

Cefepime の尿路感染症に対する臨床的検討

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新しい注射用セフェム系抗生剤 cefepime について尿路感染症および副性器感染症に対する臨床効果を検討した。本剤 1 回 0.5 g または 1.0 g を 1 日 2 回、2 日（ただし 3 回のみ投与）～ 5 日間経静脈的に投与した。UTI 薬効評価基準（第 3 版）により評価可能な 10 例について効果を判定し、有効 8 例、無効 2 例であった。投与前分離された 6 菌種 13 株中 10 株が本剤投与により消失した。副作用は顔面紅潮と腹痛が 1 例にみられたが軽度のものであった。臨床検査値の正常範囲を逸脱する変動は認められなかった。

Key words : 注射剤, Cefepime, 尿路感染症

Cefepime の尿路感染症における有用性を臨床成績の点から検討した。

対象は、慢性複雑性膀胱炎 9 例、慢性複雑性腎盂腎炎 4 例、急性前立腺炎 1 例、精巣上体炎 2 例であった (Tables 1, 2)。

方法は、本剤を 1 回 0.5 g または 1.0 g 1 日 2 回生食 20 ml に溶解し 1～3 分で静注もしくは 100 ml に溶解し約 30 分かけて点滴静注した。

UTI 薬効評価基準(第3版)¹⁾により評価可能な 10 例についての効果判定では、有効 8 例、無効 2 例であった (Table 3)。

細菌学的効果では、投与前尿中分離菌は 6 菌種 13 株検出され、本剤の使用により *Pseudomonas aeruginosa* 5 株中の 3 株を除く 10 株が消失した (Table 4)。

投与後出現菌として、*Enterococcus faecium* 2 株、*Pseudomonas pseudoalcaligenes* 1 株、*Alcaligenes*

xylosoxydans 1 株、*Candida* 3 株が分離された。

患者病態群別では、単独菌感染 7 例は全例有効、複数菌感染 3 例は、有効 1 例、無効 2 例であった。カテーテル留置は 4 例で有効 3 例、無効 1 例であった (Table 5)。

副作用として、16 例中 1 例に顔面紅潮および腹痛を認め本剤の投与を中止し改善を見た。

臨床検査値では、全例で正常範囲を逸脱する変動は認められなかった。

前立腺炎の 1 例は起炎菌は同定されなかったが、臨床症状と尿所見の改善から主治医判定で有効、精巣上体炎の 2 例は臨床症状および尿所見の改善と菌の消失から主治医判定で著効とした (Table 2)。

以上より本剤の尿路感染症における有用性は高く、副作用は 1 例で認められたもののその臨床的有用性は高いと考えられた。

Table 1. Clinical summary of complicated UTI patients treated with cefepime

| Patient no. | Age (y) | Sex | Diagnosis Underlying condition | Catheter (route) | UTI group | Treatment | | | Symptoms* | Pyuria* | Bacteriuria* | | | Evaluation** | | Side-effects |
|-------------|---------|-----|-----------------------------------|------------------|-----------|----------------|-------|-----------------|-----------|----------|-----------------------|-----------------|------|--------------|---------|-------------------------------|
| | | | | | | Dose (g ×/day) | Route | Duration (days) | | | Species | Count | MIC | UTI | Dr | |
| 1 | 56 | M | CCC prostatic cancer | + (urethra) | G-1 | 0.5 × 2 | i. v. | 4 | — — | ## ## | <i>P. aeruginosa</i> | 10 ⁶ | 12.5 | moderate | good | — |
| | | | | | | | | | | | <i>P. aeruginosa</i> | 10 | 12.5 | | | |
| 2 | 69 | M | CCC prostatic cancer | — | G-4 | 0.5 × 2 | i. v. | 1.5 | — — | ## ## | <i>S. epidermidis</i> | 10 ⁵ | 1.56 | / | unknown | hot flushes abdominal pain |
| | | | | | | | | | | | <i>S. epidermidis</i> | 10 ⁶ | 1.56 | | | |
| | | | | | | | | | | | <i>Candida</i> sp. | 10 ⁶ | | | | |

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Table 1. Continued

| Patient no. | Age (y) | Sex | Diagnosis Underlying condition | Catheter (route) | UTI group | Treatment | | | Symptoms* | Pyuria* | Bacteriuria* | | | Evaluation** | | Side-effects |
|-------------|---------|-----|-----------------------------------|------------------|-----------|---------------|-------|-----------------|-----------|---------|-----------------------|-----------------|-------|--------------|-----------|--------------|
| | | | | | | Dose (g×/day) | Route | Duration (days) | | | Species | Count | MIC | UTI | Dr | |
| | | | | | | | | | | | | | | | | |
| 3 | 72 | M | CCC | - | G-6 | 0.5×2 | i. v. | 5 | - | ## | <i>S. aureus</i> | 10 ⁴ | 200 | moderate | good | - |
| | | | prostatic cancer | | | | | | - | - | <i>P. aeruginosa</i> | 10 ⁴ | 3.13 | | | |
| | | | | | | | | | | | <i>E. faecium</i> | 10 ⁴ | >400 | | | |
| 4 | 79 | F | CCP | - | G-6 | 0.5×2 | i. v. | 5 | + | ## | <i>E. coli</i> | 10 ⁵ | 0.05 | poor | fair | - |
| | | | NBD | | | | | | + | ## | <i>E. faecalis</i> | 10 ⁵ | 50 | | | |
| | | | | | | | | | | | <i>E. faecium</i> | 10 ³ | >400 | | | |
| 5 | 25 | M | CCC | + | G-1 | 1×2 | d. i. | 5 | - | ## | <i>P. aeruginosa</i> | 10 ⁶ | 3.13 | moderate | good | - |
| | | | injury of urethra | (cystostomy) | | | | | - | - | <i>A. xyloxydans</i> | 10 ⁴ | >400 | | | |
| | | | | | | | | | | | | | | | | |
| 6 | 78 | M | CCC | + | G-1 | 1×2 | d. i. | 5 | + | + | <i>P. aeruginosa</i> | 10 ⁶ | 6.25 | moderate | excellent | - |
| | | | BPH | (urethra) | | | | | - | ## | <i>P. aeruginosa</i> | 10 | 6.25 | | | |
| | | | | | | | | | | | | | | | | |
| 7 | 67 | M | CCC | - | G-4 | 1×2 | i. v. | 5 | ## | ## | <i>E. coli</i> | 10 ⁷ | 0.05 | moderate | good | - |
| | | | prostatic cancer | | | | | | - | + | - | - | | | | |
| | | | | | | | | | | | | | | | | |
| 8 | 77 | M | CCC | - | G-4 | 1×2 | i. v. | 5 | - | ## | <i>C. freundii</i> | 10 ⁷ | 1.56 | moderate | poor | - |
| | | | BPH | | | | | | - | ## | <i>Candida</i> sp. | 10 ² | | | | |
| | | | NBD | | | | | | | | | | | | | |
| 9 | 75 | F | CCC | - | G-4 | 1×2 | i. v. | 5 | + | ## | <i>E. coli</i> | 10 ⁵ | 0.025 | moderate | good | - |
| | | | NBD | | | | | | - | ± | - | | | | | |
| | | | | | | | | | | | | | | | | |
| 10 | 78 | M | CCC | + | G-5 | 1×2 | d. i. | 5 | + | - | <i>P. aeruginosa</i> | 10 ⁶ | 0.39 | / | excellent | - |
| | | | prostatic cancer | (urethra) | | | | | - | - | <i>E. cloacae</i> | 10 ⁶ | 0.1 | | | |
| | | | | | | | | | | | <i>Candida</i> sp. | 10 ³ | | | | |
| 11 | 16 | F | CCP | - | G-3 | 1×2 | i. v. | 5 | ## | ## | <i>E. coli</i> | 10 ⁸ | 0.05 | moderate | good | - |
| | | | VUR | | | | | | - | ± | - | | | | | |
| | | | | | | | | | | | | | | | | |
| 12 | 61 | M | CCP | + | G-5 | 1×2 | i. v. | 5 | ## | ## | <i>P. aeruginosa</i> | 10 ⁷ | 6.25 | poor | fair | - |
| | | | BPH | (cystostomy) | | | | | - | ## | <i>P. rettgeri</i> | 10 ⁷ | 0.025 | | | |
| | | | | | | | | | | | <i>P. aeruginosa</i> | 10 ⁴ | 25 | | | |
| 13 | 65 | M | CCP | - | G-6 | 1×2 | d. i. | 5 | - | ## | <i>S. epidermidis</i> | 10 ³ | 200 | / | good | - |
| | | | renal pelvic tumor | | | | | | - | - | <i>Candida</i> sp. | 10 ³ | | | | |
| | | | | | | | | | | | | | | | | |

CCC : chronic complicated cystitis
 CCP : chronic complicated pyelonephritis
 NBD : neurogenic bladder dysfunction
 BPH : benign prostatic hypertrophy
 VUR : vesicoureteral reflux

*Before treatment
 After treatment

**UTI : criteria proposed by the UTI Committee
 Dr : Dr's evaluation

Table 2. Clinical summary of prostatitis and epididymitis cases treated with cefepime

| Patient no. | Age (y) | Sex | Diagnosis Underlying condition | Catheter (route) | Treatment | | | Symptoms* | Pyuria* | Bacteriuria* | | | Evaluation** | Side-effects | |
|-------------|---------|-----|-----------------------------------|------------------|---------------|-------|-----------------|-----------|---------|-----------------------|----------------------|-----------------|--------------|--------------|----|
| | | | | | Dose (g×/day) | Route | Duration (days) | | | Species | Count | MIC | | | Dr |
| | | | | | | | | | | | | | | | |
| 1 | 64 | M | acute prostatitis | - | 1×2 | i. v. | 5 | ## | + | - | - | | good | - | |
| | | | NBD | | | | | - | - | <i>S. epidermidis</i> | 10 ² | >400 | | | |
| | | | | | | | | | | <i>Candida</i> sp. | 10 ² | | | | |
| 2 | 61 | M | epididymitis | - | 1×2 | d. i. | 5 | + | ## | ## | <i>P. aeruginosa</i> | 10 ⁶ | 12.5 | excellent | - |
| | | | BPH | | | | | - | ## | - | | | | | |
| | | | | | | | | | | | | | | | |
| 3 | 73 | M | epididymitis | + | 1×2 | d. i. | 5 | + | ## | ## | <i>E. cloacae</i> | 10 ⁶ | 1.56 | excellent | - |
| | | | BPH | (urethra) | | | | - | + | <i>E. faecium</i> | 10 ⁶ | >400 | | | |
| | | | | | | | | | | <i>Candida</i> sp. | 10 | | | | |

*Before treatment
 After treatment

**Dr : Dr's evaluation

Table 3. Overall clinical efficacy of cefepime in complicated UTI
0.5g×2 or 1.0g×2/day, 4-5day treatment

| Bacteriuria | Pyuria | Cleared | Decreased | Unchanged | Effect on bacteriuria |
|--------------------------|------------|----------------------|------------|-------------------------------|-----------------------|
| | Eliminated | | | 3 | 1 |
| Decreased | | | | 2 | 2 |
| Replaced | | 2 | | 1 | 3 |
| Unchanged | | | | 1 | 1 |
| Effect on pyuria | | 2 | 3 | 5 | patient total 10 |
| Excellent | | 0 | | overall efficacy rate 8/10 | |
| Moderate | | 8 | | | |
| Poor (including failure) | | 2 | | | |
| Bacteriological response | | | | | |
| | | Total no. of strains | Eradicated | Persisted* | |
| | | 13 | 10 | 3 | |

*Regardless of bacterial count

Table 4. Bacteriological response to cefepime in complicated UTI
(0.5g×2 or 1.0g×2/day)

| Isolate | No. of strains | Eradicated | Persisted* |
|----------------------|----------------|------------|------------|
| <i>S. aureus</i> | 1 | 1 | |
| <i>E. faecalis</i> | 1 | 1 | |
| <i>E. coli</i> | 4 | 4 | |
| <i>P. aeruginosa</i> | 5 | 2 | 3 |
| <i>C. freundii</i> | 1 | 1 | |
| <i>P. rettgeri</i> | 1 | 1 | |
| Total | 13 | 10 | 3 |

*Regardless of bacterial count

Table 5. Overall clinical efficacy of cefepime classified by the type of infection (0.5g×2 or 1.0g×2/day)

| Group | | No. of patients | Excellent | Moderate | Poor | Overall efficacy rate | |
|-------------------------|----------------------------------|---------------------|-----------------|-----------|----------|-----------------------|-----------------------|
| Monomicrobial infection | group 1 (indwelling catheter) | 3 | | 3 | | 3/3 | |
| | group 2 (post-prostatectomy) | 0 | | | | | |
| | group 3 (upper UTI) | 1 | | 1 | | 1/1 | |
| | group 4 (lower UTI) | 3 | | 3 | | 3/3 | |
| | sub-total | 7 | | 7 | | 7/7 | |
| Polymicrobial infection | group 5 (indwelling catheter) | 1 | | | 1 | 0/1 | |
| | group 6 (no indwelling catheter) | 2 | | 1 | 1 | 1/2 | |
| | sub-total | 3 | | 1 | 2 | 1/3 | |
| Total | | 10 | 0 | 8 | 2 | 8/10 | |
| | | Indwelling catheter | No. of patients | Excellent | Moderate | Poor | Overall efficacy rate |
| | | Yes | 4 | | 3 | 1 | 3/4 |
| | | No | 6 | | 5 | 1 | 5/6 |
| | | Total | 10 | 0 | 8 | 2 | 8/10 |

文 献

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1) UTI研究会(代表:大越正秋):UTI薬効評価基準

CLINICAL USEFULNESS OF CEFEPIME FOR UROGENITAL
TRACT INFECTIONOsamu Wada¹⁾, Yukishige Isomatsu¹⁾, Kenichiro Okada¹⁾,
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The usefulness of cefepime for urogenital tract infection was clinically evaluated according to the criteria proposed by the Japanese UTI Committee. The overall efficacy in 10 cases were moderate in 8 and poor in 2. Side effects were observed in 1 patient (hot flushes and abdominal pain), but were mild in degree.