



Changes in creatinine and estimated glomerular filtration rate during the first 12-month period of pre-exposure prophylaxis among PrEP-30 clients at the Thai Red Cross Anonymous Clinic, Thailand

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BACKGROUND

- **Pre-exposure prophylaxis (PrEP)** is recommended as part of the combination HIV prevention packages for people at high risk for HIV infection in Thailand National Guidelines on HIV/AIDS since 2014.
- A daily oral fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg is currently the only recommended PrEP regimen.

BACKGROUND

- Renal side effects from PrEP with a clinically significant increase in serum creatinine (Cr) and a decrease in estimated glomerular filtration rate (eGFR) were reported to be less than 1% from clinical trials and demonstration programs.

AIMS

- We studied changes in Cr and eGFR (enzymatic assay by Beckman Coulter AU480) over a 12-month period among clients of the PrEP-30 service at the Thai Red Cross Anonymous Clinic (TRCAC) in Bangkok, Thailand.

MATERIALS AND METHODS

- PrEP-30 is the first fee-for-service PrEP program in Thailand, started in December 2014.
- PrEP-30 was named because the pills and laboratory monitoring cost around 30 Baht (or approximately 1 USD) per day at TRCAC.
- Anti-HIV test is recommended at month 1, 3 and then every 3 months.
- Cr/eGFR is scheduled every 6 months or as ordered by physician.

MATERIALS AND METHODS

- We analyzed Cr and eGFR data from PrEP-30 clients who started PrEP during January 2016-January 2017.
- Comparisons were made between values at
 - **baseline**
 - **month 3**
 - **month 6**
 - **month 9**
 - **month 12**and were also analyzed by ethnicity (Thai vs. non-Thai).
- Regression method was used to analyze.

RESULTS

- A total of **616 clients** (578 male and 38 female) started PrEP at TRCAC by January 2017
- Of these, 310 (50.3%) were Thais, 206 (33.4%) were non-Thais, and 100 (16.2%) did not have recorded data on nationality.
- Mean (SD) age of Thais was 31.20(7.47) , non-Thais was 37.19(10.17)
- Baseline Cr data was not available from 16 clients, thus, only 600 clients (565 male and 35 female) were analysed

RESULTS

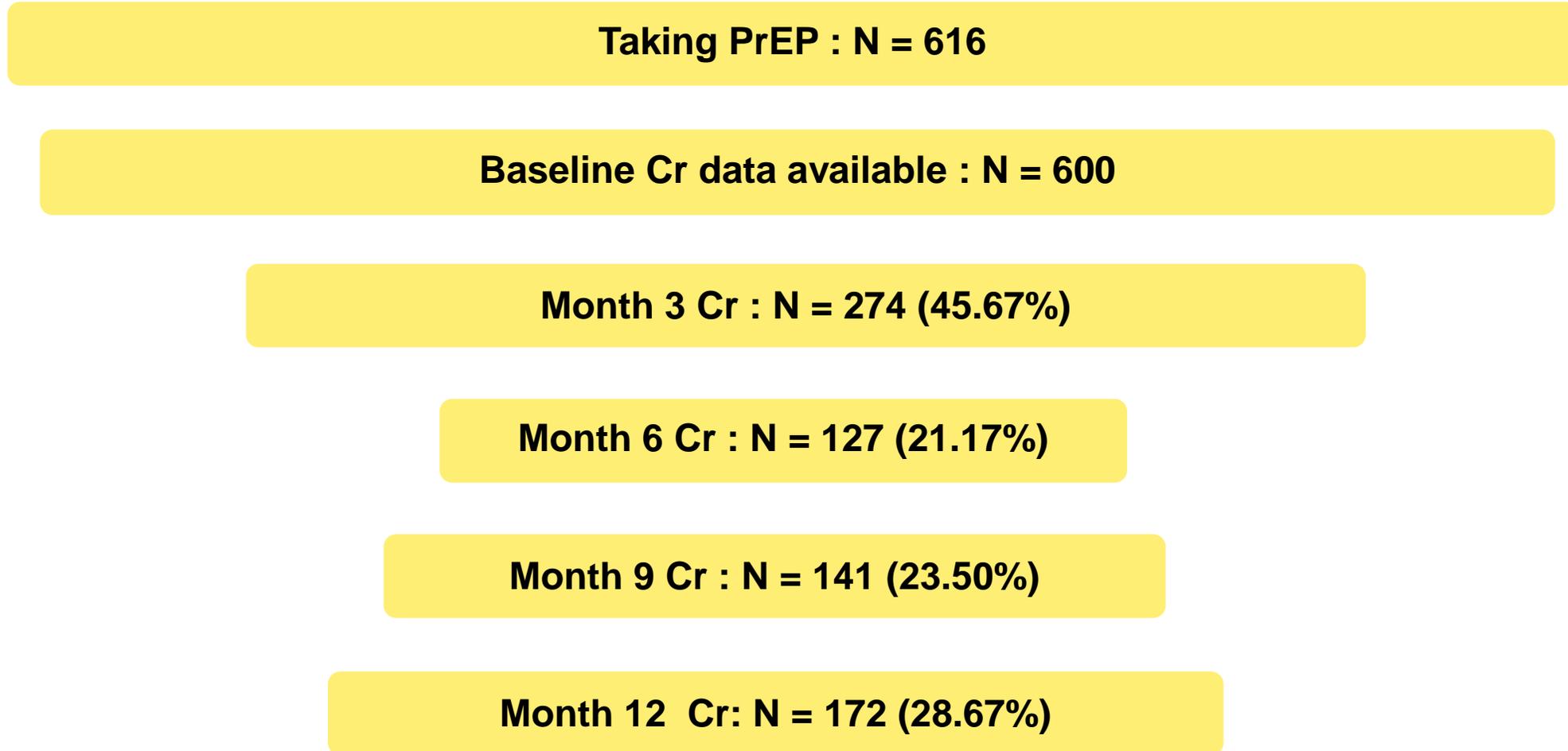


Figure1: The number of sample in each visit.

CREATININE RESULTS

Table1 : Median, total sample and p-value of creatinine in each visit.

| | Creatinine Median (IQR) | N (%) | P-value |
|---------------------------|--------------------------------|-----------------|------------------|
| Month 0 (Baseline) | 1.01 (0.90-1.13) | 600 | - |
| Month 3 | 1.01 (0.89-1.14) | 274 (45.67%) | <i>P = 0.44</i> |
| Month 6 | 0.98 (0.88-1.12) | 127 (21.17%) | <i>P = 0.03</i> |
| Month 9 | 0.95 (0.86-1.05) | 141 (23.5%) | <i>P ≤ 0.001</i> |
| Month 12 | 0.96 (0.88-1.07) | 172 (28.67%) | <i>P ≤ 0.001</i> |

Comparing Cr between visits, Cr at month 6 ($p=0.03$), month 9 ($p \leq 0.001$) and month 12 ($p \leq 0.001$) were lower than baseline value.

EGFR RESULTS

Table2 : Median, total sample and p-value of eGFR in each visit.

| | eGFR Median (IQR) | N (%) | mean change | P-value |
|---------------------------|------------------------------|-----------------|--------------------|------------------|
| Month 0 (Baseline) | 95.60 (82.95-107.90) | 600 | - | - |
| Month 3 | 96.70 (83.40-109.30) | 274 (45.67%) | + 0.52 | <i>P = 0.43</i> |
| Month 6 | 103.10 (90.40-111.80) | 127 (21.17%) | + 2.62 | <i>P = 0.03</i> |
| Month 9 | 103.10 (90.40-114.80) | 141 (23.5%) | + 4.67 | <i>P ≤ 0.001</i> |
| Month 12 | 101.00 (88.35-114.00) | 172 (28.67%) | + 5.17 | <i>P ≤ 0.001</i> |

eGFR was also higher at month 6 ($p=0.03$), month 9 ($p\leq 0.001$) and month 12 ($p\leq 0.001$) than at baseline.

RESULTS

- Fifteen clients (2.4%) were advised to stop PrEP due to eGFR < 60 ml/min/1.73m² at one or more time points, all were male.
- Including seven (2.3%) of Thais and eight (3.9%) of non-Thais; $p=0.28$
- 3 (20.0%) were younger than 35, 12 (80.0%) were older than 35; $p=0.0008$

RESULTS: HIV SEROCONVERSION

- Two men who have sex with men (MSM) had HIV seroconversion giving an incidence rate (95% confidence interval) of 0.75 (0.19-2.99) per 100 person-years as compared to 6.2 (4.5-8.6) per 100 person-years among MSM in the Test & Treat cohort at the TRC in 2012-2015.*
- In both cases PrEP was discontinued 8-9 months before seroconversion.

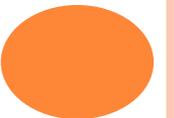
*Thai MSM/TG Test and treat study, funded by NRC, NHSO, GPD, TRCARC, 2012-2015.

CONCLUSIONS

- Experience from our real-life PrEP-30 service confirmed the low incidence of serious renal side effects among PrEP users in the first 12 months.
- Renal function follow-up every 6 months is adequate for most PrEP users but more frequent monitoring may be needed for older patients or if baseline eGFR is borderline.
- HIV seroconversion was significantly lower in our PrEP users as compared to our historical control. No HIV transmission occurred while on PrEP.

ACKNOWLEDGEMENT

- All staff in The Thai Red Cross Anonymous Clinic.
- Data management team prevention.



**THANK YOU
FOR YOUR ATTENTION**