Medical devices

Novel diagnostic marker to differentiate urogenital carcinoma by chiral amino acids in body fluids

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Project Outline

• Importance of differential diagnosis for patients with urogenital cancers including urothelial carcinoma

Early detection and early treatment are key to improving the prognosis of

patients with urogenital cancers which have been on the rise in recent years due to the aging society. However, for urothelial carcinoma and renal cell carcinoma, there is no simple and highly diagnostic blood. We have been investigating whether

D-amino acids, which are mirror images of L-amino acids and have been thought to have no bioactivity

 Urgent need of non-invasive screening tests for urogenital cancer patients

 Blood test
 Prostate Cancer

 PSA ○
 Urine △
Cytology△

 Urine test
 None

 Diagnosis
 Prostate Biopsy

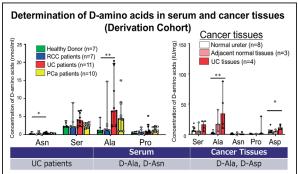
 Prostate Biopsy
 Cystoscopy

 Enhanced CT

in vivo in humans, could be a novel diagnostic marker for urogenital carcinoma.

[D-amino acids are highly expressed in cancer tissues and blood.]

D-alanine and D-asparagine were highly expressed in the serum of urothelial carcinoma patients, while D-alanine and D-aspartic acid were highly expressed in cancer tissues, respectively. D-alanine and D-aspartic acid were shown to have positive effects on cancer cells by increasing their proliferative, invasive, and migratory capacities against cancer cell lines.



[D-Amino Acids as Potential Tumor Diagnostic Agents]

The results showed that the three independent cohorts of 357 samples had high diagnostic performance in common (left figure). In addition, after comparing the

| | Derivation Cohort (n=35) | Validation Cohort 1 (n=254) | Validation Cohort 2 (n=69) |
|--|-----------------------------|--------------------------------|-------------------------------|
| Urothelial carcinoma | n=11 | n=92 | n=21 |
| Diagnostic Ability (AUC) | 0.784 | 0.851 | 0.853 |
| Sensitivity Specificity | 90.9% 66.7% | 78.4% 79.3% | 89.5% 68.0% |
| Youden's index | 0.5758 | 0.5774 | 0.5747 |
| Urine Cytology Sensitivity Specificity | | | 50% 100% |

results with urine samples and examining the possibility of differential diagnosis with renal cell carcinoma, we have succeeded in developing a diagnostic agent using blood D-amino acids to differentiate urogenital cancer, and have applied for a patent for this development.

(Patent Application No. 2023-036041).

Target disease: Urothelial carcinoma, renal cell carcinoma Patent information: Patent application 2023-036041

Characteristics of the technology: Novel blood-based urogenital carcinoma differential diagnostic agent Marketability, challenges in development: Market development through multicenter collaborative research Desired corporate collaboration: Licensing out