## Contents

**World Journal of Clinical Cases**

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>2363</td>
<td><strong>OPINION REVIEW</strong>&lt;br&gt; eHealth, telehealth, and telemedicine in the management of the COVID-19 pandemic and beyond: Lessons learned and future perspectives</td>
<td>Giacalone A, Marin L, Febbi M, Franchi T, Tovani-Palone MR</td>
</tr>
<tr>
<td>2369</td>
<td><strong>MINIREVIEWS</strong>&lt;br&gt; Developing natural marine products for treating liver diseases</td>
<td>Wei Q, Guo JS</td>
</tr>
<tr>
<td>2382</td>
<td><strong>ORIGINAL ARTICLE</strong>&lt;br&gt; Analysis of bacterial spectrum, activin A, and CD64 in chronic obstructive pulmonary disease patients complicated with pulmonary infections</td>
<td>Fei ZY, Wang J, Liang J, Zhou X, Guo M</td>
</tr>
<tr>
<td>2393</td>
<td><strong>Retrospective Cohort Study</strong>&lt;br&gt; Computed tomography perfusion imaging evaluation of angiogenesis in patients with pancreatic adenocarcinoma</td>
<td>Liu W, Yin B, Liang ZH, Yu Y, Lu N</td>
</tr>
<tr>
<td>2404</td>
<td><strong>Retrospective Study</strong>&lt;br&gt; Epidemiological features and dynamic changes in blood biochemical indices for COVID-19 patients in Hebi</td>
<td>Nie XB, Shi BS, Zhang L, Niu WL, Xue T, Li LQ, Wei XY, Wang YD, Chen WD, Hou RF</td>
</tr>
<tr>
<td>2420</td>
<td><strong>Clinical Trials Study</strong>&lt;br&gt; Identification and predictive analysis for participants at ultra-high risk of psychosis: A comparison of three psychometric diagnostic interviews</td>
<td>Wang P, Yan CD, Dong XJ, Geng L, Xu C, Nie Y, Zhang S</td>
</tr>
<tr>
<td>2429</td>
<td><strong>Observational Study</strong>&lt;br&gt; Prognostic significance of peritoneal metastasis from colorectal cancer treated with first-line triplet chemotherapy</td>
<td>Bazarbashi S, Alghabban A, Aseafan M, Aljuhran AH, Alzahrani A, Elhassan TA</td>
</tr>
<tr>
<td>2439</td>
<td><strong>Observational Study</strong>&lt;br&gt; Effect of intraoperative cell rescue on bleeding related indexes after cesarean section</td>
<td>Yu YF, Cao YD</td>
</tr>
</tbody>
</table>

The document includes various types of research articles, reviews, and studies, each with detailed titles and authors.
### Prospective Study

2447  Effectiveness of the combination of workshops and flipped classroom model to improve tube fixation training for nursing students  
Wang YC, Cheng HL, Deng YM, Li BQ, Zhou XZ

### META-ANALYSIS

2457  Mortality in patients with COVID-19 requiring extracorporeal membrane oxygenation: A meta-analysis  
Zhang Y, Wang L, Fang ZX, Chen J, Zheng JL, Yao M, Chen WY

### CASE REPORT

2468  Escitalopram-induced hepatitis: A case report  
Wabont G, Ferret L, Houdre N, Lepied A, Bene J, Cousein E

2474  Fatal community-acquired bloodstream infection caused by Klebsiella variicola: A case report  

2484  Endoscopic extraction of a submucosal esophageal foreign body piercing into the thoracic aorta: A case report  
Chen ZC, Chen GQ, Chen XC, Zheng CY, Cao WD, Deng GH

2491  Severe tinnitus and migraine headache in a 37-year-old woman treated with trastuzumab for breast cancer: A case report  

2497  Metastatic urothelial carcinoma harboring ERBB2/3 mutations dramatically respond to chemotherapy plus anti-PD-1 antibody: A case report  
Yan FF, Jiang Q, Ru B, Fei XJ, Ruan J, Zhang XC

2504  Retroperitoneal congenital epidermoid cyst misdiagnosed as a solid pseudopapillary tumor of the pancreas: A case report  
Ma J, Zhang YM, Zhou CP, Zhu L

2510  Immunoglobulin G4-related kidney disease involving the renal pelvis and perirenal fat: A case report  
He JW, Zou QM, Pan J, Wang SS, Xiang ST

2516  Fluoroscopic removal of fractured, retained, embedded Z self-expanding metal stent using a guidewire lasso technique: A case report  
Bi YH, Ren JZ, Li JD, Han XW

2522  Treatment and five-year follow-up of type A insulin resistance syndrome: A case report  
Chen YH, Chen QQ, Wang CL

2529  Effective response to crizotinib of concurrent KIF5B-MET and MET-CDR2-rearranged non-small cell lung cancer: A case report  
Liu LF, Deng JY, Lizaso A, Lin J, Sun S
<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>2543</td>
<td>Immunoglobulin G4-related disease involving multiple systems: A case report</td>
<td>An YQ, Ma N, Liu Y</td>
</tr>
<tr>
<td>2550</td>
<td>Daptomycin and linezolid for severe methicillin-resistant <em>Staphylococcus aureus</em> psoas abscess and bacteremia: A case report and review of the literature</td>
<td>Hong XB, Yu ZL, Fu HB, Cui ZH, Chen J</td>
</tr>
<tr>
<td>2559</td>
<td>Isolated scaphoid dislocation: A case report and review of literature</td>
<td>Liu SD, Yin BS, Han F, Jiang HJ, Qu W</td>
</tr>
<tr>
<td>2577</td>
<td>Cardiac rehabilitation in a heart failure patient after left ventricular assist device insertion and subsequent heart transplantation: A case report</td>
<td>Yang TW, Song S, Lee HW, Lee BJ</td>
</tr>
<tr>
<td>2584</td>
<td>Large retroperitoneal atypical spindle cell lipomatous tumor, an extremely rare neoplasm: A case report</td>
<td>Bae JM, Jung CY, Yun WS, Choi JH</td>
</tr>
<tr>
<td>2591</td>
<td>Hepatocellular carcinoma effective stereotactic body radiotherapy using Gold Anchor and the Synchrony system: Two case reports and review of literature</td>
<td>Masuda S, Tsukiyama T, Minagawa Y, Koizumi K, Kako M, Kinbara T, Haruki U</td>
</tr>
<tr>
<td>2604</td>
<td>Mantle cell lymphoma with endobronchial involvement: A case report</td>
<td>Ding YZ, Tang DQ, Zhao XJ</td>
</tr>
<tr>
<td>2616</td>
<td>Takotsubo cardiomyopathy misdiagnosed as acute myocardial infarction under the Chest Pain Center model: A case report</td>
<td>Meng LP, Zhang P</td>
</tr>
<tr>
<td>2629</td>
<td>Silver dressing in the management of an infant's urachal anomaly infected with methicillin-resistant <em>Staphylococcus aureus</em>: A case report</td>
<td>Shi ZY, Hou SL, Li XW</td>
</tr>
<tr>
<td>2637</td>
<td>Drain-site hernia after laparoscopic rectal resection: A case report and review of literature</td>
<td>Su J, Deng C, Yin HM</td>
</tr>
</tbody>
</table>
Contents

Thrice Monthly Volume 10 Number 8 March 16, 2022

2644  Synchronized early gastric cancer occurred in a patient with serrated polyposis syndrome: A case report
       Ning YZ, Liu GY, Rao XL, Ma YC, Rong L

2650  Large cystic-solid pulmonary hamartoma: A case report
       Guo XW, Jia XD, Ji AD, Zhang DQ, Jia DZ, Zhang Q, Shao Q, Liu Y

LETTER TO THE EDITOR

2657  COVID-19 pandemic and nurse teaching: Our experience
ABOUT COVER
Editorial Board Member of *World Journal of Clinical Cases*, Nicolae Gica, Doctor, PhD, Assistant Professor, Chief Doctor, Surgeon, Department of Obstetrics and Gynecology Surgery, Carol Davila University of Medicine and Pharmacy, Bucharest 063377, Romania. gica.nicolae@umfcd.ro

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https://www.wjgnet.com/bpg/gerinfo/208

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https://www.wjgnet.com/bpg/gerinfo/242

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https://www.wjgnet.com/bpg/gerinfo/239

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Effective response to crizotinib of concurrent KIF5B-MET and MET-CDR2-rearranged non-small cell lung cancer: A case report

Lian-Fang Liu, Jia-Ying Deng, Analyn Lizaso, Jing Lin, Si Sun

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Abstract

BACKGROUND
Due to the rarity of mesenchymal-epithelial transition factor (MET) fusions, the clinical efficacy of crizotinib has only been described in a few patients with MET fusions involving various fusion partners. Herein, we report the clinical response to crizotinib of a patient with advanced poorly differentiated non-small cell carcinoma (NSCLC) having concurrent MET fusions.

CASE SUMMARY
A 46-year-old woman was diagnosed with poorly differentiated NSCLC (T4N3M1). With no classic driver mutations, she was treated with two cycles of gemcitabine and cisplatin without clinical benefit. Targeted sequencing revealed the detection of two concurrent MET fusions, KIF5B-MET and novel MET-CDR2. Crizotinib was initiated at a dose of 250 mg twice daily. Within 4 wk of crizotinib therapy, repeat computed chromatography revealed a dramatic reduction in primary and metastatic lesions, assessed as partial response. She continued to benefit from crizotinib for 3 mo until disease progression and died within 1 mo despite receiving nivolumab therapy.
CONCLUSION
Crizotinib sensitivity was observed in an advanced poorly differentiated NSCLC patient with concurrent MET fusions KIF5B-MET and MET-CDR2. Crizotinib can serve as a therapeutic option for patients with MET fusions. In addition, our case also highlights the importance of comprehensive genomic profiling particularly in patients with no classic driver mutation for guiding alternative therapeutic decisions.

Key Words: Poorly differentiated; Non-small cell carcinoma; Mesenchymal-epithelial transition factor fusion; Crizotinib; Case report

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Core Tip: The most common mesenchymal-epithelial transition factor (MET) gene aberrations are gene amplifications and exon 14 splice variants found in approximately 2% to 10% of lung cancer patients. Chromosomal rearrangements resulting in gene fusions involving MET are generally rare but could account for MET-driven oncogenesis. The rarity and diversity of MET fusions in non-small cell lung cancer (NSCLC) limit the volume of evidence documenting the clinical efficacy of crizotinib in treating MET-rearranged NSCLC patients. Herein, we report the clinical response to crizotinib of a patient with advanced poorly differentiated NSCLC harboring concurrent MET-involving rearrangements, including a novel MET-CDR2 gene fusion.

INTRODUCTION
The mesenchymal-epithelial transition (MET) gene, located on chromosome 7q21-31, encodes a receptor tyrosine kinase and is activated by its ligand, hepatocyte growth factor[1,2]. The MET signaling pathway is often upregulated in various human malignancies, including non-small cell lung cancer (NSCLC)[2]. The most common MET gene aberrations are gene amplifications and exon 14 splice variants found de novo in approximately 2% to 10% of lung cancer patients[2]. Chromosomal rearrangements resulting in gene fusions involving MET are generally rare but could account for MET-driven oncogenesis[4]. Currently, a total of five MET fusion partner genes have been reported in NSCLC, including KIF5B[5-6], STARD3NL[3], HLA-DRB1[7-8], UBE2H[9], and ATXN7L1[10] (Table 1). Crizotinib, an FDA-approved tyrosine kinase inhibitor for ALK-rearranged and ROS1-rearranged NSCLC, has been originally designed to target MET amplifications and mutations[11]. Several cases and clinical studies have reported the efficacy of crizotinib and cabozantinib in targeting MET amplification[12,13], exon 14 skipping[14], and certain rearrangements[5-7,10] in NSCLC patients. A recent meta-analysis analyzed six clinical trials (cohort size range: 8-69) on MET-altered NSCLC revealed an objective response rate of 40.6% (95%CI: 28.3%–53.0%) and disease control rate of 78.9% (95%CI: 70.3%–87.4%) for crizotinib, with a median progression-free survival and overall survival of 5.2 and 12.7 mo, respectively[15]. Most of these studies enrolled few MET fusion-positive patients, because they are exceedingly rare. Current knowledge regarding MET fusions is mostly derived from two cohort studies in Chinese lung cancer patients, which identified one (0.04%, 1/2410) fusion[16] and fifteen (0.26%, 15/5695) fusions involving the MET kinase domain[17], respectively.

Herein, we report the clinical efficacy of crizotinib in a patient with poorly differentiated NSCLC with KIF5B-MET and a concurrent novel MET-CDR2 fusion.

CASE PRESENTATION

Chief complaints
In November 2018, a 46-year-old female never-smoker presented in our clinic with a complaint of persistent dry cough.
Table 1 Summary of case reports of crizotinib (250 mg/b.i.d. orally) in treating MET-rearranged non-small cell carcinoma

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Age</th>
<th>Sex</th>
<th>Smoker</th>
<th>Stage</th>
<th>Histology</th>
<th>MET fusion</th>
<th>Best overall response</th>
<th>PFS (mo)</th>
<th>Grade ≥ 3 AEs</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>[5]</td>
<td>33</td>
<td>F</td>
<td>Yes</td>
<td>IV</td>
<td>ADC</td>
<td>KIF5B-MET</td>
<td>PR</td>
<td>8</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>[5]</td>
<td>62</td>
<td>F</td>
<td>No</td>
<td>IV</td>
<td>ADC</td>
<td>KIF5B-MET</td>
<td>PR</td>
<td>14</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>[6]</td>
<td>51</td>
<td>F</td>
<td>No</td>
<td>IV</td>
<td>ADC</td>
<td>KIF5B-MET</td>
<td>PR</td>
<td>10</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>[7]</td>
<td>74</td>
<td>F</td>
<td>No</td>
<td>Recurrent</td>
<td>ADC</td>
<td>HLA-DRB1-MET</td>
<td>Complete resolution of nodules while pleural effusion persisted</td>
<td>8</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>[8]</td>
<td>59</td>
<td>F</td>
<td>No</td>
<td>Recurrent</td>
<td>ADC</td>
<td>HLA-DRB1-MET</td>
<td>Complete radiographic response</td>
<td>/</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>[9]</td>
<td>43</td>
<td>F</td>
<td>No</td>
<td>IV</td>
<td>ADC</td>
<td>MET-UBE2H</td>
<td>PR</td>
<td>6.5</td>
<td>NR</td>
<td>MET fusion was acquired on EGFR-targeted therapy</td>
</tr>
<tr>
<td>[10]</td>
<td>56</td>
<td>F</td>
<td>No</td>
<td>IV</td>
<td>ADC</td>
<td>MET-ATXN7LI</td>
<td>PR</td>
<td>4</td>
<td>NR</td>
<td></td>
</tr>
</tbody>
</table>

ADC: Adenocarcinoma; AE: Adverse event; NR: Not reported; PR: Partial response.

**History of present illness**
The cough had been lasted for over a week.

**History of past illness**
Past medical history was not remarkable for this patient.

**Laboratory examinations**
Histopathological analysis of tissue biopsy samples collected from the right lung revealed poorly differentiated NSCLC (Figure 1) with the immunohistochemistry results of AE1/AE3 (+), SMACA4 BRG1 (+), CK18 (+), INI-1 (+), CD56 (-), chromogranin A (-), synaptophysin (-), CK7 (-), ERG (-), GATA3 (-), CD34 (-), CDX2 (-), P40 (-), SALL4 (-), TTF-1 (-), Desmin (-), and S-100 (-). In addition, PD-L1 expression analysis revealed a tumor proportion score of 80%. Molecular analysis of the biopsies detected no driver alterations in EGFR, ALK, or ROS1.

**Imaging examinations**
Computed tomography (CT) and magnetic resonance imaging revealed a tumor in the lower lobe of the right lung, right hilar and mediastinal lymph node involvement, and multi-organ metastasis including the left pleura, liver, pericardium, and bone.

**FINAL DIAGNOSIS**
The final diagnosis of the patient was NSCLC stage IV (T4N3M1).

**TREATMENT**
Based on the findings presented above, the patient was then treated with two cycles of gemcitabine (1.0 g/m² on days 1 and 8) plus cisplatin (75 mg/m² on day 1) with no clinical benefit.

**OUTCOME AND FOLLOW-UP**
In January 2019, an abdominal CT scan revealed the enlargement of the lung primary and liver metastases. To explore potentially actionable mutations, tumor biopsy samples were submitted for capture-based targeted sequencing using a panel with 520 cancer-related genes (OncoScreen Plus, Burning Rock, China). As shown in Figure 2, the analysis revealed the detection of two concurrent MET fusions with respective partner genes KIF5B (K24:M15) and CDR2 (M15:C3). No other classic lung cancer driver mutations were detected apart from TP53 C277X. Due to economic and insurance conditions and out of concern over evidence suggesting reduced efficacy of immunotherapy in non-
small cell lung cancer patients carrying oncogenic driver alterations[18], crizotinib (250 mg, p.o. bid) was started as the second line treatment in February 2019. After 4 wk of therapy, review of chest CT revealed a dramatic reduction of the lesions in the left and right lobes of the lungs with no new lesions, which was evaluated as partial response with Response Evaluation Criteria in Solid Tumors v.1.1 (RECIST 1.1) (Figure 3A and B). At approximately 3 mo from the start of targeted therapy, the patient continued to benefit from crizotinib without side effects. However, the disease progressed afterwards in May, 2019 as per RECIST 1.1. Specifically, compared with the previous evaluation (Figure 3B), new lesions emerged mostly in the right lung, accompanied by growth of the previously reduced tumor (Figure 3C and D).

After crizotinib failure, we chose nivolumab (a human IgG4 PD-1 antibody) as a salvage therapy because of the high PD-L1 expression. However, the patient did not benefit from nivolumab and her condition was declining significantly. She was hospitalized for worsening respiratory function and died shortly thereafter with an overall survival (OS) of 7 mo from diagnosis.

**DISCUSSION**

Gene alterations in MET are emerging as clinically relevant biomarker for predicting the response to MET inhibitors[2]. However, due to the rarity of MET fusions, treatment responses have only been clinically evaluated for MET amplification and exon 14 skipping[12-14] and only a few case reports have reported the efficacy of crizotinib in patients with MET fusions with various partners[5-7]. In our report, we describe the detection of KIF5B-MET co-occurring with a novel gene fusion involving MET and CDR2 and provided the clinical evidence of the efficacy of crizotinib in a KIF5B-MET and MET-CDR2-rearranged poorly differentiated NSCLC patient. KIF5B-MET K24:M15 has been reported in 0.5% (1/206) of adenocarcinoma and 4% (2/28) of sarcomatoid lung cancer patients in a recent study in Taiwanese patients[19]. In vitro and in vivo studies consistently demonstrated the oncogenic potential of KIF5B-MET fusion and sensitivity to crizotinib[19]. Consistently, several case reports have observed clinical efficacy of crizotinib in K24:M14[6] and K24:M15[5] KIF5B-MET-rearranged NSCLC[5,6]. The dramatic response to crizotinib observed in our patient highly suggests that the fusions acting either solely or in synergy served as oncogenic driver/s in the patient’s tumor which confers sensitivity to crizotinib. The oncogenic potential and sensitivity to crizotinib or other MET inhibitors of the novel gene fusion MET-CDR2 as well as the presence of two concurrent MET fusions require further investigations.

The negative results for histopathologic markers TTF-1, CK7, P40, and CDX2 and classic driver mutations in EGFR, ALK, and ROS1 provided neither clear indication of the cell differentiation nor any therapeutic targets. With a poor response to the first-line chemotherapy regimen, our patient had a very poor prognosis. Comprehensive genomic profiling allowed us to understand the mutation landscape of the tumor and explore alternative therapeutic targets that provided benefit to our patient. The detection of the potentially targetable MET fusions in our patient with poorly differentiated NSCLC highlights the importance of comprehensive genomic profiling regardless of tumor histology, particularly in patients with no known driver mutations to guide therapeutic decisions.

After the failure of crizotinib, we chose an immune checkpoint inhibitor (ICI) as a salvage therapy. Although with high PD-L1 expression, the patient did not benefit from the ICI. This is similar with the finding of previous studies that ICIs are less effective in NSCLC with EGFR mutation or EML4-ALK fusion[18,20].
Figure 2 Next-generation sequencing revealed two concurrent MET fusions with different fusion partners, MET-CDR2 and KIF5B-MET. A: Images from the Integrative Genomics Viewer demonstrating the chromosomal rearrangement involving MET (chromosome 7, sequencing reads with gray background) and CDR2 (chromosome 16, sequencing reads with blue background); B: KIF5B (chromosome 10, sequencing reads with blue background). Illustrations below demonstrate the protein structure resulting from the gene fusions indicating the breakpoints of the nearby exons.

Attention should be paid to managing toxicities associated with crizotinib monotherapy. In a study of 2028 Japanese ALK-rearranged patients receiving crizotinib, adverse drug reactions occurred in 91.6% of patients, the most common (incidence ≥ 15%) of which were nausea (32.2%), diarrhea (24.3%), photopsia (18.9%), vomiting (17.5%), and dysgeusia (16.8%). A considerable proportion of patients (623, 30.7%) discontinued treatment within 12 wk after therapy initiation due to adverse events. Only 68.2% of patients remained on crizotinib after 3 mo, 55.2% after 6 mo, and 36.1% after 12 mo, with a median duration of 7.9 mo[10]. Therefore, it is advised to monitor patients for these adverse reactions during the
Figure 3 Clinical efficacy of crizotinib treatment in a patient with KIF5B-MET and MET-CDR2-rearranged, poorly differentiated lung cancer. A: Thoracic computed tomographic image at baseline; B: 1 mo after initiating crizotinib therapy; C and D: After disease progression and another 2 mo later in May, 2019.

CONCLUSION

The efficacy of crizotinib in an advanced poorly differentiated NSCLC patient with concurrent KIF5B-MET and MET-CDR2 gene fusions suggests that crizotinib can serve as a therapeutic option in patients with MET fusions. Further clinical studies are required to confirm the clinical value of crizotinib or other MET inhibitors in patients with MET fusion.

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FOOTNOTES

Author contributions: Liu LF and Deng JY contributed to the study concept and design and performed the statistical analysis; Liu LF, Deng JY, and Lin J contributed to the acquisition, analysis, and interpretation of the data; Liu L, Deng J, and Lizaso A contributed to the drafting of the manuscript; Sun S contributed to the critical revision of the manuscript for important intellectual content.

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ORCID number: Lian-Fang Liu 0000-0001-5450-0711; Jia-Ying Deng 0000-0002-1744-1203; Analyn Lizzas 0000-0002-4175-7398; Jing Lin 0000-0001-5789-0970; Si Sun 0000-0001-8849-6343.

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