北京协和医院
PEKING UNION MEDICAL COLLEGE HOSPITAL

Evaluation of Safety, Biodistribution and Dosimetry of a Long-Acting Radiolabeled Somatostatin Analogue ^{177}Lu-DOTA-EB-TATE with and without Amino Acid Infusion

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Disclosure

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Background

^{177}Lu-DOTATATE is considered one of the most commonly used radiopharmaceuticals for peptide receptor radionuclide therapy (PRRT).

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Phase 3 Trial of ^{177}Lu-Dotatate for Midgut Neuroendocrine Tumors

J. Strosberg, G. El-Haddad, E. Wolin, A. Hendifar, J. Yao, B. Chasen, E. Mittra,

Approved in Europe in September 2017

A. Benson, R. Srirajaskanthan, M. Pavel, J. Mora, J. Berlin, E. Grande, N. Reed,

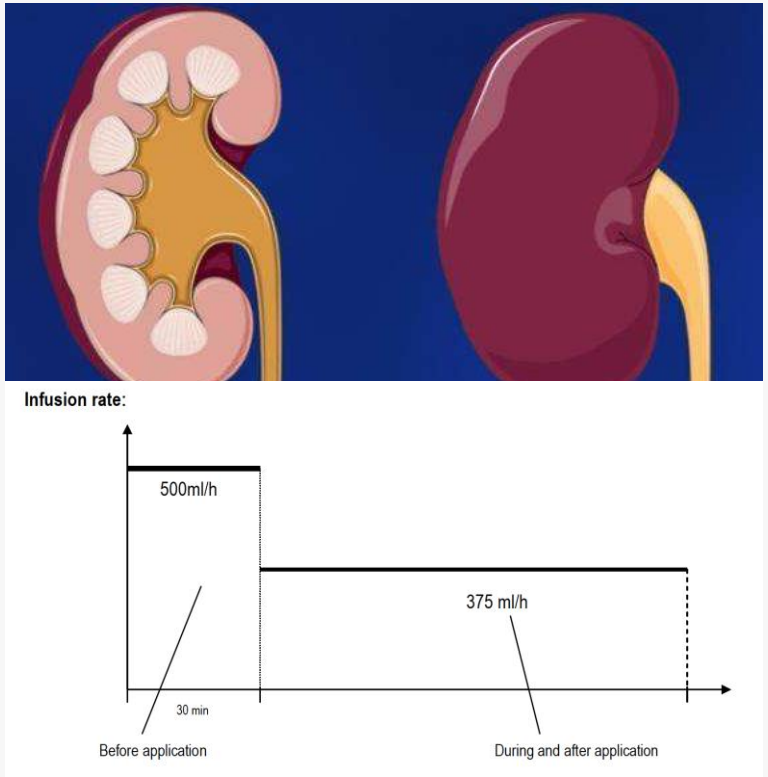
Approved in United States in January 2018

ABSTRACT

BACKGROUND

Patients with advanced midgut neuroendocrine tumors who have had disease progression during first-line somatostatin analogue therapy have limited therapeutic options. This randomized, controlled trial evaluated the efficacy and safety of lutetium-177 (^{177}Lu)–Dotatate in patients with advanced, progressive, somatostatin-receptor–positive midgut neuroendocrine tumors.

Strosberg, J et.al, N Engl J Med. 2017 Jan 12;376(2):125-135

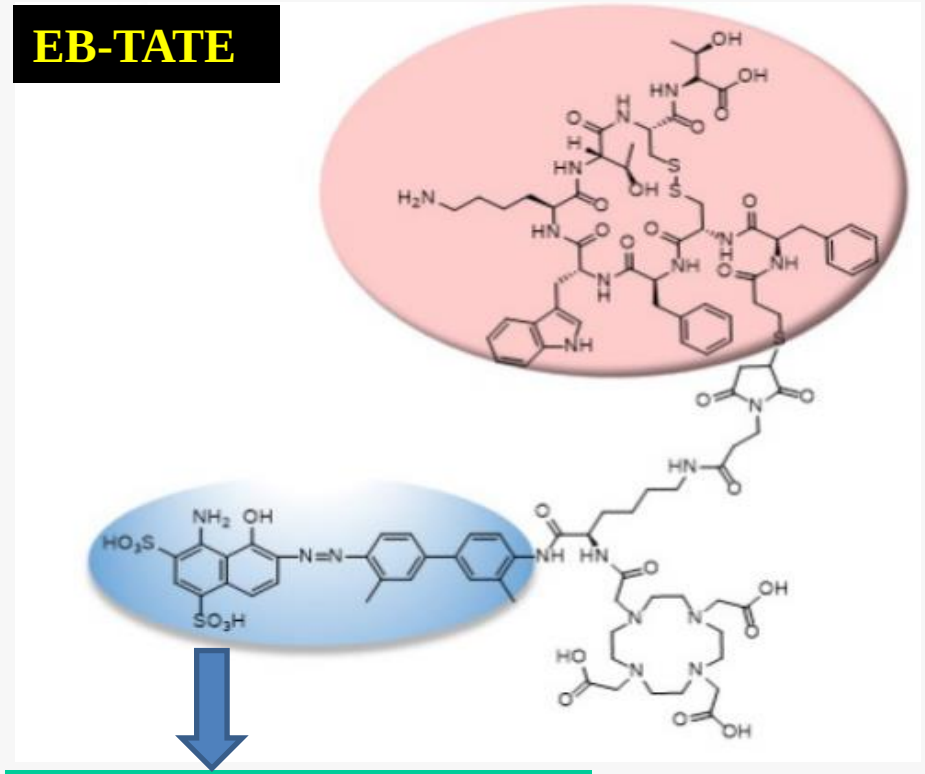


Infusion scheme for amino-acid solution with lysine+arginine

Background

^{177}Lu-DOTA-EB-TATE has an extended circulation in the blood, which may make the amino acid infusion unnecessary.

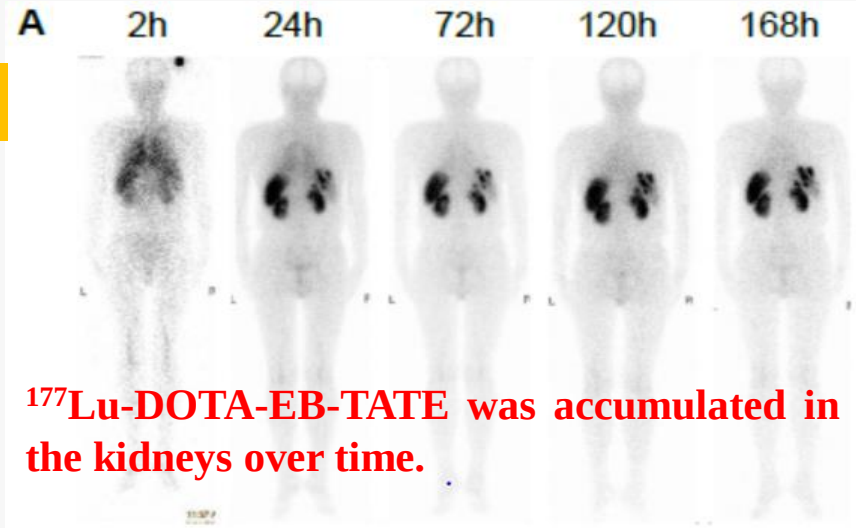
EB-TATE



Binding to serum albumin

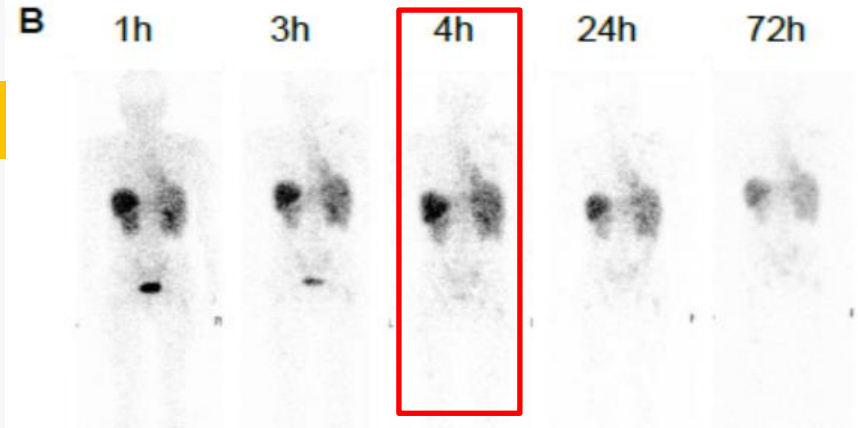
Zhang et.al, J Nucl Med. 2018 Nov;59(11):1699-1705

EB-TATE



^{177}Lu-DOTA-EB-TATE was accumulated in the kidneys over time.

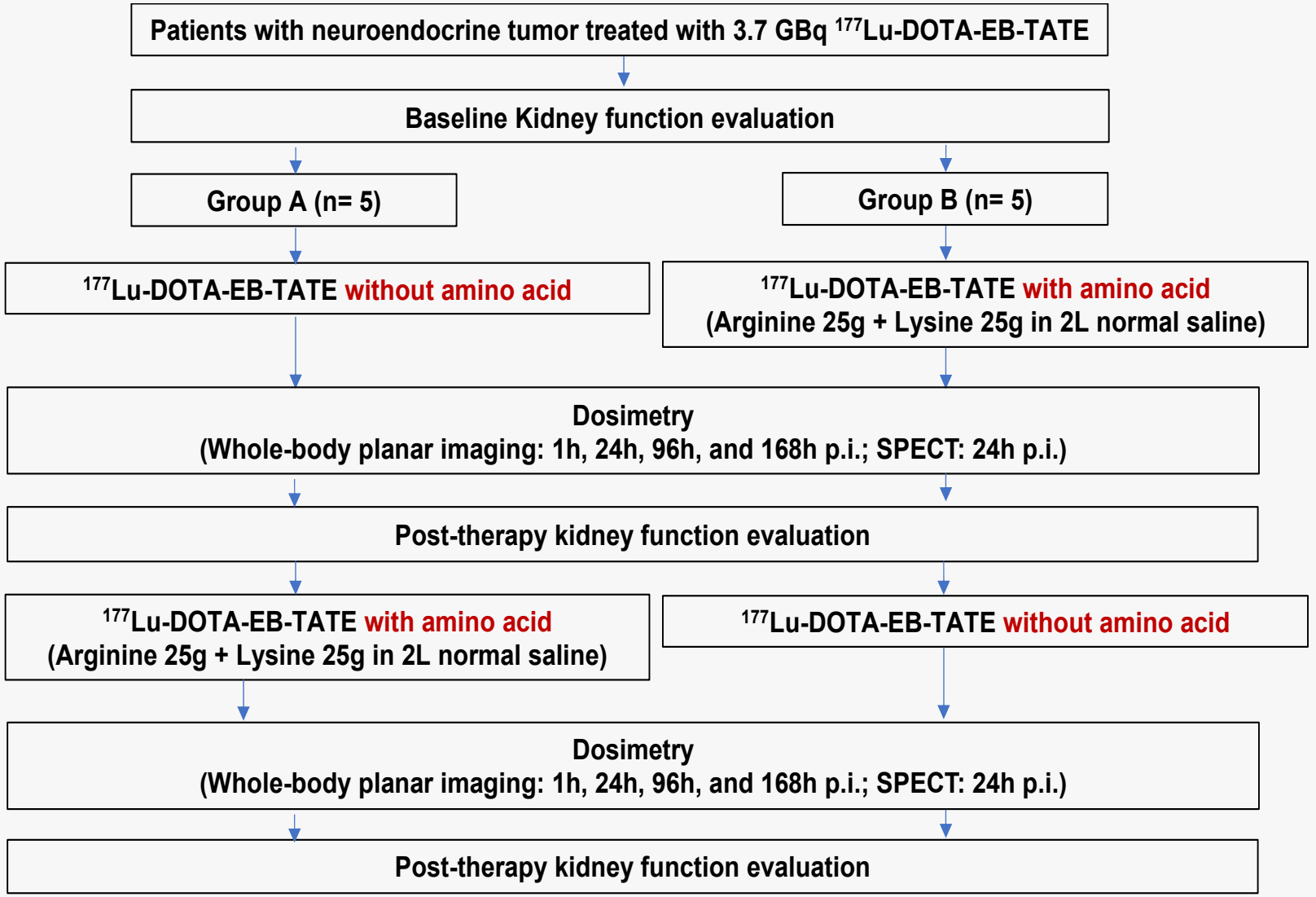
TATE



Aim

To evaluate the safety, biodistribution and dosimetry of ^{177}Lu-DOTA-EB-TATE with and without amino acid infusion in the treatment of neuroendocrine tumors (NETs).

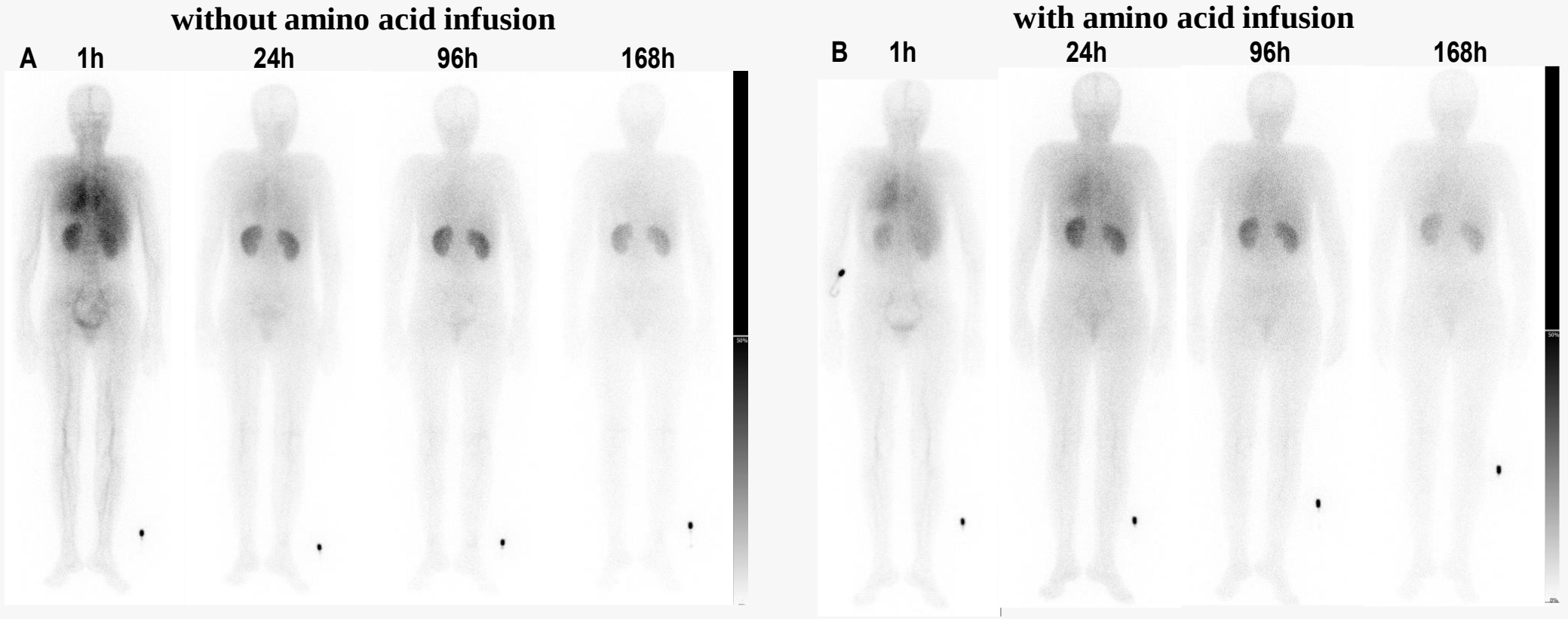
Methods



Kidney function:
creatinine and BUN at baseline, 1 week and 4 weeks after PRRT; GFR at baseline and 8 weeks after PRRT.

Dosimetric calculations:
HERMES software

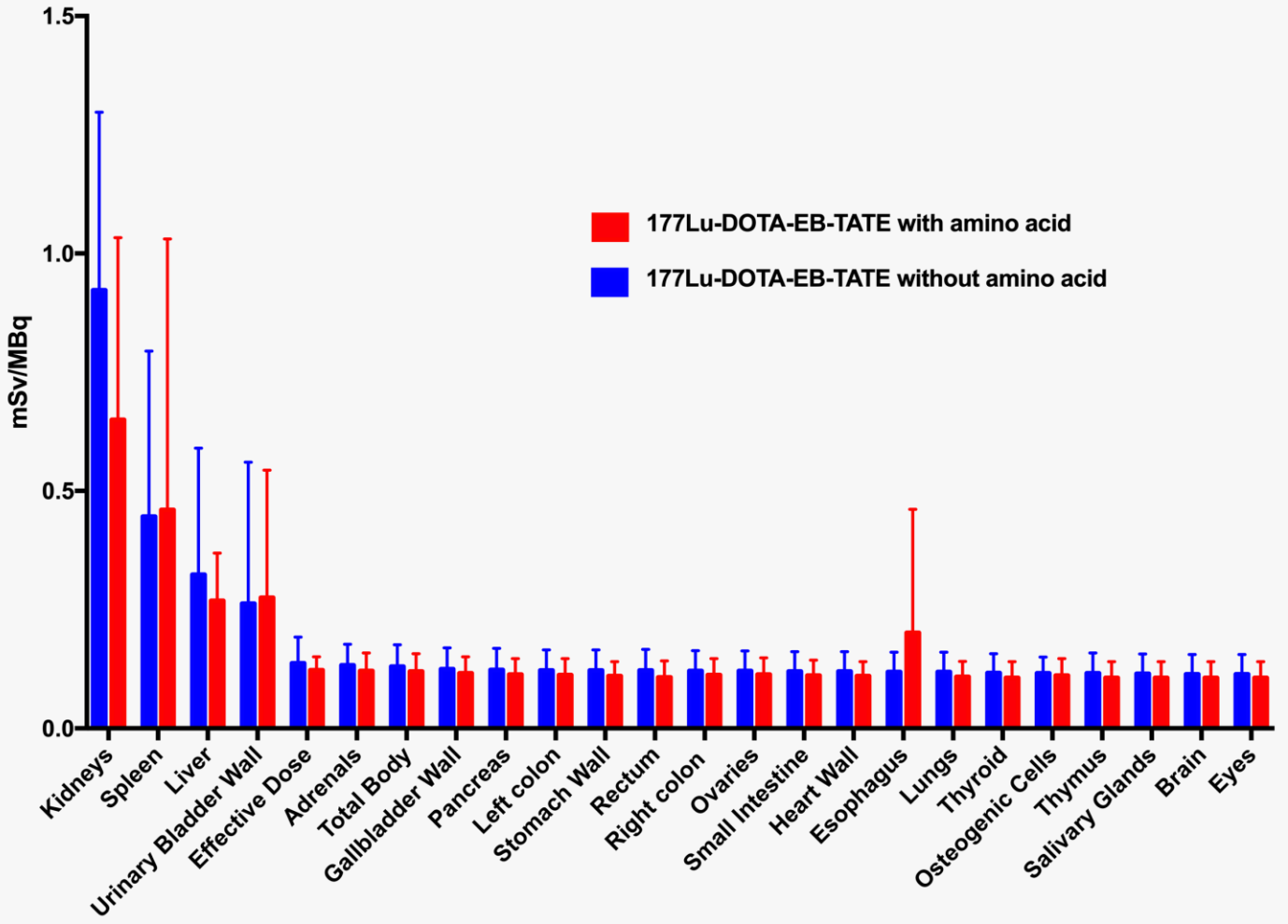
Biodistribution



Representative whole-body posterior projection images of a 41-y-old female patient at 1, 24, 96 and 168 h after intravenous administration of ^{177}Lu-DOTA-EB-TATE with or without amino acid infusion.

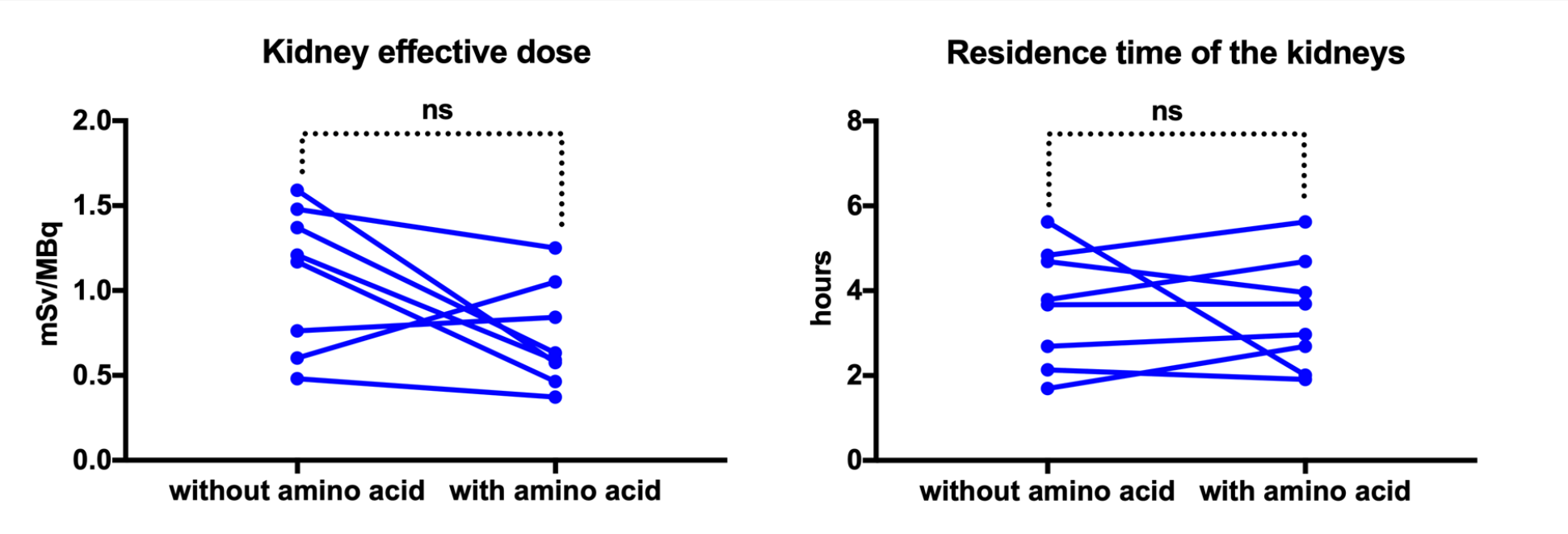
The renal uptake was lower at 1h after administration with amino acid infusion, but the accumulation in the kidney from 24 hours to 168 hours was similar after administration with or without amino acid infusion.

Biodistribution



Dosimetry

(Paired t test)



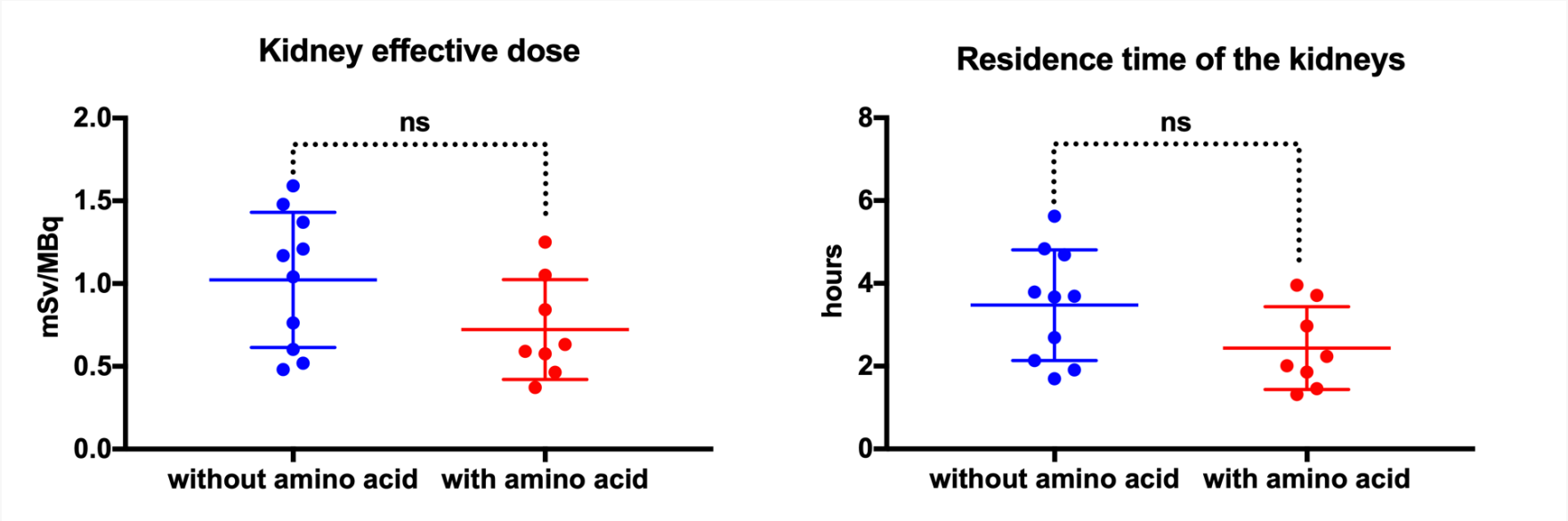
d= -0.361±0.490, P=0.076 (n=8)

d= -0.200±1.501, P=0.718 (n=8)

**Two patients failed to receive the 2nd- PRRT because of the epidemic control policy.*

Dosimetry

(Unpaired t test)

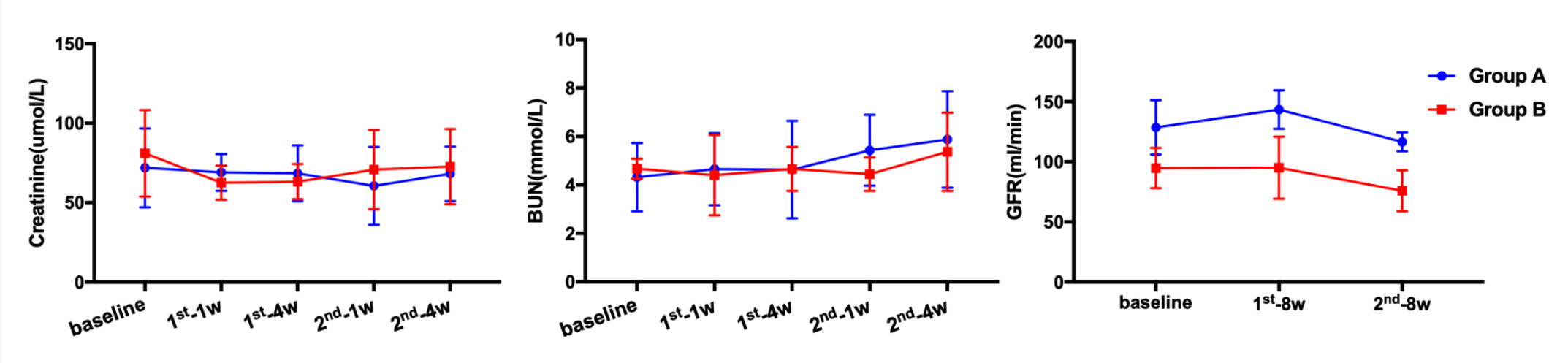


1.023±0.129 (n=10) *vs* 0.722±0.107 (n=8) (mSv/MBq)

3.474±0.423 (n=10) *vs* 2.439±0.354 (n=8) (h)

Renal Function Evaluation

(Two-way Repeated Measurement ANOVA with Sidak's multiple comparisons test)



- There was no significant difference in Creatinine, BUN or GFR between each time point in group A or group B (P< 0.05).
- There was no significant difference on renal function in the order of administration of ^{177}Lu-DOTA-EB-TATE with or without amino acid infusion.

Conclusions

- **Administration of ^{177}Lu-DOTA-EB-TATE without amino acid infusion has acceptable slightly increased kidney absorbed dose and residence time of the kidneys, and does no harm to kidney function.**

Acknowledgement

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Thanks!

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