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국내 3차 대학병원에서 카바페넴분해효소 생성 장내세균목 검출을 위한 Xpert Carba-R Assay의 평가

Evaluation of the Xpert Carba-R Assay for Detection of Rectal Carbapenemase-producing *Enterobacterales* in a Korean Tertiary Hospital

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Background: Carbapenemase-producing *Enterobacterales* (CPE) have been highlighted as an urgent threat by international health authorities. Rapid detection of carbapenemase will allow implementation of infection control measures.
Methods: We assessed the performance of the Xpert Carba-R assay (Cepheid, USA) designed for rapid detection of five most common carbapenemases (*bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, and *bla*$_{IMP-1}$) from rectal swab specimens by comparing with the reference method, culture plus in-house PCR. A total of 26,178 specimens were collected from August 2018 to July 2020 and tested using the Xpert Carba-R assay and culture plus in-house PCR.
Results: Among the 26,178 specimens collected from 12,889 patients, 1,615 (6.2%) were detected using the Xpert Carba-R assay, whereas 1,525 specimens (5.8%) were detected using a reference method. The sensitivity, specificity, and positive and negative predictive values of the Xpert Carba-R assay compared to the results of the culture method were 97.4% (95% confidence interval [CI], 96.5% to 98.1%), 99.4% (95% CI, 99.3% to 99.5%), 91.8% (95% CI, 90.5% to 93.0%), and 99.8% (95% CI, 99.7% to 99.8%), respectively. The prevalence of CPE and carbapenem-resistant *Enterobacteriaceae* were 1.7% (220/12,889) and 5.4% (695/12,889), respectively. *Klebsiella pneumoniae* (108/220, 49.1%) was the most common species, followed by *Escherichia coli* (68/220, 30.9%) and *Citrobacter freundii* (17/220, 7.7%). *bla*$_{KPC}$ was the most common carbapenemase gene (123/220, 55.9%), followed by *bla*$_{NDM}$ (56/220, 25.4%), *bla*$_{OXA-48}$ (27/220, 12.2%), and *bla*$_{NDM/OXA-48}$ (9/220, 4.1%).
Conclusions: Based on our results, we conclude that the Xpert Carba-R assay is a very useful tool for rapid identification of CPE rectal colonization.

Key Words: Carbapenemase, Carbapenemase-producing *Enterobacterales*, Xpert Carba-R assay, Surveillance, Infection control

INTRODUCTION

The rapid spread of carbapenemase-producing *Enterobacterales* (CPE) worldwide is a serious threat to public health [1], as it is capable of spreading resistance genes through horizontal transfer and has been related to several outbreaks [2]. In Korea, reporting CPE infections to the Korean Center for Disease control and Prevention (KCDC) has been made mandatory for hospitals since 2012 (http://www.kdca.go.kr/). According to the KCDC, there were 11,954 carbapenem-resistant *Enterobacteriaceae* (CRE) cases in 2018 and 15,369 cases in 2019. Among the 2019 cases, 57.8% (8,887/15,369) were confirmed as CPE infections [3]. For infection control, rapid identification of patients colonized with CPE has become a routine clinical aim in many parts of the world and is recommended by public health organizations [4]. Various methods to detect CPE in rectal swabs, including culture with specific chromogenic media and commercial molecular tests, have been used [5]. Although concomitant culture is necessary for bacterial

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species identification and epidemiological typing, it requires more than two days of turnaround time. To overcome this limitation, molecular tests have been developed with reduced processing time to rapidly implement proper infection control measures [6, 7]. As a rapid molecular test, the Xpert Carba-R assay is capable of detecting five carbapenemase genes (*bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, and *bla*$_{IMP-1}$) in approximately one hour and has been used in our laboratory since July 2017 for active surveillance of CPE. In this study, we evaluated the performance of the Xpert Carba-R assay compared with the conventional method culture plus in-house PCR.

MATERIALS AND METHODS

1. Study design

We retrospectively analyzed the routine test results of the Xpert Carba-R assay (Cepheid, Sunnyvale, CA, USA) and the conventional method culture plus in-house PCR from August 2018 to July 2020. Screening for CPE was performed using rectal swab specimens from patients with high risk of intestinal colonization with CPE in accordance with the infection control policy of Seoul St. Mary's Hospital. Screening was performed for all patients admitted to the intensive care unit or the general ward if the patient had been transferred from another hospital after a stay longer than 1 week within the last 4 weeks. For all patients admitted to the intensive care unit, testing was performed at admission, after every subsequent seven days, and before discharge.

The rectal swab specimens were collected in eSwab 480CE (Copan Diagnostics, Inc., Brescia, Italy) and submitted to a clinical microbiology laboratory. The Xpert Carba-R assay and culture plus in-house PCR were performed simultaneously, as described below.

This study was approved by the Institutional Review Board of Seoul St. Mary's Hospital, Seoul, South Korea (KC21RASI0674).

2. Xpert Carba-R assay

The rectal swabs were processed using Xpert Carba-R assay, a real-time PCR assay designed to detect the five most common carbapenemases, i.e., *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, and *bla*$_{IMP-1}$. The assay was performed according to the manufacturer's instructions. The transport media was sent to the laboratory and vortexed, and a 100 µL sample was mixed with Xpert Carba-R assay sample buffer. After vortexing the mixture, 1.7 mL of the sample buffer was transferred to an Xpert Carba-R assay cartridge and was placed on the GeneXpert™ system.

3. Reference method: Confirmation of culture positivity using in-house PCR

For conventional culture method, 100 µL of each specimen was placed in 8 mL of MacConkey broth (BD, Franklin Lakes, NJ, USA) containing a 10 µg ertapenem disk (BD). After 24 hours and 48 hours of incubation at 37°C, if the solution turned yellow or turbid, an aliquot of 100 µL was removed and inoculated onto MacConkey agar (Asan Pharmaceutical, Seoul, Korea) and CHROMagar mSuperCARBA agar (CHROMagar, Paris, France) plates. Next, 10 µg ertapenem disks were placed in the first and second quadrants of MacConkey agar for detection of carbapenem-resistant isolates. The colonies that grew within 27 mm of the ertapenem disks after overnight incubation at 37°C were suspected as CRE [8].

Additionally, for cases showing positive results in the Xpert Carba-R assay, 100 µL of each specimen was inoculated directly onto a CHROMagar plate for more rapid identification of CPE species. The species identification was performed using matrix assisted laser desorption ionization time-of-flight (MicroIDSys, ASTA, Suwon, Korea), and the antimicrobial susceptibility test was performed using Vitek-2 (bioMérieux, Marcy L'Etoile, France). To confirm the presence of carbapenemase genes, colonies were suspended in 1 mL distilled water in a 1.5 mL micro tube and vortexed. After washing, the pellet was boiled for 20 minutes for DNA extraction, followed by PCR using a C1000 Thermal Cycler Chassis (Bio-Rad, Hercules, CA, USA) to detect the most common five genes, *bla*$_{SIM}$, and *bla*$_{GES}$. The primer sequences used for PCR are described in previous studies [9, 10].

4. Data analysis

Growth of CPE either on MacConkey agar or CHROMagar with carbapenemase gene confirmation using in-house PCR was defined as true-positive. No growth of CPE was defined as true-negative. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) including 95% confidential interval (CI) were calculated for all test results [11]. Statistical analysis was performed using the MedCalc Statistical Software version 18 (MedCalc Software Bvba, Ostend, Belgium; http://www.med-

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calc.org; 2018). Differences in the threshold cycle (Ct) values between CPE and non-CPE (false-positive results of Xpert Carba-R assay) specimens were analyzed using the Mann-Whitney U-test. *P* values <0.05 were considered significant. Samples that found positive result with the Xpert Carba-R assay, 24 hours earlier-inoculation was done on CHROMagar directly. And the samples were compared with that inoculated on MacConkey broth. For analysis of prevalence, only one specimen per patient was used. The Chi-square test was used to compare culture results of specimens found to be true- or false-positives in the Xpert Carba-R assay. This test was also used to compare the results of the prevalence of CPE during the two periods.

RESULTS

1. Xpert Carba-R assay results

A total of 26,178 specimens from 12,889 patients were tested from August 2018 to July 2020.

In the Xpert Carba-R assay, 6.2% positive cases (1,615/26,178 specimens) were detected. Furthermore, in the reference method, 5.8% positive cases (1,525/26,178 specimens) were detected (Table 1).

2. Comparison of the Xpert Carba-R assay with the reference method

Table 2 shows the overall performance of the Xpert Carba-R assay compared to the reference method. Sensitivity, specificity, PPV, and NPV of the Xpert Carba-R assay were 97.4% (95% CI, 96.5% to 98.1%), 99.4% (95% CI, 99.3% to 99.5%), 91.8% (95% CI, 90.5% to 93.0%), and 99.8% (95% CI, 99.7% to 99.8%), respectively. There were 26,178 specimens analyzed for five individual genes, providing 130,890 test results. The results were defined as positive for the Xpert Carba-R assay if at least one carbapenemase gene was detected.

3. Discrepant results

Table 3 shows discrepant results between the Xpert Carba-R assay and the reference method. Here, 39 cases that showed negative in the Xpert Carba-R assay but showed positive in the reference method were considered false-negative results of the Xpert Carba-R assay. Most of these were bla_{KPC}-producing *Klebsiella pneumoniae* (N=29). In contrast, 131 specimens yielded false-positive results in the Xpert Carba-R assay. Among these, bla_{IMP-1} was the most common gene (N=48), followed by bla_{NDM}, bla_{KPC}, and bla_{OXA-48}. In 90 of the 131 cases, CRE did not grow. In the remaining 41 cases, the carbapenemase genes were detected in

Table 1. Xpert Carba-R assay results by target gene for clinical specimens

Carbapenemase gene		Clinical specimens (N=26,178)	
		Xpert Carba-R assay	Reference method (Culture plus in-house PCR)
Single target gene	Positive	1,615	1,525
	KPC	802	811
	NDM	353	324
	OXA-48	277	262
	IMP	52	4
	VIM	5	4
	Total	1,489	1,405
Combined target genes	NDM+OXA48	93	93
	KPC+IMP	8	8
	KPC+VIM	6	6
	KPC+NDM	5	5
	KPC+NDM+VIM	4	4
	NDM+IMP	3	2
	IMP+VIM	3	0
	KPC+NDM+IMP	1	1*
	KPC+OXA48	1	1
	NDM+VIM	1	0
	NDM+IMP+VIM	1	0
	Total	126	120
	Negative	24,563	24,653

*Only KPC was positive in the Xpert Carba-R result.

Table 2. Overall Xpert Carba-R assay performance compared to the reference method (culture plus in-house PCR) for clinical specimens

Carbapenemase gene	No. of specimens				% (95 % confidence interval)			
	TP	FP	TN	FN	Sensitivity	Specificity	PPV	NPV
KPC	806	21	-	30	96.4 (94.9-97.5)	99.9 (99.9-100)	97.4 (96.1-98.3)	99.9 (99.9-100)
NDM	427	34	-	2	99.5 (98.3-99.9)	99.9 (99.9-100)	92.6 (89.9-94.6)	99.9 (99.9-100)
OXA-48	350	21	-	6	98.3 (96.3-99.3)	99.9 (99.9-100)	94.3 (91.5-96.2)	99.9 (99.9-100)
VIM	13	7	-	1	92.8 (66.1-99.8)	99.9 (99.9-100)	65.0 (46.6-79.8)	99.9 (99.9-100)
IMP	20	48	-	0	100 (83.1-100)	99.9 (99.9-100)	29.4 (23.9-35.6)	99.9 (99.9-100)
Total	1,484	131	130,890	39	97.4 (96.5-98.1)	99.4 (99.3-99.5)	91.8 (90.5-93.0)	99.8 (99.7-99.8)

Abbreviations: TP, true-positive; FP, false-positive; TN, true-negative; FN, false-negative; PPV, positive predictive value; NPV, negative predictive value.

Table 3. Discrepancy analysis of the Xpert Carba-R assay and the reference method (culture plus in-house PCR)

Xpert Carba-R Assay		True results	Reference method (culture plus in-house PCR)						
			KPN	ECO	PAE	ABA	Other*	NG	Total
FN		KPC	29	1					30
		OXA-48	3	3					6
		NDM	1	1					2
		VIM	1						1
		Total	34	5					39
FP	IMP-1	Negative			9	5	4	30	48
	NDM	Negative			11	5		18	34
	OXA-48	Negative			2			15	21
	KPC	Negative					4	21	21
	VIM	Negative			1			6	7
	Total				23	10	8	90	131

*For *bla*$_{KPC}$, four ertapenem-susceptible Gram-negative bacilli were found. For *bla*$_{IMP-1}$, two *E. cloacae*, one *K. aerogenes*, and one *A. xylosoxidans* were found.
Abbreviations: FN, false-negative; FP, false-positive; KPN, *K. pneumoniae*; ECO, *E. coli*; PAE, *P. aeruginosa*; ABA, *A. baumannii*; NG, no growth.

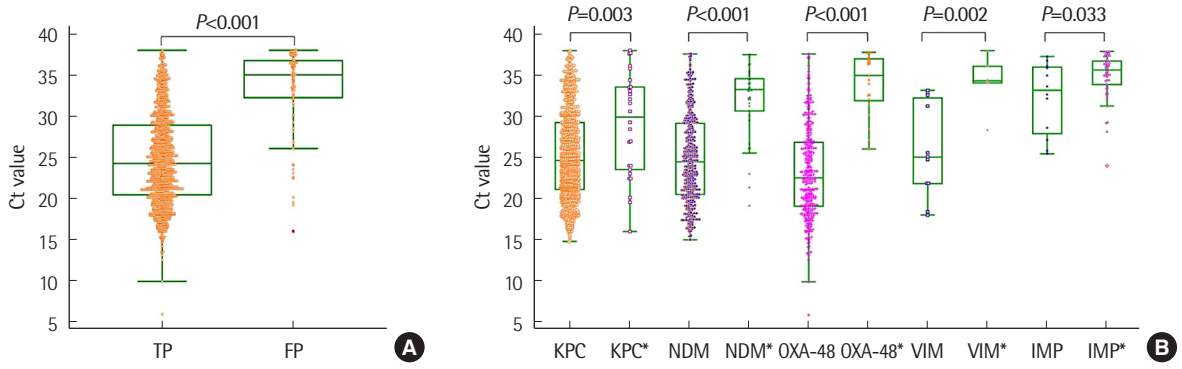

Fig. 1. Comparison of median Ct value and interquartile range in (A) total true-positive (24.4, 20.4-28.8) and false-positive (35.1, 32.3-36.8) cases, (B) each true/false-positive carbapenemase type, KPC (24.7, 21.2-29.3), KPC* (29.9, 23.6-33.6), NDM (24.4, 20.6-29.2), NDM* (33.2, 30.7-34.4), OXA-48 (22.7, 19.1-26.9), OXA-48* (35.0, 32.1-37.0), VIM (25.1, 21.9-32.1), VIM* (34.2, 34.1-36.1), IMP (33.2, 28.1-35.9), and IMP* (35.4, 33.9-36.8). Each boxplot represents the range from the 25th to the 75th percentiles of each group.
*carbapenemase genes with/without the star symbol indicate false/true-positive cases as observed in the Xpert Carba-R assay.
Abbreviations: TP, true-positive; FP, false-positive.

non-fermentative bacilli, most of which were identified as *Pseudomonas aeruginosa* (23/41, 56.1%), followed by *Acinetobacter baumannii* (10/41, 24.4%).

Compared to the true-positive cases detected in the Xpert Carba-R assay, the median Ct value of false-positive cases was significantly higher (24.3 vs. 35.0, $P<0.001$, Mann-Whitney U-test) (Fig. 1). According to carbapenemase type, the median Ct values of true-positive groups were 25.4, 24.9, 23.3, 26.0, and 32.3 for *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, and *bla*$_{IMP-1}$, respectively. The median Ct values of false-positive groups were 29.0, 32.0, 34.1, 34.2, and 35.0 for *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, and *bla*$_{IMP-1}$, respectively. Differences in Ct values were statistically significant for all five genes, *bla*$_{KPC}$ ($P=0.003$), *bla*$_{NDM}$ ($P<0.001$), *bla*$_{OXA-48}$ ($P<0.001$), *bla*$_{VIM}$, ($P=0.002$), and *bla*$_{IMP-1}$ ($P=0.033$).

Additionally, in the MacConkey broth culture, one *bla*$_{GES}$-producing *K. pneumoniae* and two *bla*$_{SIM}$-producing *C. freundii* were found using the in-house PCR method.

4. Prevalence of CPE

The prevalence of CPE and CRE were 1.7% (220/12,889) and 5.4% (695/12,889), respectively. *Klebsiella pneumoniae* (108/220, 49.1%) was the most common species, followed by *E. coli* (68/220, 30.9%) and *C. freundii* (17/220, 7.7%). *bla*$_{KPC}$ was the most common carbapenemase gene (123/220, 55.9%), followed by *bla*$_{NDM}$ (56/220, 25.4%), *bla*$_{OXA-48}$ (27/220, 12.2%), and *bla*$_{NDM/OXA-48}$ (9/220, 4.1%).

The prevalence of CPE from August 2018 to July 2020 is shown on Fig. 2. During the first period (2018.08-2019.07) of the study,

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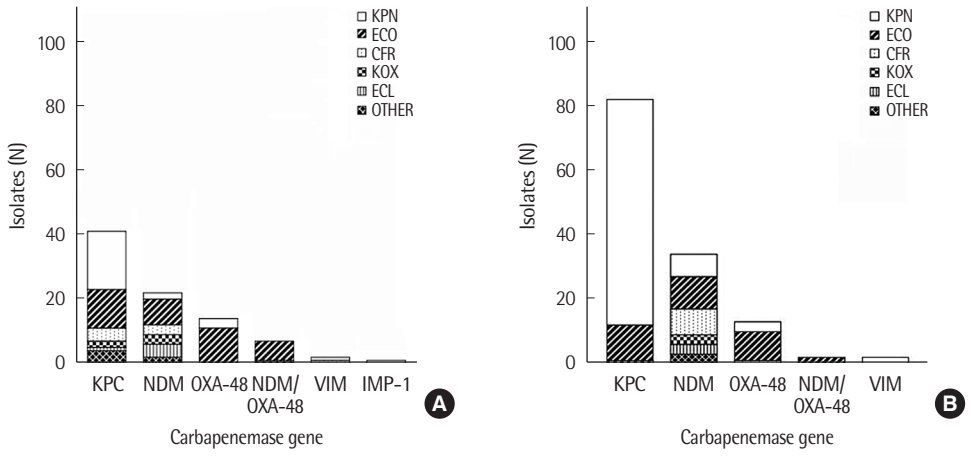

Fig. 2. Distribution of genotypes of CPE for two periods: (A) August, 2018-July, 2019 and (B) August, 2019-July, 2020.
Abbreviations: KPN, *K. pneumoniae*; ECO, *E. coli*; CFR, *C. freundii*; KOX, *K. oxytoca*; ECL, *E. cloacae*.

the prevalence of CPE was 1.3% (87/6,546), and the proportion of CPE isolates among CRE isolates was 38.1% (87/228). Of these 87 isolates, 41 harbored the bla_{KPC} gene, while the remaining isolates carried bla_{NDM} (N=22) or bla_{OXA-48} (N=14) genes. *Escherichia coli* (37/87, 42.5%) was the most common species, followed by *K. pneumoniae* (25/87, 28.7%) and *C. freundii* (8/87, 9.2%). During the second period (2019.08-2020.07) of the study, the prevalence of CPE increased to 1.7% (133/6,343), and the proportion of CPE patients among CRE patients was 28.4% (133/467) due to the increase in the number of CRE patients. Of these 133 CPE cases, 82 harbored bla_{KPC}, followed by the remaining cases carrying bla_{NDM} (N=34) or bla_{OXA-48} (N=13). *Klebsiella pneumoniae* (83/133, 62.4%) isolates were the most common species during this period, followed by *E. coli* (31/133, 23.3%) and *C. freundii* (9/133, 6.8%). The most common species over the two years of the study showed different and increased bla_{KPC}-producing *K. pneumoniae* up to 53.3% (71/133) from 20.6% (18/87). The results of the Chi-square test for carbapenemase gene and species showed *P*-value<0.05 for bla_{KPC}-producing *K. pneumonia*; no other combination showed significant result.

DISCUSSION

The Xpert Carba-R assay detected 1,615 positive targets (827 bla_{KPC}, 461 bla_{NDM}, 371 bla_{OXA-48}, 20 bla_{VIM}, and 68 bla_{IMP-1}) and multiple genes in 126 specimens (Table 1). Among multiple genes detected, bla_{NDM}+bla_{OXA-48} were most common (73.8%, 93/126), consistent with previous studies in Korea [3, 12], and were followed by bla_{KPC}+bla_{IMP-1} (6.3%, 8/126) and bla_{KPC}+bla_{VIM} (4.8%, 6/126). Species of bla_{NDM},+bla_{OXA-48} were *E. coli*, except for three specimens (two specimens for *E. coli* and Klebsiella oxytoca, and one specimen for *E. coli* and *Kluyvera cryocrescens*). In other multiple gene detected carbapenemases (33/126), bla_{KPC} was the most common gene (25/33).

The Xpert Carba-R assay demonstrated high sensitivity and specificity (97.4% and 99.4%, respectively). Our results are in agreement with results from several studies showing excellent performance for each carbapenemase [13, 14]. The PPV for bla_{KPC} was 97.4% in our study; however, Tato et al. [13] reported relatively low PPV for bla_{KPC} (87.9%). Higher PPV in our study for bla_{KPC} might be due to higher sensitivity of our reference method [15-17] or higher prevalence of bla_{KPC} in the studied population. Higher sensitivity of CHROMagar than MacConkey agar with a meropenem disk for CPE screening was reported previously [5], and inclusion of CHROMagar as reference method might have increased the specificity and PPV of the Xpert Carba-R assay. This finding indicates that the high sensitivity of the reference method is critical for evaluation of molecular methods and that studies of the performance of the Xpert Carba-R assay can show differences in results [13, 18]. Additionally, 89 out of 1,484 CPE specimens showed negative results with the MacConkey broth after 24 hours incubation, while seven showed negative results with MacConkey broth after 48 hours incubation. Seven specimens were only confirmed using CHROMagar, four bla_{KPC}-producing *E. coli*, one bla_{OXA-48}-producing *E. coli*, and two bla_{KPC}-producing *K. pneumoniae*. In contrast, no isolate was identified using MacConkey

broth only. Therefore, inoculation of rectal swabs onto a CHROMagar plate allows faster and more accurate identification of CPE, which could prevent dissemination.

The PPV for *bla*$_{IMP}$ was 29.4%, which was lower than the PPV values of other carbapenemase genes, partly because of the low prevalence of *bla*$_{IMP}$ in Korea [3]. Additionally, *bla*$_{IMP}$ was mainly detected in non-fermentative bacilli, consistent with a previous study [19].

Among the 39 false-negative specimens, 29 harbored *bla*$_{KPC}$-producing *K. pneumoniae* (Table 3). The small number of organisms in the rectal swab specimens might be the cause of false-negatives in these specimens. This is supported by the findings that most (94.0%, 1,395/1,484) of the true-positive specimens showed growth after 24 hours incubation in MacConkey broth, whereas as many as 30.8% (12/39) of the false-negative specimens showed growth after 48 hours incubation (Chi-square test, *P*-value < 0.001).

Among the 131 false-positive results, growth of carbapenem-resistant isolates was not observed in 90 cases (68.7%). Among the remaining 41 cases, growth of *P. aeruginosa* and *A. baumannii* was observed in 23 and 10 cases, respectively (Table 3). A high median Ct value of 35.0 was found for the false-positive results (Fig. 1). This could be explained by a low level of target gene expression of the organism or the possibility of medicinal treatment or modified sequence of the target gene. Compared to the true-positive cases detected using the Xpert Carba-R assay, the median Ct value of false-positive cases was significantly higher (24.3 vs. 35.0, $P < 0.001$) (Fig. 1).

In our study, rare carbapenemase genes (*bla*$_{SIM}$ and *bla*$_{GES}$) were detected from three isolates; the *bla*$_{SIM}$ was found in two *C. freundii* isolates, while the *bla*$_{GES}$ was found in one *K. pneumoniae* isolate. The prevalence of *bla*$_{GES}$ and *bla*$_{SIM}$ genes was very low in our study (0.2%), in line with the population results of studies conducted in Korea, the United States, and Europe [12, 20]. However, it is essential to verify the absence of *bla*$_{GES}$ and *bla*$_{SIM}$ genes to prevent dissemination through horizontal spread. A recent study in India about dissemination of plasmids encoding carbapenemases in gram-negative bacteria showed *bla*$_{GES}$ as the third most common gene (11 of 37, 29.7%, 6 for *bla*$_{GES-1}$ and 5 for *bla*$_{GES-9}$) in *E. coli*.

One of the limitations of our study is that we did not perform a direct PCR or sequencing of the MacConkey broth. Tato et al. [13] demonstrated that 11 of 18 specimens previously classified as false-positives using the Xpert Carba-R assay were reclassified as true-positives after discrepant sequencing analysis of the MacConkey broth. This might be due to low bacterial load of carbapenemase in the rectal swab specimens or failure of carbapenemase-harboring species to recover using the initial culture method. And Our study did not include the new emerging *bla*$_{OXA}$ variants, such as *bla*$_{OXA-232}$ [21].

However, to the best of our knowledge, this study included the largest number of clinical specimens. Based on the results obtained, we confirmed high NPV (99.8%) of the Xpert Carba-R assay, with the prevalence of up to 27%. Considering the high sensitivity (97.4%) and NPV (99.8%) of the Xpert Carba-R assay, for cases showing culture positivity, confirmatory PCR might be omitted in regions with a very low prevalence of other carbapenemases not included in the Xpert Carba-R assay such as *bla*$_{GES}$, and only species identification and antimicrobial susceptibility test would be needed for identification of CRE.

In conclusion, the prevalence of both CPE and CRE was higher in 2020 compared to that in 2019. The Xpert Carba-R assay showed excellent performance and can be used as a useful tool for active surveillance for CPE.

요 약

배경: Carbapenemase-producing *Enterobacterales* (CPE)의 확산은 전 세계적으로 큰 위협이 되고 있으며 이들의 신속한 검출은 감염 확산 방지에 필수적이다.

방법: 고위험환자군에서의 능동 감시를 위해 시행한 Xpert Carba-R assay (Cepheid, USA)의 5가지의 대표적인carbapenemase 유전자(*bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48}$, *bla*$_{VIM}$, *bla*$_{IMP-1}$)의 검출 성능을 후향적으로 평가하였다. 2018년 8월부터 2020년 7월까지 내원한 총 12,889명 환자의 직장 도말 검체 26,178개를 참고 방법(증균배양과 in-house PCR로 유전자 확인)과 비교하였다.

결과: 12,889명의 환자로부터 수집된 26,178개의 검체 중에서 1,615 검체(6.2%)가 Xpert Carba-R assay로 양성으로 확인되었으며, 1,525 검체(5.8%)가 참고 방법으로 양성으로 확인되었다. 참고 방법과 비교하여 민감도, 특이도, 양성 예측도 및 음성 예측도는 각각 97.4% (95% confidence interval [CI], 96.5%-98.1%), 99.4% (95% CI, 99.3%-99.5%), 91.8% (95% CI, 90.5%-93.0%) 및 99.8% (95% CI, 99.7%-99.8%)이었다. CPE와 CRE의 유병률은 각각 1.7% (220/12,889)와 5.4% (695/12,889)였다. 균 별로 *Klebsiella pneumoniae* (108/220,

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49.1%)가 가장 많고, *Escherichia coli* (68/220, 30.9%)와 *Citrobacter freundii* (17/220, 7.7%) 순이었다. *Carbapenemase* 유전자 별로는 bla_{KPC}가 가장 많았고(123/220, 55.9%), bla_{NDM} (56/220, 25.4%), bla_{OXA-48} (27/220, 12.2%) 그리고 $bla_{NDM/OXA-48}$ (9/220, 4.1%) 순이었다.
결론: 본 결과에 의하면, Xpert Carba-R assay는 직장도말 검체에서 CPE를 검출하는 데 있어 매우 유용한 것으로 사료된다.

Disclosure of conflict of interest

None declared.

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