Therapeutic Effectiveness of the Generic Preparation of Meropenem (Mapenem®) in the Treatment of Moderate to Severe Infection in Children

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Objective: *To compare treatment effectiveness and tolerability between generic meropenem (Mapenem®, Siam Pharmaceutical) and the original formulation.*
Material and Method: *A retrospective review using historical control of children hospitalized at Queen Sirikit National Institute of Child Health was conducted. The demographics, clinical, and treatment outcomes of 180 children receiving generic meropenem were compared with that of 180 children receiving original meropenem.*
Results: *Baseline demographics, clinical characteristics were comparable between both groups. The treatment outcomes on day 3, 7, and 14 of treatment were comparable between the two groups with overall improvement rates of 73.9% and 71.7% for generic and original meropenem, respectively (absolute difference: 2.2%, 95% CI: -6.9%, 11.4%). Both drugs were well tolerated, with only 1.6% of patients in each group who experienced adverse reactions.*
Conclusion: *Mapenem® exhibited comparable therapeutic effectiveness and tolerability with that of the brand-name formulation in the treatment of moderate to severe infections in a pediatric population.*

Keywords: *Generic drug, Meropenem, Pediatrics, Therapeutic equivalence*

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Given the global emergence and increasing prevalence of extended spectrum beta-lactamase (ESBL) producing gram negative bacteria, the use of carbapenem has been increased substantially in the past decade. Since the cost of original or brand leader preparation is relatively high (approximately 900 to 1,000 Thai Baht/day for a 10 Kg body weight child), there is an effort to replace the brand-name preparation with a generic product that costs approximately one-third of the original medication. A recent study in Thailand showed that a generic meropenem (Mapenem®) from Siam Pharmaceutical had similar bioequivalence, antibacterial activity, and tolerability compared to the original product[1]. This generic meropenem has been approved by the Thai Food and Drug Administration. In addition, an existing multi-center observational study in Thailand has demonstrated therapeutic equivalence between Mapenem® and the brand-name formulation among adults with serious bacterial infections[2]. Nevertheless, no data were available among the pediatric population. The original meropenem (Meronem®, AstraZenaca) has been used in Queen Sirikit National Institute of Child Health (QSNICH) more than 10 years whereas the generic one (Mapenem®, Siam Pharmaceutical) has been available since March 2008. Given that this type of antibiotic is generally used among severely/critically ill patients with serious bacterial infections, the major concern in using the generic drug is the lack of documented adequacy of safety and therapeutic efficacy. As a result, the aim of the present study was to evaluate the therapeutic equivalence of generic meropenem as compared to the original formulation for the treatment of serious bacterial infections in hospitalized children at QSNICH. If they deem to have therapeutic equivalence, the original meropenem can be substituted by the generic one with a lower cost.

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Material and Method

A retrospective observational study was conducted using a convenient sample of children 0-18 years of age hospitalized at QSNICH. Those receiving meropenem antibiotic were identified via Pharmacology Department Database. Although generic meropenem has become available since early March 2008, the transition from original to generic drug use at QSNICH was not completed until late March 2008. Sample size calculation was based on Blackwelder's formula for non-inferiority trials[3]. A recent study in a Thai adult population has shown that a favorable response rate (cure and clinical improvement) of the patients who received original and generic meropenem were 56% and 54%, respectively[2]. Based on the outcome of this particular study, a sample size of 180 patients per group would be needed in order to claim non-inferiority of generic meropenem when hypothesized difference was set as less than or equal to 15% and the type I and type II errors were 5% and 20%, respectively. Therefore, the authors included 180 consecutive cases of children aged 0-18 years who received generic meropenem treatment from April 2008 to March 2010 (generic group) and another 180 consecutive cases who received original meropenem from February 2006 to December 2007 (original group). The Ethical Committee's approvals were obtained from QSNICH (IRB approval numbers: 53-076). Medical records of all subjects were retrieved from the Department of Medical Records of QSNICH. The following information was abstracted from medical records: demographic data, underlying co-morbidities, therapeutic indications, sites of infection, prior use of antibiotics, types of causative pathogens, meropenem dosage and duration, concomitant antibiotics, clinical and microbiological outcomes, and meropenem-related adverse events.

The data were analyzed using both descriptive and inferential statistics. Bivariate analyses were conducted using Chi-square statistics, Fisher exact test, and student t-test where appropriate. A p-value of < 0.05 was considered statistically significant. Multivariate analysis was applied to determine whether the use of generic meropenem is associated with unfavorable outcomes.

Results

The demographics and clinical characteristics of participants were relatively comparable between the two groups except for the age distribution and infection onset (nosocomial/healthcare associated or community acquired) (Table 1). Approximately one-fourth of patients had critical illness requiring admission to an intensive care unit. More than 90% of cases have underlying chronic conditions of which multiple co-morbidities were rather common: *i.e.*, almost half of all cases had more than one co-morbidities of which congenital heart disease, prematurity, and neurodevelopmental disorder were among the most common (Table 1).

Blood stream and respiratory tract infections were among the two most common sites of infections followed by intra-abdominal and urinary tract infection (Table 2). The distribution of infection sites were generally comparable between the two groups except for the significant lower rate of blood stream infection/ clinical sepsis and higher urinary tract infection between the generic and original meropenem group, respectively.

Receipt of antibiotic prior to meropenem treatment were documented in approximately 90% of all cases among which third generation cephalosporins and aminoglycoside were most commonly used (Table 3). The rates of concomitant use antibiotics are shown in Table 4. The proportions of patients receiving concomitant antibiotics were not significantly different between the two groups *i.e.*, 42.2% and 50% for generic and original meropenem group, respectively. Most commonly used concomitant antimicrobial agents were glycopeptide for both groups. However, intravenous colistin was the second most commonly use concomitant antibiotics among the generic meropenem group whereas aminoglycoside was the second most commonly use concomitant antibiotics among the original group.

Microbiologically confirmed infections were observed in 40% and 32% among generic and original meropenem group, respectively. Only pathogens isolated in normally sterile sites or those with higher than 10^5 colony forming units isolated in urine were regarded as true pathogens in the present study. The distribution of documented causative pathogens is shown in Table 5. Nevertheless, the proportion of those obtained from invasive sites only *e.g.* blood, cerebrospinal fluid was relatively lower. Positive blood cultures were identified in only 35 cases (19.4%) and 42 cases (23.3%) among generic and original meropenem group, respectively. Positive cerebrospinal fluid cultures were identified in 2 cases (1.1%) and 8 cases (4.4%) among generic and original meropenem group, respectively.

Table 1. Baseline demographics and clinical characteristics (n = 180/group)

	Generic meropenem n (%)	Original meropenem n (%)	p-value
Male	95 (52.8)	100 (55.6)	0.597
Median age in months (IQR)	6.72 (42.0)	2.95 (22.33)	0.016*
ICU admission	46 (25.6)	39 (21.7)	0.385
Nosocomial/healthcare associated infection	152 (84.4)	166 (92.2)	0.022*
Underlying diseases	166 (92.2)	165 (91.7)	0.846
HIV	6 (3.3)	5 (2.8)	0.759
Chronic pulmonary diseases	22 (12.2)	21 (11.7)	0.871
Chronic kidney disease	12 (6.7)	7 (3.9)	0.239
Chronic liver disease	6 (3.3)	4 (2.2)	0.521
Heart diseases	51 (28.3)	55 (30.6)	0.644
Solid tumor	10 (5.6)	9 (5.0)	0.814
Hematologic malignancy	18 (10.0)	19 (10.6)	0.862
Prematurity	41 (22.8)	50 (27.8)	0.275
Febrile neutropenia	17 (9.4)	13 (7.2)	0.446
Neuro-developmental disease	33 (18.3)	43 (23.9)	0.197
Gastrointestinal disease	29 (16.1)	33 (18.3)	0.577
Chromosomal disorder/multiple congenital anomalies	17 (9.4)	17 (9.4)	1.000
Multiple co-morbidities	81 (45.0)	89 (49.4)	0.398

* Significant at p-value < 0.05, IQR = interquartile ranges

Table 2. Site of infections (n =180/group)

Site of infections	Generic meropenem, n (%)	Original meropenem, n (%)	p-value
Respiratory tract	83 (46.1)	86 (47.8)	0.751
Urinary tract	19 (10.6)	7 (3.9)	0.015*
Skin and soft tissue	14 (7.8)	10 (5.6)	0.398
Blood stream/clinical sepsis**	87 (48.3)	115 (63.9)	0.003*
Intra-abdominal	23 (12.8)	19 (10.6)	0.511
Brain abscess	1 (0.6)	6 (3.3)	0.056
Meningitis	17 (9.4)	20 (11.1)	0.603
Others	9 (5.0)	11 (6.1)	0.645

* Significant at p-value < 0.05

** This category includes both culture proven blood-stream infections (35 cases (19.4%) and 42 cases (23.3%) among generic and original meropenem group) and clinical sepsis with presumed blood stream infection)

Including all sites of positive culture, the rates identification (infection/colonization) of extended spectrum beta-lactamase (ESBL) producing gram negative enteric bacteria and multi-drug resistant (MDR) *Acinetobacter baumannii* were not significantly different between the two treatment groups. ESBL-producing bacteria were identified in 25 cases (13.8%) and 24 cases (13.3%) among generic and original meropenem group, respectively (p = 0.878). In addition, MDR *A. baumannii* were identified in 11 cases (6.1%) and 15 cases (8.3%) among generic and original meropenem group, respectively (p = 0.415).

The use of high dose meropenem was commonly observed among those with suspected

Table 3. Previous receipt of antibiotics within the past 2 weeks (n = 180/group)

	Generic meropenem n (%)	Original meropenem n (%)	p-value
Previous receipt of antibiotics within the past 2 weeks	162 (90.0)	161 (89.4)	0.862
Type of antibiotic receipt			
Aminoglycosides	99 (55.0)	128 (71.11)	0.002*
Carbapenem	8 (4.44)	11 (6.11)	0.479
Colistin	1 (0.56)	1 (0.56)	1.000
Penicillin	63 (35.0)	92 (51.11)	0.002*
1st generation cephalosporin	6 (3.33)	4 (2.22)	0.521
3rd generation cephalosporin	143 (79.44)	143 (79.44)	1.000
Quinolone	11 (6.11)	9 (5.0)	0.645
Others	21 (11.67)	24 (13.33)	0.633

* Significant at p-value < 0.05

Table 4. Concurrent antimicrobial therapy (n = 180/group)

	Generic meropenem, n (%)	Original meropenem, n (%)	p-value
Concurrent antimicrobial therapy	76 (42.2)	90 (50.0)	0.139
Aminoglycosides	5 (2.78)	14 (7.78)	0.034*
Colistin	8 (4.44)	5 (2.78)	0.397
Penicillin	6 (3.33)	11 (6.11)	0.214
3rd generation cephalosporin	6 (3.33)	9 (5.00)	0.429
Quinolone	5 (2.78)	3 (1.67)	0.475
Glycopeptide	47 (26.11)	38 (21.11)	0.264

* Significant at p-value < 0.05

Table 5. Causative pathogens** identified (n = 180/group)

	Generic meropenem, n (%)	Original meropenem, n (%)	p-value
Pathogen isolates n (%)	72 (40.0)	58 (32.2)	0.125
E. coli	24 (13.3)	10 (5.5)	0.001*
K. pneumoniae	12 (6.7)	18 (10.0)	0.053
P. aeruginosa	4 (2.2)	1 (0.6)	0.259
A. baumannii	7 (3.8)	6 (3.3)	0.906
Salmonella spp.	1 (0.5)	4 (2.0)	0.104
Enterococcus spp.	6 (3.3)	1 (0.6)	0.097
S. aureus	3 (1.6)	1 (0.6)	0.423
Fungus	6 (3.3)	6 (3.3)	0.694

* Significant at p-value < 0.05

** Only those isolated from normally sterile site and those with more than 10^5 colony forming unit/ml isolated from urine

or confirmed bacterial meningitis which was identified in 22.7%, otherwise the usual dose used was 60 mg/kg/day were employed in almost all cases. However, there was some dosage modification/ adjustments among premature neonate or very low birth weight infants during their first week of life. The

dosage and duration of meropenem treatment in both groups were comparable.

The treatment outcomes of both groups on day 3, 7, and 14 are shown in Table 6. The overall favorable outcomes in the generic and original meropenem group were 73.9% and 71.7%, respectively (absolute difference: 2.2%, 95% CI: -6.9%, 11.4%). The overall in-hospital mortality rates were 10% and 15% (absolute difference: -5%, 95% CI: -11.8%, 1.8%) among the generic and original group, respectively. Microbiological cure rates were also comparable: 70.4% and 70.8% (absolute difference: 0.4%, 95% CI: -25.5%, 24.58%) on day 3; and 80.9% and 81.3% (absolute difference: 0.4%, (95% CI: -25.7%, 25.15%) day 7 for the generic and original group, respectively.

The overall mortality rates at day 28, and in-hospital mortality were 10%, and 10% for generic meropenem and 13.9%, and 15% for original drug,

Table 6. Treatment outcomes

	Generic meropenem, n (%)	Original meropenem, n (%)	p-value
Clinical outcomes on day 3, n (%)	n = 180	n = 180	0.807
Complete resolution	3 (1.7)	1 (0.6)	
Improved	106 (58.9)	105 (58.3)	
Stable	45 (25.0)	52 (28.9)	
Worse	4 (2.2)	5 (2.8)	
Died	11 (6.1)	9 (5.0)	
Not evaluable	11 (6.1)	8 (4.4)	
Clinical outcomes on day 7, n (%)	n = 158	n = 162	0.078
Complete resolution	13 (8.2)	19 (11.7)	
Improved	110 (69.6)	99 (61.1)	
Stable	15 (9.5)	24 (14.8)	
Worse	8 (5.1)	2 (1.2)	
Died	4 (2.5)	10 (6.2)	
Not evaluable	8 (5.1)	8 (4.9)	
Clinical outcomes on day 14, n (%)	n = 90	n = 103	0.290
Complete resolution	18 (20.0)	33 (32.0)	
Improved	54 (60.0)	53 (51.5)	
Stable	6 (6.7)	9 (8.7)	
Worse	3 (3.3)	3 (2.9)	
Died**	3 (3.3)	3 (2.9)	
Not evaluable	6 (6.7)	2 (1.9)	
Overall treatment outcomes	n = 180	n = 180	0.316
Improved	133 (73.9)	129 (71.7)	
Not improved	34 (18.9)	43 (23.9)	
Cannot determine	13 (7.2)	8 (4.4)	
Microbiological outcomes*			
Day 3	n = 27	n = 24	
Cure rate	19 (70.4)	17 (70.8)	0.971
Day 7	n = 21	n = 16	
Cure rate	17 (80.9)	13 (81.3)	0.982

* Proportions of those with positive initial culture only

** 5 more cases of original meropenem group died after two week of meropenem treatment and were not included in Table 6

Table 7. Adverse drug reaction (ADR) of meropenem (n = 180/group)

Outcomes	Generic, n (%)	Original, n (%)	p-value
Total adverse drug reaction	3 (1.67)	3 (1.67)	1.0
Rash	1	2 (1.11)	
Drug fever	1 (0.56)	0	
Hypoglycemia	0	1 (0.56)	
Anaphylaxis	1 (0.56)	0	

respectively (p = 0.152). Logistic regression analyses were also conducted to determine predictors of favorable outcomes on day 7 and day 14 comparing between generic and original formulations controlling for age, confirmed bloodstream infections, nosocomial/healthcare associated infection, and presence of multidrug resistant *A. baumannii*. The results showed that except for age, none of the aforementioned variables was significantly associated with treatment success including the types of meropenem antibiotics (generic vs. original formulation). Table 7 shows that the rates of adverse drug reaction of meropenem were rather low and comparable between the two groups.

Discussion

Generic substitution for brand-name medications has been a common practice especially in public hospitals. Nevertheless, there remain suspicions and/or uncertainties about efficacy and safety of generic preparation as well as the Food and Drug Administration (FDA) standards for bioequivalence. In general, bioequivalence studies, based primarily on single dose pharmacokinetics, are the requirement for the registration of generic preparations. However, there are some evidences suggesting that the results of single dose pharmacokinetics studies among healthy volunteers may not reflect therapeutic equivalence among patients who require repeated dosage of medication. Therefore, the lack of interchangeability between the generic and original medication has been a cause of concern among clinicians. One pronounced example was demonstrated by the work of Crowford et al about anticonvulsants[4]. The results indicated that switching from branded antiepileptics to generic preparations could result in increased risk of therapeutic failure or adverse reactions. In addition, a recent systematic review of generic anticonvulsants demonstrates statistically higher overall healthcare costs during periods of generic antiepileptic drugs use than during periods when branded preparation were used. The finding was consistently illustrated across settings as well as among both stable and unstable epileptic patients[5]. The cost increased apparently in patients receiving multiple generic versions. Therefore, brand-to-generic substitutions of antiepileptic drugs, and/or certain other medications, might result in the increase rather than decrease overall healthcare costs[5].

Regarding antibacterial agents, which consist of various pharmacological classes, the therapeutic activity of which relies significantly on pharmacokinetic and pharmacodynamic parameters[6]. As a result, differences in pharmaceutical properties (generic as compared to brand-name) might result in alteration of pharmacokinetic/pharmacodynamic relationships, and, eventually, variations in their clinical efficacy with respect to the brand-name counterparts[7]. Existing evidence indicates that generic and branded preparation antibiotics do not always provide comparable therapeutic efficacy. For example, certain generic antimicrobial agents such as teicoplanin[8], piperacillin/tazobactam[9], and imipenem/cilastatin[10] fail to provide therapeutic equivalence by demonstrating the reduction in *in-vitro* and/or *in-vivo* antimicrobial activity compared to the original preparations.

Meropenem is a broad spectrum antibiotic belonging to the carbapenem group. Its antibacterial action is exhibited through binding to penicillin binding proteins of most of gram-positive and gram-negative bacteria. The stability of meropenem to most bacterial beta-lactamases and good penetration through the outer membrane contribute to its broad-spectrum antimicrobial activity. Despite its significant stability to hydrolysis by the majority beta-lacatamase, meropenem is susceptible to carbapenemase, and metallo-beta-lactamase. Most commonly used indication is the treatment of hospital-acquired infection caused by cephalosporin-resistant gram negative enterobacteriaceae such as intra-abdominal infection, ventilator-associated pneumonia, febrile neutropenia, urinary tract infections[11]. Being a broad-

spectrum and potent antimicrobial agent, meropenem is commonly used for the treatment of serious or life-threatening bacterial infections as reflected in the present report: the overall in-hospital mortality among the present study subjects was rather high (12.5%). Therefore, documented therapeutic equivalence of generic meropenem should be established prior to its use as a substitute for the original one. The results from the current study demonstrated the comparability of therapeutic effectiveness and tolerability of the generic and original meropenem among pediatric population. The authors' findings indicate that the point estimate of a difference in overall favorable response rates between the original and the generic meropenem group was less than 5%. In addition, although more than 90% of the present cases had underlying diseases, of which approximately half had multiple co-morbidities, the occurrence of adverse drug events was rare (1.6%) and much lower compared to those reported from an adult/ population (2.9-6.8%)[2]. The present results thus add to the body of evidence regarding the interchangeability between the generic and the original preparation. Nevertheless, the results of the present study are specific to the studied medication (Mapenem®) and may not be generalizable to other generic meropenem products.

Study limitations

Although a randomized control trial (RCT) is preferable when evaluating the comparative efficacy of treatment interventions, this method is not generally feasible for the authors' purpose due to its complexity and high cost incurred by the process. In addition, RCT is not required by Thai FDA during the registration process of generic medications. As a result, the authors employed existing drug utilization database in the identification of study subjects and reviewed their clinical data and treatment outcomes of generic and original meropenem at QSNICH. Without randomization, baseline demographic and clinical characteristics were not expected to be similar between the two groups. In addition, as the data of the generic group were obtained from more recent cases (1 April 2008-24 March 2010) compared to those of the original meropenem group (10 February 2006-December 2007), there might be some existing differences between the two comparison groups. For example, the use of meropenem to treat community acquired infection was higher (15.6% vs. 7.8%) among the more recent cases (generic treatment group) than that of the original meropenem group. This is probably due, in part, to the increased rate of community acquired ESBL-producing bacteria especially among those with upper urinary tract infections. The authors found that although most of demographic and clinical characteristics of the patients between both groups were rather comparable, there were significant differences in terms of age, rates of blood stream infection/clinical sepsis, urinary tract infection, and previous receipt of aminoglycoside and/or penicillin antibiotics. Although the authors attempted to control these potential confounders in the multivariate analysis, some residual confounding have not been accounted for in the analysis.

Further, the authors are cognizant that the range of hypothesized difference to determine non-inferiority margins is generally preferable at less than or equal to 5%-10%. With that, the sample size would be much higher to fulfill this pre-specified condition. Given the authors' limited available resource, the present sample size was calculated based on a wider margin of 15% difference. Nevertheless, the present findings do not suggest any significant difference in terms of therapeutic effectiveness or tolerability between the two treatments.

Conclusion

Although some residual confounding cannot be excluded and the result should be interpreted with caution, Mapenem® exhibited comparable therapeutic effectiveness with that of the brand-name formulation in the treatment of serious bacterial infections among pediatric population. Both formulations appeared to be well tolerated with few adverse drug reactions despite their use among severely ill children with substantial co-morbidities.

Potential conflicts of interest

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ประสิทธิผลของยาสามัญเมโรพีเนมในการรักษาการติดเชื้อรุนแรงในเด็ก

วารุณี พรรณพานิช, สุชาดา ศรีศรัง, อุไรวรรณ ประจันตะเสน

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิผลและความปลอดภัยในการใช้ยาสามัญเมโรพีเนมเปรียบเทียบกับยาต้นแบบ*

วัสดุและวิธีการ: *ทำการศึกษาแบบวิเคราะห์ข้อมูลย้อนหลัง ในผู้ป่วยเด็กที่เข้ารับการรักษาที่สถาบันสุขภาพเด็กแห่งชาติมหาราชินี โดยเปรียบเทียบข้อมูลพื้นฐานประชากร อาการทางคลินิก และผลการรักษาในเด็กที่ได้รับยาสามัญเมโรพีเนมกับเด็กที่ได้รับยาต้นแบบ จำนวนกลุ่มละ 180 คน*

ผลการศึกษา: *ข้อมูลพื้นฐานประชากร อาการทางคลินิก ส่วนใหญ่มีความใกล้เคียงกันในทั้ง 2 กลุ่ม ผลการรักษา ณ วันที่ 3, 7 และ 14 มีความใกล้เคียงกัน โดยอัตราการตอบสนองต่อการรักษาในภาพรวม เท่ากับร้อยละ 73.9 และร้อยละ 71.7 สำหรับกลุ่มที่ได้รับยาสามัญและยาต้นแบบตามลำดับ (absolute difference: 2.2%, 95% CI: -6.9%, 11.4%) ผลข้างเคียงจากการใช้ยาพบเพียงร้อยละ 1.6 ในทั้ง 2 กลุ่ม และไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติ*

สรุป: *ยาสามัญเมโรพีเนม (Mapenem®) มีประสิทธิผลและอัตราการเกิดผลข้างเคียงไม่แตกต่างจากยาต้นแบบในการรักษาโรคติดเชื้อรุนแรงปานกลางถึงรุนแรงมาก*