阻害薬、GLP-1 受容体作動薬である exendin-4、PPAR-γ agonist ならび AGEs-aptamer が少なくとも実験糖尿病性腎症モデルに対する有効性をもつことが見出された。現在、ヒト糖尿病性腎症に対する CCR2 阻害薬であるプロパゲルマニウムの有効性についての臨床研究を検討しており、すでに倫理審査を経て臨床試験が開始されている。

さらに、それぞれの作用機序も徐々に明らかになってきている。たとえば、レスベラトロールの分子機構は、SIRT1 活性化ではなく、抗酸化作用であることを見出した。さらに、カロリー制限がミトコンドリアの代謝を制御している p62Sqstm 発現低下を介して機能改善、腎保護に働くことが判明し、今後、カロリー制限模倣薬の臨床応用が待たれる。今後も、糖尿病性腎症に対す

るこれら新規薬剤の臨床への応用を展開すべく基盤研究の継続が期待される。特に、今後は早期に臨床応用に移行するための前段階試験等を行う必要がある。

E. 結論

本研究において、腎症前期から顕性腎症にいたる幅広い病期の糖尿病性腎症例を対象とし、尿検体の収集を伴う、長期経過観察可能なレジストリーシステムを構築・運用することが可能となった。さらに、本邦を代表するコホートによる事前登録前向き研究、メタ解析、腎生検例による解析から、糖尿病性腎症病期分類の改訂にむけた具体的な提言案と今後の課題を示した。また、バイオマーカーならびに新規治療開発は基盤研究が進行した。いずれも、当初の計画に沿って、独創性、公共性の高い研究を展開しえ、目的を達したものと考える。今後、これらの成果を通じて、本邦における糖尿病性腎症の病態解明、予後改善、有効な治療法開発に向けた総合的なシステム構築につながることが期待される。

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