THERAPEUTIC DRUG MONITORING IN OPAT: A PROSPECTIVE PILOT OF A PHARMACIST-LED WORKFLOW AND EARLY OUTCOMES

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BACKGROUND

Hospital-at-Home/OPAT is expanding, yet marked pharmacokinetic (PK) variability and complex dosing regimens may compromise PK/PD target attainment and increase toxicity risk, particularly in older patients with fluctuating renal function. A structured, pharmacist-led TDM workflow can support individualized dosing (including continuous infusion strategies), improve exposure target attainment, and enhance safety in OPAT.

AIM AND OBJECTIVES

Aim: To evaluate a pharmacist-led therapeutic drug monitoring (TDM) workflow in OPAT/HaH.

Objectives: (i) describe feasibility and dosing strategies, including continuous infusion; (ii) characterize first-sample concentrations by agent; (iii) quantify TDM frequency per patient; and (iv) report clinical and microbiological outcomes and adverse events (AEs).

MATERIALS AND METHODS

Design: Single-centre prospective PK pilot. Population: Consecutive OPAT/HaH patients for whom the clinical team requested TDM.

Workflow: Initial dosing was prescribed by infectious-diseases physicians (renal function–adjusted). A clinical pharmacist reviewed each case and issued dosing recommendations, which were implemented by the responsible physician. Clinical and microbiological outcomes and AEs were prospectively recorded.

RESULTS

Patient characteristics and outcomes

A total of **32** patients were included (updated dataset used for the final poster) (Table 1). Median age was **66 years (IQR 55–83)**, with a Charlson Comorbidity Index of **4 (IQR 2–7)** and baseline eGFR **70.5 mL/min (IQR 38–96)** (Table 1). **Clinical cure** was achieved in 28/32 (87.5%) (Table 1). Among patients with follow-up cultures, **microbiological eradication** was **19 (73%)** (Table 1). Antibiotic-related AEs occurred in **4/32 (12.5%)**, mostly neurological events (3/4) and one leukopenia (Table 1).

Indications and antimicrobials monitored

Main OPAT indications were **complicated UTI**, respiratory infection, skin/soft-tissue infection, and osteoarticular infection (Figure 1). The most frequently monitored agents were **ertapenem, piperacillin, and ceftazidime** (Figure 2).

TDM findings, pharmacist interventions, and exposure variability

On the **first TDM**, concentrations were **therapeutic in 46.9%, supratherapeutic in 34.4%**, and **infratherapeutic in 18.8%** (Table 2). **Continuous infusion** was used in **51.9%** of patients/courses (Table 2).

Pharmacist recommendations were frequent and clinically actionable: **no change** (43.8%), **dose reduction due to PK/PD target or toxicity risk** (21.9%), **dose adjustment for toxicity** (6.25%), **extend infusion** (6.25%), **increase exposure** (6.25%), and **end of therapy** (15.6%) (Table 2).

Marked interpatient variability was observed at first sampling. Drug-specific first-sample concentrations (median [p25–p75], mg/L) included: **ertapenem 6.6 (3.7–17.7), piperacillin 59.2 (22.1–59.4), cefepime 64.8 (29.9–99.7), and ceftazidime 59.4 (32.6–73.2)** (Table 2). This dispersion highlights the limitations of "one-size-fits-all" dosing in OPAT/HaH.

Table1. Patient characteristics, outcomes, and antibiotic-related adverse events (N=32)

Variable	N = 32
Age, years, median (IQR)	66 (55-83)
Male Sex, n (%)	17 (53.12)
Charlson Comorbidity Index, median (IQR)	4 (2-7)
Baseline eGFR, mL/min/1.73 m², median (IQR)	70.5 (38-96)
Clinical cure, n (%)	28 (87.5)
Antibiotic-related adverse events, n (%)	4 (12.5)
- **Neurotoxicity, n (% of AEs)**	3 (75)
- **Leukopenia, n (% of AEs)**	1 (25)
Microbiological eradication, n/N (%)	19 (73)

Table 2. TDM results, infusion strategy, pharmacist recommendations, and first-sample exposure variability (N=32)

Variable	N = 32
First TDM classification	-
- **Therapeutic, n (%)**	15 (46.9)
- **Supratherapeutic, n (%)**	11 (34.4)
- **Infratherapeutic, n (%)**	6 (18.8)
Continuous infusion	15 (51.9)
Pharmacist recommendations, n (%)	-
- **No change**	14 (43.8)
- **Dose reduction (PK/PD target or toxicity risk)**	7 (21.9)
- **Dose adjustment due to toxicity**	2 (6.25)
- **Prolong/extend infusion**	2 (6.25)
- **Increase exposure**	2 (6.25)
- **End of treatment**	5 (15.6)
First-sample concentrations, median (p25-p75), mg/L	-
- **Ertapenem**	6.6 (3.7-17.7)
- **Piperacilin**	59.2 (22.1-59.4)
- **Cefepime**	64.8 (29.9-99.7)
- **Ceftazidime**	59.4 (32.6-73.2)

Figura 1. OPAT/HaH indications among patients undergoing TDM (N=32)

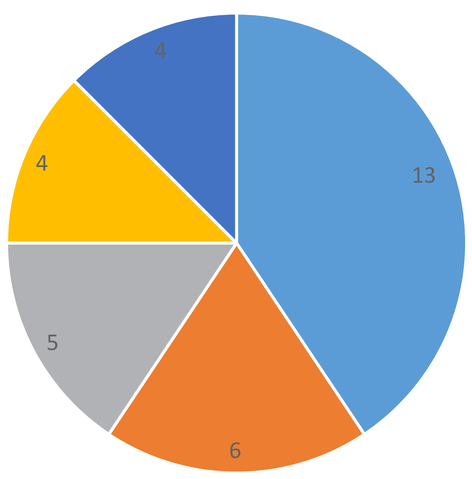
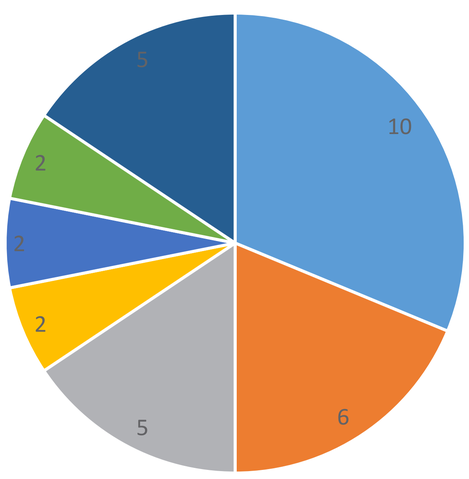


Figure 2. Antimicrobials monitored for TDM in OPAT/HaH (N=32)



DISCUSSION

In this real-world OPAT/HaH cohort, first-sample TDM showed substantial variability and a high proportion of non-therapeutic exposures, with **one-third supratherapeutic** results (Table 2). These findings support integrating pharmacist-led TDM in OPAT/HaH, particularly where continuous infusion is used (Table 2), and in patients with renal impairment or other risk factors for toxicity. The high cure rate with a relatively low AE incidence suggests that a structured pharmacist-led workflow is feasible and may enhance safe individualized dosing in OPAT/HaH (Table 1–2).

CONCLUSIONS

A pharmacist-led TDM workflow in OPAT/HaH was feasible and supported dose optimization across monitored agents. The pronounced interpatient variability observed at first sampling and the substantial proportion of supra-/infra-therapeutic exposures underscore the value of routine TDM, especially with continuous infusion strategies and in patients with impaired renal function (Table 2).

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